

**AGRICULTURE, RURAL DEVELOPMENT, FOOD AND  
DRUG ADMINISTRATION, AND RELATED AGEN-  
CIES APPROPRIATIONS FOR FISCAL YEAR 2013**

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**HEARINGS**

BEFORE A

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

SECOND SESSION

ON

**H.R. 5973/S. 2375**

AN ACT MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES PROGRAMS FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2013, AND FOR OTHER PURPOSES

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

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U.S. GOVERNMENT PRINTING OFFICE

72-302 PDF

WASHINGTON : 2013

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**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION, AND RE-  
LATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 2013**

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**THURSDAY, MARCH 29, 2012**

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

The subcommittee met at 2:03 p.m., in room SD-192, Dirksen Senate Office Building, Hon. Herb Kohl (chairman) presiding.

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

DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

STATEMENT OF HON. THOMAS VILSACK, SECRETARY

ACCOMPANIED BY:

**KATHLEEN MERRIGAN, DEPUTY SECRETARY**

**JOSEPH GLAUBER, CHIEF ECONOMIST**

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

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. The subcommittee will come to order. Today, we begin our first hearing on the fiscal year 2013 budget request for the U.S. Department of Agriculture (USDA). Secretary Vilsack, we thank you for being here. We also want to welcome Deputy Secretary Kathleen Merrigan, USDA Chief Economist, Joseph Glauber, and Budget Officer, Michael Young. We look forward to hearing from you today.

The fiscal year 2013 budget request for the USDA is \$18.3 billion. This represents a 7-percent increase over last year. Some programs are cut, while some programs are eliminated entirely. Several new initiatives are proposed and substantial increases are requested in some areas.

The Women, Infants, and Children (WIC) program provides healthy food for women, infants, and children, and is increased by \$422 million. This is mainly due to higher food prices.

Public Law 480 program is reduced by \$66 million. This is somewhat of a concern, as the humanitarian and food needs around the world, as we all know, have increased.

Our job is to review all the priorities in the budget ensure that programs vital to people's health, safety, and livelihoods are adequately funded. We also need to make sure that tax dollars are spent wisely, as we all know we need to do more with less.

The USDA is broad in scope and affects the lives of every American. Now, more than ever, it's essential that we set the priorities correctly to ensure the Department is both effective, efficient, and also serves the American people in the proper way.

We face many challenges this year, as we move through the appropriations process. I hope to work closely with the Department, so we can produce a responsible bill.

We also very much look forward to working with Senator Blunt and all members of the subcommittee. I'd like to thank Senator Blunt for the helpful and the bipartisan manner in which we have worked together. This subcommittee has a tradition of working in a bipartisan manner, and I assure all members that we will continue that practice as we move forward.

Secretary Vilsack, we thank you again for being here, and we look forward to your statement. Before that, I would like ask Senator Blunt for any comments that he may have.

#### STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. Thank you, Mr. Chairman, and thank you for holding this hearing. I hope that with your leadership we can produce a bill again this year, and I'm going to do everything I can to be helpful in your efforts to get that done, as I believe others on the subcommittee will. It was good that the agriculture appropriations bill was the bill that became the host for the first appropriations bills that passed last year, and I hope we can do our work in the same manner this year.

The President's budget proposes a net increase in spending in the USDA. Of course, as our Nation's debt increases, we have to look carefully at every part of the budget, including this one. But over the past year, the Agriculture subcommittee has made difficult and necessary decisions, as the Department has, including cutting discretionary spending by 15 percent.

This year represents a significant anniversary for the USDA. It was 150 years ago, in 1862, that President Lincoln signed into law the bill that created the USDA. And today, the Department touches the lives of every American, every day. Activities undertaken by USDA include agriculture research, conservation, housing and business loan programs for rural communities, domestic and international nutrition programs, food safety, and trade promotion.

The same year that President Lincoln signed the bill that created the USDA, he also signed a bill that was the Morrill Land Grant College Act. And over the course now of a century-and-a-half research and extension conducted at those land grant universities, and now others, has transformed American agriculture into the most innovative and productive in the world. As a result, agriculture remains the brightest spot in our country's economy today.

Last year, American farmers supported record agricultural exports and earned their highest income since the 1970s. U.S. farm exports alone helped support more than 1 million U.S. jobs in 2011. At the same time, however, USDA predicts farm income will de-

cline by 6.5 percent this year, and recent studies show that farmers are less optimistic as surging fuel prices and increases in other inputs increase their costs.

As we look ahead to fiscal year 2013, we have to be mindful of the important role that agriculture plays in our economic recovery. We have to make wise investments in those programs that will increase our agricultural community's competitiveness here and abroad, and sound agricultural research is the cornerstone to success in all aspects of the agriculture industry, whether it's developing more efficient production methods, eradicating pest and disease, developing biofuels, maintaining a safe food supply, or enhancing the nutritional quality of our diets, USDA is and will be involved.

Agriculture research today makes it possible for one American farmer to feed 155 people. Continued investment in research will make it possible for us to meet the global food demand, which is expected to double, a number that always surprises me, but the global food demand expected to double by 2050.

I'm pleased to see the Department has increases in its plans for research. These programs and others are critical to our farmers' ability to increase production, and every \$1 spent on research results in a \$20 return to the U.S. economy.

I'm glad the Secretary and his team are here today, and really believe that they are managing the Department in a really challenging time in a way that's transparent, and effective, and forward looking. And Mr. Secretary, glad you could join us today.

Senator KOHL. Thank you very much.

Secretary Vilsack.

#### SUMMARY STATEMENT OF HON. THOMAS VILSACK

Secretary VILSACK. Mr. Chairman, and Senator Blunt, and Senator Moran, thank you very much for the opportunity to appear today. You have my statement, and I would just simply ask for an opportunity to amplify on it just a bit.

We want to thank the subcommittee for this opportunity, and we would like to start with a plea, and the plea is for an understanding that we need time and flexibility during these difficult times.

While the budget that we propose does increase over last year, I would like to point out that it is several billion dollars less than it was in 2010. And that has resulted in us at USDA taking a look very carefully at the ways in which we expend taxpayer resources and are in the process of a variety of steps to try to make this a more efficient and more effective USDA.

We need time to absorb the reductions that have taken place. We need time to fully implement our plans for additional savings, which includes a very top to bottom review of our administrative functions. And we need to have the opportunity and the flexibility to build on the success that we've experienced at USDA in the recent past.

Senator Blunt mentioned the fact that we had record income last year. And while it is true that income is expected to be down just a bit, it will still be one of the best years in farm income in our history. It is a result of record exports, a record number of acres

enrolled in conservation, a record number of crop insurance programs, a record amount of credit extended to producers, homeowners, and businesses, a record amount of investment in bio-based products, and a bio-based economy, as well as the expansion of local and regional food systems, a record investment in business growth in rural areas and community development, record lows in fraud and in error rates in many of our nutrition programs, including the Supplemental Nutrition Assistance Program (SNAP), expanded food safety efforts, and expanded effort to improve the nutrition of American families, with a particular emphasis on our school children. And as Senator Blunt indicated, an expanded effort at agriculture research, which is extraordinarily important for us to be able to meet the growing demands, not here just in the United States, but also globally.

This has required us to make some tradeoffs, and you'll find that we actually had to make some difficult decisions concerning programs that were either duplicative, ineffective, inefficient, unnecessary, or in some cases, just inadequately funded to make a difference. We also had to take into consideration the impact of the farm bill discussions, which have just begun in the Senate and the House.

We have very specific goals, and I'll conclude with that. We want a Farm Service Agency (FSA) that provides appropriate credit and maintains a safety net for our producers. We want to continue to expand trade and to establish food security globally through our Foreign Agricultural Service. We want to promote job growth and improve quality of life and energy security through rural development.

Through our food safety efforts, we want better food safety more focused on prevention, surveillance, and detection, and more rapid recovery and response.

Through the natural resources portion of our budget, we want to expand technical assistance to landowners so that we can get conservation on the ground sooner, and we want to focus on some high-priority landscaped areas, so we can improve soil and water quality, increase wildlife diversity, work with our friends and neighbors in the sportsmen field to expand outdoor recreational opportunities.

In the Marketing and Regulatory Programs (MRP) area, we'd like to continue our efforts at expanding local and regional food systems, as well as prioritizing animal and plant health. The research area, we want to continue to focus on our ability to maintain competitive targeted research towards priorities, and within the administration of our food programs, we want to continue to provide access while improving the integrity of each and every one of the programs.

Finally, in the administration of the Department, we want to continue the cultural transformation efforts to improve employee moral, expand on our process improvement efforts, which is provided for a more efficient use of our time, realign our workforce through early retirement incentives, and consider taking a look at our footprint, which has involved some very difficult and tough decisions concerning office consolidations, and at the same time, con-

tinue, as I indicated earlier, a fairly extensive process that's looking at our administrative services.

PREPARED STATEMENT

It has been a busy time at USDA, and we appreciate the subcommittee's opportunity to appear today, and look forward to your questions.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF HON. THOMAS VILSACK

Mr. Chairman and distinguished members of this subcommittee, I appreciate the opportunity to appear before you to discuss the administration's priorities for the Department of Agriculture (USDA) and provide you an overview of the President's 2013 budget. I am joined today by Deputy Secretary Kathleen Merrigan, Joseph Glauber, USDA's Chief Economist, and Michael Young, USDA's Budget Officer.

When I made my first appearance before this subcommittee, our country and the Department of Agriculture faced historic challenges. The economy had deteriorated significantly. It was a crisis that cost the United States more than 8 million jobs and plunged the economy and the world into a crisis from which we are still fighting to recover. Three years later, thanks to the President's bold actions, the economy is growing again and creating millions of jobs in the private sector. Over the past 22 months, the Nation's businesses have created 3.2 million jobs. Last year, we added the most private sector jobs since 2005.

I am proud to say that America's farmers, ranchers, and producers have helped fuel the beginnings of the recovery. The establishment of the Department 150 years ago underscored the importance of agriculture and rural America to the country. What was true then remains true today—agriculture and rural America matter. Agriculture plays a fundamental role in our economy—responsible for 1 in 12 jobs. That's not surprising, because at the time the Department was created, the Morrill Act established the partnership between USDA and the land grant universities. Because of this partnership, these institutions have graduated 20 million people, people who went on to jobs that built our economy. So, when American producers earn record income, as they did last year, everyone benefits through the creation of more jobs and higher wages, whether in food processing, packaging, or farm equipment manufacturing, the reduction of our dependence on foreign oil supplies, or the increased availability of more nutritious food.

On February 10, 2012, I announced another record-breaking calendar year for farm exports. Total agricultural exports for calendar year 2011 were a robust \$136.3 billion. We saw a rise in both the value and volume of U.S. agricultural exports worldwide in 2011, as international sales rose \$20.5 billion over the previous record set in calendar year 2010. Agricultural exports have supported the creation of over a million jobs. USDA has expanded markets for American goods abroad by working aggressively to break down barriers to trade and provide U.S. businesses with the resources needed to reach consumers around the world. Last year, we exported an all-time high of \$5.4 billion worth of beef and beef products, surpassing the previous record by more than \$1.6 billion. The volume of shipments also surpassed the 2003 levels, the last year before a detection of bovine spongiform encephalopathy (BSE) disrupted U.S. trade. The return to pre-2003 levels marks an important milestone in USDA's steadfast efforts to open and expand international markets. The ratification of the trade agreements with South Korea, Colombia, and Panama will increase U.S. farm exports by an additional \$2.3 billion—supporting nearly 20,000 American jobs—by eliminating tariffs, removing barriers to trade and leveling the playing field for U.S. producers.

Agriculture has also led the development of our bio-based economy, where what we grow and raise is used to make fuel, chemicals, and polymers to complement our traditional production of food, feed, and fiber. Resilient, hard-working rural residents provide a model for creating economically thriving communities, which underscores why the unemployment rate is dropping more quickly in rural America than anywhere else in the country.

At USDA we have been working to fulfill President Obama's vision for a Nation where everyone gets a fair shot and an economy that makes, creates and innovates. We have been working to implement the President's vision by laying a foundation for sustainable economic growth and job creation. USDA is at the forefront of devel-

oping the technology and tools necessary to transform rural America so that it can create and take advantage of new economic opportunities.

We have generated rural wealth with our conservation and rural development programs. These programs help create green jobs, improve recreation and tourism, and facilitate the production of renewable energy. We have maintained a strong agriculture safety net through a system of income support, disaster mitigation, and a record number of farm loans.

The Department has programs to help people in need by ensuring that they have access to a plentiful supply of safe and nutritious food. This is fundamental to the healthy development of every child in America and to the well-being and productivity of every family. In recent years, the Supplemental Nutrition Assistance Program (SNAP) has helped millions of families meet basic nutritional needs. The program currently serves as a bridge to recovery for over 46 million Americans who are at risk of being hungry when they face challenging economic times. More than half of those who rely on the program are children, elderly, or the disabled, and many participants are newly unemployed who may have never thought they would need this assistance.

While SNAP has increased steadily since its last low point in 2000, and sharply during the recent economic downturn, the rate of increase has been declining since January 2010. And now, we estimate that rising employment and household income will reduce participation in SNAP in 2013, even as the program serves a larger share of those eligible. This is how the program is designed to work; participation rises during difficult economic times and falls in better times. Even under this period of rapid growth in participation, this administration has achieved historically high accuracy rates in SNAP, saving the taxpayer billions of dollars. We will continue to make improvements that protect program integrity, even as Federal and State budgets for oversight of the program are declining.

We have accomplished a critical step on the road to deliver healthier, more nutritious food to our Nation's schoolchildren and to help them develop healthy eating habits for life. On January 26, 2012, we published the final rule that refines and improves the standards for meals available to over 51 million school children across the country every day. The new rule implements provisions of the Healthy, Hunger-Free Kids Act of 2010 that are simpler and less burdensome than the ones they replace. The rule substantially increase offerings of fruits, vegetables, and whole grains; reduce saturated fat, trans fats and sodium; and set sensible calorie limits based on the age of children being served. Our understanding of the nutritional quality of food is built upon USDA science. We have seen the connection between what our kids eat and how well they perform in school. And we know that America's success in the 21st century is dependent on having the best-prepared and best-educated workforce in the world. So it is critical that that all children have the basic nutrition they need to learn, to grow, and to pursue their dreams.

These are just a few of the ways that USDA is helping to create jobs and work towards an economy built to last. But it's going to take more to keep moving forward, and that's the goal of President Obama.

I share the President's vision for investing in activities that promote economic growth, while reducing our deficits over the long-term. We need to cut what we can't afford in order to pay for what really matters, but in a way that does not hamper growth or prevent us from helping businesses and American families that need assistance. At USDA we recognized, like families and businesses across the country, that we could not continue to operate as we did in the past and that we must innovate, modernize, and be better stewards of the taxpayers' dollars.

Over the past decade, USDA has seen an increase in program complexity and demand for services while staffing has decreased. Therefore, for fiscal year 2012, I led a Department-wide review of operations to make USDA work better and more efficiently for the American people. Agency leaders took a hard look at all their operations, both in headquarters and field offices. The result was our Blueprint for Stronger Service. The plan identifies administrative efficiencies, office closures, and targeted staffing reductions, to help us deal with reductions in funding. This plan will create optimal use of USDA's employees, better results for USDA customers, and greater efficiencies for American taxpayers.

Under the Blueprint for Stronger Service, USDA is reducing expenditures for certain IT products, supplies, travel, printing, and other services. The Blueprint also calls upon USDA to strengthen its administrative services. Under this initiative, the Department identified 379 recommendations for improving USDA's office support and operations, which includes ways to streamline the provision of administrative services, such as civil rights, information technology, finance, human resources, homeland security, procurement, and property management. Twenty-seven initial improvements have been identified for first-phase implementation of this project

that will realize efficiencies through improved administrative services, such as leveraging USDA's size through strategic and volume purchases as is demonstrated by the consolidation of over 700 cell phone plans down to approximately 10.

To realize further efficiencies, USDA has proposed closure of 259 domestic offices, facilities, and labs across the country, as well as seven foreign offices while ensuring that the vital services they provide are not diminished. In some cases, the offices being closed are no longer staffed or are staffed by one or two people; many are within 20 miles of other USDA offices. In other cases, technology improvements, advanced service centers, and broadband service have reduced the need for brick and mortar facilities.

Last year, many agencies put hiring controls in place, followed by voluntary early retirement programs and targeted separation incentive programs. We have offered these programs on a broader basis in fiscal year 2012. Over the last 15 months, nearly 7,800 people have elected to take advantage of regular and early retirement opportunities. These departures have provided agencies the flexibility to eliminate or restructure positions to be more relevant to customer needs. Many of the vacated positions will not be refilled, and many of those refilled will be at lower grades than before. We opted to manage change rather than implement reductions-in-force or furloughs, which would have disrupted services that matter to the public.

When fully implemented, these immediate actions along with other recommended changes will generate efficiencies valued at about \$150 million annually. Further improvements are expected based on the realignment of the workforce. Most important, these actions will ensure that USDA continues to provide an optimal level of service to the American people within available funding levels. Ultimately, the Blueprint for Stronger Service will allow us to manage change in a way that allows us to provide a high level of services despite reduced operating budgets.

I have made it a priority to transform USDA into a high-performing and diverse organization. Under our Cultural Transformation initiative, we are focusing on improving several aspects of employee culture, including leadership accountability, employee development, talent management, labor relations, customer focus, and diversity of the workforce. By strengthening management operations and engaging employees, USDA will also improve customer service; increase employment satisfaction; and implement strategies to enhance leadership, performance, diversity, and inclusion.

This in-depth evaluation and improvement of our operations provided a firm foundation for us to develop the fiscal year 2013 budget. For 2013, the budget we are proposing reflects the difficult choices we are making to control spending, while maintaining investments that are critical to long-term economic growth and job creation.

In total, the 2013 budget we are proposing before this subcommittee is \$141 billion, an increase of \$6.9 billion above the 2012 estimate. Of the increase, \$6.4 billion is for mandatory programs, due primarily to a one-time shift in the timing of certain crop insurance costs mandated by the 2008 farm bill. The budget also increases funding for the nutrition assistance programs to fully fund estimated participation levels. As we continue to create jobs and grow the economy, fewer families will need nutrition assistance.

For discretionary programs, our budget proposes \$19.3 billion, approximately \$478 million above the 2012 level. The majority of the increase is for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and agricultural research. The discretionary funding request reflects the Department's continued efforts to innovate, modernize, and be better stewards of the taxpayers' dollars. Discretionary spending is partially offset through about \$1 billion of proposed limits on selected mandatory programs and other adjustments. For 2013, further administrative efficiencies, realignment of staff, and other actions are proposed to reduce costs. In addition, the budget proposes to reduce or terminate selected programs and reallocate resources to fund targeted investments in priority programs and infrastructure to provide a foundation for sustainable economic growth.

This budget provides the resources we need to effectively deliver the level of service our customers and your constituents expect from USDA—whether it is applying for a farm operating loan, enrolling more acres into conservation programs, supporting business creation, seeking nutrition assistance, or any of the multitude of services provided by our dedicated workforce. Any further reduction in funding for our back office operations would significantly impair our ability to deliver critical services and would imperil our efforts to manage an increasingly complex workload with less money and fewer workers.

Reducing the deficit is a critical part of the President's economic plan. The long-term stability of the economy depends on whether we have the will to act now. Farmers and ranchers know the importance of a healthy economy, which raises in-

comes and increases demand for their products. Therefore, the 2013 budget reflects the President's Plan for Economic Growth and Deficit Reduction. The President's plan reduces the deficit by \$32 billion over 10 years by eliminating direct farm payments, decreasing crop insurance subsidies, and better targeting conservation funding to high-priority areas.

As Congress initiates its deliberations on the reauthorization of the farm bill, we must remember that American agriculture has achieved its success today because of the policies and the investments that have been made over many decades. We are here because we've maintained a strong safety net so there is adequate financial help when times are tough and disaster strikes. We have supported research that has led to a significant increase in agricultural productivity and promoted vibrant markets. We are also here because policies in the farm bill for research, renewable energy, and broadband are providing rural America the tools to take advantage of new economic opportunities. Statutory authority for all disaster programs expired on September 30, 2011; accordingly, USDA cannot provide assistance through these programs to producers for losses due to natural disasters occurring after that date. As the farm bill is drafted, I encourage Congress to provide USDA the tools and the flexibility needed to address the challenges faced by American producers.

Our 2013 budget protects the farm safety net, while achieving the President's goal for deficit reduction. Income support programs, including 2012 direct payments, 2013 counter-cyclical payments, and Average Crop Revenue Election (ACRE) payments, are expected to total about \$4.9 billion and outlays under the Federal crop insurance program are projected to reach \$9.3 billion. Despite a strong farm economy, demand for USDA farm loans remains strong due, in part, to tighter private credit standards including higher down-payment requirements. The 2013 budget provides nearly \$4.8 billion for loans to meet the expected demand for financing. The requested loan levels will serve nearly 30,000 farmers.

In order to better serve producers with faster and simpler service, the budget continues to fund IT modernization activities of our Farm Service Agency (FSA). This investment will improve the Agency's ability to deliver increasingly complex farm program benefits, securely, reliably, and rapidly. Since 2003, staffing levels at FSA have declined over 30 percent, making investments in IT infrastructure even more important.

One of USDA's most important objectives is to protect our abundant natural resources. Over the last 3 years, we enrolled a record number of acres of private working lands in conservation programs. These programs help to preserve the soil, improve water quality, and promote wildlife diversity and add hundreds of millions of dollars to local economies in rural areas. For 2013, the budget provides approximately \$6.2 billion to support approximately 358 million acres in farm bill conservation programs.

For the Natural Resources Conservation Service (NRCS), the 2013 budget proposes \$828 million for conservation operations. NRCS will continue efforts to leverage technical assistance funds through agreements with its traditional partners, such as conservation districts, as well as with nonprofit organizations and State and local agencies. This approach of voluntary conservation works. That is why we are embracing locally driven conservation programs and entering partnerships that focus on large landscape-scale conservation programs, such as the Chesapeake Bay, the Bay-Delta region in California, the Mississippi River Basin, Gulf Coast, and the Great Lakes.

Our budget for 2013 contributes significantly to the economic growth goals of the White House Rural Council by continuing to fund programs that promote renewable energy, job training, infrastructure investment, access to capital, and green jobs throughout rural America. Approximately \$6.1 billion in direct loans will be made available to support the transformation from fossil fuels to cleaner technologies. Allowing financing for environmental upgrades will support the continued development of a national clean energy strategy. Almost \$1 billion in loans will be used to support rural business and entrepreneurs, which will put more people back to work. USDA's efforts, including a regional approach to wealth and job creation, is one reason why the unemployment rate is dropping more quickly in rural America than anywhere else in the country. We are giving renewed opportunity to the nearly 50 million people who live in those areas who don't necessarily farm.

Cutting edge research remains key to the United States retaining its competitive edge and global leadership in agricultural productivity—estimated to need to increase 70 to 100 percent by 2050 to meet growing global demands for food. The correlation between research and improved productivity could not be clearer. As a result of research at USDA, our land grant universities, and the private sector, American agriculture ranks second in productivity gains of all segments of the U.S. economy since 1980. Over the past 60 years, yields per acre of major crops—corn, soy,

wheat, and cotton—have doubled, tripled, and in some cases even quadrupled. At the same time, livestock production and specialty crop production have become far more efficient. These incredible productivity gains were achieved through a sustained investment in research. We will continue to support a robust research program that will ensure sustainable agricultural production, economic growth for growers and greater choice for consumers. The 2013 budget proposes funding of \$325 million for the Agriculture and Food Research Initiative (AFRI), an increase of \$60.5 million, and \$1.1 billion for our Agricultural Research Service (ARS). We will continue to focus additional research dollars in key areas, such as biofuel feedstocks, livestock and crop production and protection, and enhancing American agriculture's ability to meet growing global demand sustainably.

Because we are still in a recovering economy, USDA recognizes the need to support those in need by ensuring access to safe and nutritious food, which is essential to the healthy development of every American child and to the well-being and productivity of every American family. The budget fully funds the expected requirements for the Department's three major nutrition assistance programs—WIC, the National School Lunch Program, and SNAP.

The Department has had great success in promoting healthy eating habits and active lifestyles. Too many adults and children have poor diets and gain excessive weight contributing to poor health and increased medical costs. The Centers for Disease Control and Prevention data show that the prevalence of obesity among children tripled from 1970 to 2008 and it doubled among adults. However, data for 2009–2010 show the obesity rate for both children and adults has stopped increasing. Policies aimed at increasing access to more nutritious diets, promoting eating habits consistent with the Dietary Guidelines and encouraging healthy lifestyles are partly responsible for this change.

One of the key challenges for providing healthier school meals is to modernize cafeteria equipment appropriately so schools can prepare attractive, wholesome meals with more whole grain, fruit and vegetables, and less fat and saturated fat. Helping schools to upgrade the nutritional quality of meals served is essential. So an important part of the budget request is \$35 million to continue competitive grants to help schools purchase equipment to serve healthier meals as well as to expand the breakfast program. These grants will help about 10,000 schools across America.

The budget not only supports domestic food assistance, but also provides \$1.4 billion to support programs that further the administration's global food security objectives, including those supporting preschool and school feeding programs carried out under the McGovern-Dole International Food for Education and Child Nutrition Program. In fiscal year 2013, the McGovern-Dole program is expected to benefit more than 4 million women and children. Through the U.S. Government's leadership in global food security, we advance global stability and prosperity by improving the most basic of human conditions—the need that families and individuals have for a reliable source of quality food and sufficient resources to purchase it.

The Obama administration and USDA are committed to partnering with rural communities to increase their economic competitive by helping them provide residents access to quality healthcare services, modern library facilities and school buildings, and reliable emergency equipment and services. Financing totaling \$2 billion, an increase of approximately \$700 million, will provide assistance to over 1,700 rural communities. Investing in rural communities is essential for growth and job creation.

Helping rural residents obtain safe and affordable housing is also a key to maintaining stable communities and creating jobs. The 2013 President's budget requests a significant level of funding for housing programs. USDA continues to request that single family housing assistance be provided primarily through loan guarantees. The 2013 budget includes funding to support \$24 billion for guaranteed loans. USDA's single family housing direct loan program is funded at \$653 million, and will be targeted to teachers in rural areas, and very-low-income recipients of mutual and self help grants. These funds will create job opportunities and make the dream of home ownership a reality for over 184,000 families in rural America.

Since the founding of President's Obama's Food Safety Working Group in 2009, USDA has collaborated extensively with other Federal partners to safeguard the food supply, prevent foodborne illnesses and improve consumers' knowledge about the food they eat. USDA is working to strengthen Federal efforts and develop strategies that emphasize a three dimensional approach to prevent foodborne illness: Prioritizing prevention; strengthening surveillance and enforcement; and improving response and recovery. Between 2000 and 2010, USDA reached a national goal of reducing *E. coli* rates by 50 percent, largely because of strengthened beef safety policy and enforcement. In 2011, stricter *Salmonella* and *Campylobacter* performance

standards were implemented to reduce these pathogens in turkeys and young chickens, which are expected to prevent as many as 25,000 foodborne illnesses annually.

Despite this success, we can and must do a better job of ensuring the safety of meat and poultry products regulated by USDA, but we need to do it more efficiently and effectively. The Food Safety and Inspection Service (FSIS) recently published a proposed regulation that will prevent thousands of food-borne illnesses, streamline poultry inspections, and reduce spending by approximately \$90 million over the first 3 years of implementation. We will revise current procedures and remove outdated regulatory requirements that do not help combat foodborne illness. The new procedures will use taxpayer dollars more effectively and efficiently; even with these program efficiencies, the budget includes approximately \$1 billion for FSIS.

The economic vitality and quality of life in rural America and the U.S. economy at large depends on a competitive, efficient, and productive agricultural system. In an era of market consolidation and intense competition, producers rely on fair and open access to markets and control over their decisions to thrive. Producers also rely on animal and plant resources being protected against the introduction of foreign agricultural pests and diseases. For 2013, the budget includes over \$880 million in discretionary funding to improve agricultural market competitiveness and production for the overall benefit of consumers and producers.

We have taken a close look at the budget for the Animal and Plant Health Inspection Service and have proposed a number of program reductions and implemented identified program efficiencies to ensure that scarce resources are being used efficiently. The budget achieves savings through a variety of means. It includes decreases for activities where eradication campaigns have been successful, such as boll weevil, and for pests and diseases where management is currently more prudent than eradication, such as emerald ash borer. Savings are also possible in animal disease testing while still meeting international standards. Further, the budget achieves other savings by acknowledging the role of the producer and other cooperators to directly reduce certain pests and diseases, such as Johne's disease. The budget also proposes modest increases to improve overall animal disease traceability and to provide protections against animal diseases that could impact human health. At the requested budget level, we estimate we will prevent and mitigate about \$1.18 billion in damages as a result of selected plant and animal health monitoring and surveillance efforts.

USDA's central Departmental Management provides human resource, procurement, information technology, and financial management oversight and services to agencies. Departmental staff offices provide legal and economic support, communications coordination, and program appeal hearings for the Department's program activities. These activities are vital to USDA's success in creating opportunities for America's farmers, ranchers, and rural communities. The 2012 appropriations act made deep cuts in funding for these offices. Under these reduced funding levels, we took prudent actions to maintain critical functions needed to support the agencies' effective delivery of program operations. But further reductions in these areas cannot be sustained without deterioration in service. For 2013, the budget proposes funding to ensure that these offices maintain the staffing levels needed to provide leadership, oversight, and coordination. These efforts are critical to making the Department an efficient and effective organization.

Since coming to USDA, I have made it a priority to resolve all of the civil rights cases facing the Department which the administration inherited. During this time, we have resolved large-scale class action lawsuits involving allegations of past discrimination by Black and Native American farmers and ranchers and provided an additional path to justice for women and Hispanic farmers and ranchers who allege discrimination. We have corrected past errors, learned from mistakes, and charted a stronger path for the future where all USDA employees treat all Americans with dignity and respect. The 2013 budget builds upon our progress by increasing funding for selected key priorities that will improve USDA's handling of civil rights matters and will address claims of potential discrimination in the delivery of programs.

In conclusion, the President is deeply committed to reducing the deficit so that the economy can continue to grow over the longer term. This is a responsible, balanced budget that continues to meet key priorities and is consistent with the President's commitment. We will continue to achieve significant progress in administering more complex programs with fewer staff and resources by adopting reforms that will improve our programs and service to our customers.

At this time, I will be glad to answer questions you may have on our budget proposals.

Senator KOHL. Thank you very much, Secretary Vilsack.

## WIC PROGRAM FUNDING

Mr. Secretary, the fiscal year 2013 budget includes \$422 million increase for WIC. Do you believe this budget is sufficient to cover the demand for the WIC program? How will the Department adjust should cost food costs and participation increase in 2013?

Secretary VILSACK. Mr. Chairman, we do believe it is adequate. We do believe it's based on accurate estimates. We're a bit off this year, and so we wanted to be doubly sure that we focused on maintaining the WIC program so that there weren't waiting lines. We know that's something the Congress does not want us to have. But, also point out that we are expecting and anticipating that the food inflation will be moderate in comparison to last year. We saw fairly significant spikes at various points in time. We don't expect to see quite the high level of food price increases that we experienced last year. So, we do believe that that estimate is accurate.

## SNAP CONTINGENCY FUND

Senator KOHL. Mr. Secretary, the food stamp program, which is now called SNAP, saw a \$2 billion increase to its contingency fund. This is not a small amount of money. Why is this additional amount of money needed, given the current state of the economy? Do you envision using any of the contingency?

Secretary VILSACK. Mr. Chairman, what we have seen with reference to SNAP is a plateauing of our SNAP numbers, which is obviously a good sign, may very well be reflective of the fact that we're beginning to see an improved economy.

Having said that, as noted earlier, high energy costs could potentially derail that recovery, and so we want to be in a position that if things don't continue to proceed in a positive way that we can respond to the nutritional needs of families, and also continue to focus on the fact that their nutrition assistance programs are not just for the struggling families, but it is, in a sense, part of the overall program to ensure the safety net for our producers. Sixteen cents of every food dollar goes into a farmer's pocket. So, as we look at the totality of our support, and help, and assistance for our farmers and producers, you have to look at all of the programs, including SNAP.

## SNAP PROGRAM INTEGRITY

Senator KOHL. Mr. Secretary, over the past few months we've heard a lot about the integrity of the SNAP program. This program provides a crucial safety net for millions of people. We certainly need to ensure that this program is managed in the most effective and efficient manner possible. What is your Department doing to address waste, fraud, and abuse in this program?

Secretary VILSACK. Mr. Chairman, let me start off by pointing out that the fraud rates and the error rates are at historic lows. We've taken a number of steps.

First, as it relates to individuals, we have in place a program that will allow us to check against death records, Social Security records, et cetera, to make sure that people are not inappropriately using other's identity. We also have a program for those individuals

who live near border States to ensure that they don't try to collect in a number of States.

I will tell you that in 2010, our latest numbers, nearly 800,000 investigations were conducted by States, in terms of individuals, and more than 44,000 individuals were disqualified from the program as a result of being disqualified in those inspections.

We have looked at approximately 15,000 businesses, stores, and we have an alert program, which allows us to begin looking at 18 different demographic factors and demographic pieces of information and data about how SNAP proceeds are being processed.

For example, if we see a continuation of even no-cent purchases, \$35, \$50 even, that is a tip-off for us to really do a more thorough investigation of how the program is being utilized.

We are also making sure that if a location is disqualified from the program, that there's not a transfer of ownership that is basically hiding the previous owner, so we're going into greater detail in terms of looking at the paperwork of these transfers.

So, we take all of this very, very seriously. We understand it's important and necessary to maintain the integrity of these programs. While we are pleased that we are at record lows, we're not satisfied. We want to continue to work to ensure the integrity of these programs.

#### FOOD SAFETY AND INSPECTION SERVICE POULTRY INSPECTION

Senator KOHL. Thank you. The Food Safety and Inspection Service (FSIS) program, is responsible for ensuring that the Nation's commercial supply of meat, poultry, and processed egg products is safe and wholesome. This is done to a large degree by Federal inspectors and meat processing plants.

However, FSIS's budget includes a \$13 million cut in funding associated with implementing new methods of poultry inspection and reducing staff by 500 employees. Certain inspection responsibilities would shift from Federal inspectors to company employees.

In light of continuing outbreaks of food-borne illness, we're concerned that this decision may put consumers at risk solely for budget savings. Do you believe this new inspection method will keep our food safe? What training will be required of company employees prior to assuming these new tasks?

Currently, FSIS inspectors can evaluate up to 35 birds per minute. The new process is supposed to be five times faster, and is this safe for workers?

Secretary VILSACK. Mr. Chairman, thank you for asking that question. First of all, let me suggest to you that we believe that this process will actually make the food safer, not as safe, but safer. And the reason for this is, based on the fact that we have had a number of pilot facilities around the country for a number of years use this new system that we're proposing, and from that, the data suggests that we can save 5,200 food-borne illness incidences as a result of this new system.

Second, it's important to know that essentially what we're doing in terms of company inspection is not so much in terms of food inspection and in terms of food safety, it has more to do with the cosmetic appearance of the poultry. At the beginning of the process, we are currently using individuals to look for defects in the cos-

metic nature of poultry, which we think is really more about the marketing of the product, not the safety of it.

What we'd like to be able to do is to have the company assume that responsibility for cosmetic review, and then shift the responsibility of the people that we currently have on that line to taking a look at the locations along the line where the hazards are greatest, and beef up that effort.

It is true that this will result ultimately over time in roughly 500 to 800 fewer positions, but it will also result in more than 1,000 people actually receiving a higher paying job and a more sophisticated job, for which there will be additional training. We expect and anticipate that this will be factored in or phased in over a couple-of-years period in order to ensure the training is accurate.

As it relates to the worker safety question, we are going to institute a study at the beginning of this process. We have a study, but we want to make sure that the results of that study are verified. And we are going to essentially look at a very complicated review of the safety of workers. If we see a problem with the safety, we will obviously adjust accordingly.

The last thing I would say is that this whole process, this review process, this inspection process has been peer reviewed. And I think that the review suggests very strongly that this will actually result in a safer system, a safer food supply. It just happens to also save money for the Government and for the companies, but it is primarily for food safety that we're looking at this.

Senator KOHL. Thank you, Mr. Secretary.

Secretary VILSACK. Thank you.

Senator KOHL. Senator Blunt.

Senator BLUNT. Thank you, Chairman.

#### WIC PROGRAM INCREASES IN CALIFORNIA

Mr. Secretary, in the WIC program, I think there's been, particularly in California, an increase in costs. It's the largest program, of course, but it's increased a whole lot faster than in other States. And I wonder if you could tell us a little bit about what you're doing to look at that, and what might be the cause for that.

Secretary VILSACK. Senator, there may be a number of reasons, but the one that concerns us the most is that there are very, very small stores that have dramatically overpriced products in the WIC package. And we have advised the State of California that this has taken place. We have asked the State of California to first and foremost stop any further approvals or permission for those sized stores to continue to participate in the WIC program. We've asked them to review their protocols for the analysis of those smaller stores, and we have been advised by the State of California that they will be coming up with a new regime this spring that will address in a very serious way, in a very concrete way, and a very quick way, the fact that there have been stores that have taken advantage of folks, and taken advantage of this program.

So, that's one of the concerns that we've had, and we've notified the State, the State has responded, and they are in the process of fixing the problem.

Senator BLUNT. Just a curiosity here. I'm glad you're looking at this carefully, and it sounds like you're working with them to solve

it. Do these stores have a different section for WIC customers, or do they just assume that most people won't buy the more expensive gallon of milk, the more expensive loaf of bread, or whatever they're pricing at this higher rate?

Secretary VILSACK. Senator, I'm not sure if they have a different section. My understanding was, and I could be wrong about this, that this was sort of mixed in with their overall operation, and basically taking a fairly significant advantage of folks. When we're seeing the price of various items being two, three, four, maybe even higher at times what you would normally see in a regular grocery store. And I think one of the keys for us, as this is—

Senator BLUNT. Did you say two, three, or four times as high?

Secretary VILSACK. Or higher.

Senator BLUNT. To understand this, if you're a WIC recipient, you have a coupon that allows you to get this product that has nothing to do really with the price of the product where you buy it.

Secretary VILSACK. That's correct. And then the grocery store or the convenience store puts in a bill, if you will, for reimbursement for that, and were charging a substantial amount for that product far, far in excess of what the market was currently charging for that product, whether it be cereal, or whatever it might be.

We noticed this in our review of the data, and we contacted the State and said this is a serious problem. First and foremost, what we are going to tell you is we don't want any further businesses of this size, if you will, in these high-risk areas to basically be permitted, and then second, we want you to take this very seriously and rethink the way in which you are providing oversight. As you know, these programs, the administrative oversight is initially at the State level to provide oversight so that this doesn't happen.

And, again, I think California did respond. Governor Brown and his team have looked at this, and they said, yes, you're right. This is not right. We're going to fix it, and we're going to fix it quickly.

Senator BLUNT. Do you feel like this might be happening on maybe even a lesser level, but in other places?

#### NUTRITION PROGRAMS FRAUD DETECTION

Secretary VILSACK. I'm not aware of it happening in other States, Senator. I know that we're looking at this, and being careful about it. And the point I would make, with reference to nutrition programs, generally, is—as we look at the farm bill, and as we talk about this issue—I think we need to take a look at the definition of stores that qualify for these various programs, because right now we see a lot of issues with relatively small facilities. That's where many of our concerns are relative to error rates or fraud in many of these nutrition programs. So, I think we really need to be careful about the permission we grant. There are more than a quarter-of-a-million stores, for example, that provide SNAP, and a relatively small percentage of those stores sell a disproportionate amount of SNAP food. It's maybe less than 20 percent sells 80 percent of the food. That type of ratio. So, I think we need to really take a look at that.

Senator BLUNT. I'm going to ask a technology question next, so it may be the answer.

Is there any way your system can monitor whether some area is way out of bounds on pricing of specific products?

Secretary VILSACK. I think there is. Certainly, in a couple of programs we do have that review, and we're continuing to look at ways in which we can mine data that we collect to be able to identify problems, as I said earlier.

For example, if we see a store where there are a lot of even purchases. I mean no one goes into a grocery store and gets \$35 worth of groceries. They get \$35.18 or \$35.16. We see a pattern of that. That gives us a tip that there's a problem there, and that triggers a review and investigation.

Senator BLUNT. And you say for both WIC and SNAP this is something that you're watching carefully.

Secretary VILSACK. Yes. And that's why we had 15,000 store reviews. That's why we had nearly 800,000 individual investigations and reviews, in terms of the program. And that's why several hundred stores were disqualified, and 44,000 individuals were taken off the program. And that's why our fraud rate and our error rate are at historic lows.

Senator BLUNT. On technology, I thought about that. I thought well, I probably ought to go to this technology question, too.

#### FARM SERVICE AGENCY INFORMATION TECHNOLOGY

With the FSA offices, I understand the technology there has been about as old as any technology anybody's still using, and to some extent, individual farm records were essentially captive to whatever machine they were in 1984, or whatever. You could tell me more about this. The Modernize and Innovate the Delivery of Agricultural Systems (MIDAS) program is the program that would upgrade that?

Secretary VILSACK. That's correct. And we spent the last several years, with the resources provided by this subcommittee, building the design for the new system. And the good news, this year we'll begin to see actual on-the-ground construction or building of the system, starting with acreage reports, and starting with some of the farm record development as a strong foundation. And then the following year, we will build on top of that foundation, and hopefully, within the next year or 2, our farmers will begin to see a much more convenient approach from the FSA offices. And hopefully, we will get to a point in those places where there's sufficient broadband Internet access that folks can work literally from their homes.

Senator BLUNT. From their home. Now, my belief is that the equipment that the FSA office has been using is like mid-1980s.

Secretary VILSACK. It's not so much the equipment. It's the software.

Senator BLUNT. It's the software system.

Secretary VILSACK. Yes. And so when you have a farm bill every 5 years, what happens is oftentimes those systems, many of them have to be manually coded, if you can imagine that. And that's why it takes a long time to implement things. But, MIDAS is designed to address that. And it's taken a number of years to do it right, a lot of feedback from those who work on the ground, in the field, to make sure that we design it properly, and to test it properly.

Senator BLUNT. And this has almost \$12 million in it. Would that complete MIDAS?

Secretary VILSACK. Oh, no. No. No. It's far more than that, Senator. This is a very, very significantly expensive operation.

Senator BLUNT. There's a \$12 million increase, though. \$11.78 million, I guess.

Secretary VILSACK. We are asking for a substantial increase this year. Just to give you a sense of this, the implementation, in fiscal year 2011, we asked for \$45 million. In fiscal year 2012, it's \$112 million. And the reason it goes from \$45 million to \$112 million is because we're not actually building the infrastructure to do this. And we're going to build the foundation this year, and a lesser amount next year should complete the process.

Overall, we had anticipated and estimated years ago that this would cost several hundred million dollars, and that estimate is going to be correct.

Senator BLUNT. So, in fiscal year 2012, the budget year we're in right now, this is the big year for MIDAS.

Secretary VILSACK. This is the big year. And fiscal year 2013, we're reducing it, but it's still a substantial amount of money. It's nearly \$100 million. So, it's less than this year, but it's still substantially more than the previous years, because we're now building it, as opposed to designing it and testing it.

Senator BLUNT. And this is more of a software problem than a hardware problem?

Secretary VILSACK. That's my understanding. I'm not a technical expert, and maybe someone here on the panel can amplify on this. But it's primarily—

Senator BLUNT. No one's raising their hand on the panel.

Secretary VILSACK. It's primarily.

Senator BLUNT. You're on your own.

Secretary VILSACK. It's, as I understand it, primarily a software issue. If I'm wrong about that, we will let you know. But the reality is, it is an expensive proposition, but eventually, it should get to the point where if you have Internet access, you will be able to be at your kitchen table, call up your files, and basically be able to work with FSA offices online. That's the goal.

[The information follows:]

MIDAS focuses on software, specifically adapting commercial-off-the-shelf software (COTS) to run Farm Program applications in a Web-accessible environment. The Department's Common Computing Environment (CCE) focuses on refreshing the system hardware and upgrading the network used by the USDA Service Centers.

Regarding MIDAS, the Farm Service Agency (FSA) has completed the initial design for MIDAS, which includes business requirements documentation, design of re-engineered processes, improved access to data, and creation of a network comprised of Service Center employees to ensure the new software meets the needs of the business. The MIDAS Program is now in the build phase, during which the system software is configured to meet the requirements, and all technical components are set up and tested.

In fiscal year 2012 the emphasis of CCE is network optimization which is the effort to replace the aging infrastructure—desktop computers, servers, data storage capacity, bandwidth to support applications—to ensure that the core network infrastructure meets the demands of many of USDA's and FSA's IT modernization efforts including MIDAS. At completion, it will be possible for farmers and ranchers to access MIDAS online, via Internet access, e.g., "from your kitchen table."

## FARM SERVICE AGENCY OFFICE CONSOLIDATION

Senator BLUNT. Now, if you go to a new FSA office, based on consolidation, will your records be there? Do you know that they're there?

Secretary VILSACK. Not only will the records be there, but most likely, the person who dealt with you at the previous office will also be there. There are about 170 people that are impacted specifically by what we're proposing, and all 170 of those folks will still be able to work at FSA, if they choose to do so.

Senator BLUNT. Mr. Chairman, do you think we'll have time for a second round?

Senator KOHL. Yes.

Senator BLUNT. If so, I'll go ahead and wait for that second round for other questions.

Senator KOHL. Thank you very much.

Senator Pryor.

Senator PRYOR. Thank you, Mr. Chairman. I thought Senator Moran was here before me.

Senator KOHL. I thought I'd rotate.

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

## FARM SERVICE AGENCY OFFICE CONSOLIDATION CRITERIA

Mr. Secretary, I think a bad way to start a hearing is when one of us writes you a letter on February 21, and we don't get the response until March 28, at 4 p.m., hand-delivered the day before a hearing. I'd like to follow-up on some of the questions I asked in that letter, one, in particular, that you did not answer. And that would be my question No. 2 in the letter, where I ask you "to provide all relevant criteria relating to the closure of offices within specific distances, along with the formula used to determine mileage between county offices. I'd appreciate if this included copies of mapping data, provided by any internal or external source, used to determine the mileage between all proposed office closures in Arkansas."

And the reason I ask that is because you have chosen to use Euclidean miles, which is defined "as the crow flies," as compared to road miles. Had you used road miles, 7 of the 10 offices in Arkansas would not be closing now, but you chose to use Euclidean miles. So, could you tell us why you decided to use "as the crow flies," instead of the mileage that people actually have to drive to get to the office?

Secretary VILSACK. Senator, we had a process that involved not just the offices in DC, but also the State offices that assisted us in making the calculations. And candidly, we're confronted and faced with two realities in the farm service world. One is that over a period of time, we have seen operating budgets reduced by the Congress. And second, 10 years ago, there were 18,000 people working for FSA. Today, there are around 12,000 people. So, we have seen one-third fewer workers. We've seen an increase in workload. We were faced with a very difficult decision, whether we would take a look at roughly 130 offices that were within 20 miles "as the crow flies," as you have indicated, for closure, or whether we would institute furloughs or layoffs. And I will tell you, sir, from my perspec-

tive, as long as I'm Secretary, the last thing I want to do is furlough a worker or lay one off. And if I can prevent it, that's what I'm going to do.

Senator PRYOR. Why did you choose to use "as the crow flies," as opposed to road miles? Was it to close more offices?

Secretary VILSACK. Not necessarily. It was what the staff recommended. It was not necessarily to close more offices. It was basically to make sure that we were operating within the directive of the Congress. The Congress was not clear, and was not definitive and specific. It just said 20 miles. So, we felt that that was the simplest way to do it.

And it's true that there may be situations and circumstances in your State and other States where it may take longer, or it may require more of a distance, but again, the reality is the choices. You either do that, or you basically create potential chaos in 2,000 offices with furloughs or potentially chaos in a number of offices with layoffs. We felt focusing on offices that had no employees, we found that 35 of the 131 offices had no full-time employees. Offices that had one employee, where if you were sick or if there was a ballgame you needed to see, there was no one there to service the needs. It was a better idea to basically provide for larger staffed offices, and perhaps within 20 miles or so of where the previous office was.

#### BLUEPRINT FOR STRONGER SERVICE

Senator PRYOR. Now, I've heard that your proposed savings on this are going to be \$150 million. Is that per year?

Secretary VILSACK. No, sir. That's not accurate.

Senator PRYOR. How much do you save on this?

Secretary VILSACK. The office closings themselves are about \$6.5 million. The \$150 million figure comes from a combination of a number of things that we've done. A reduction in travel, a reduction in supply purchases, a reduction in conferences, and the administrative services process, in which we've identified 379 recommendations for changes internally within USDA, 27 of which we're in the process of implementing. An example is taking over 700 cell phone contracts that we had at USDA and consolidating them into 10 to 15 contracts, so we get quantity discounts, things of that nature. When you combine all of those steps, that's where you get the \$150 million number.

Senator PRYOR. Yes. That's a helpful clarification. All right.

#### FARM SERVICE AGENCY OFFICE CONSOLIDATION

I want to ask you about three offices in Arkansas. I'll probably have to come back on the second two. But, we have one in Izard County, in Melbourne, Arkansas, that is 18.5 miles "as the crow flies," but it's 21.8 miles to the nearest FSA office if you drive it. The problem is, to drive it on those highways and those roads it's 44 minutes each way. So, it's 1.5 hours roundtrip, if you want to go over to that next county's office and pick up a form, or whatever it may be.

Now, in the farm bill in 2008, in the closure criteria, we use the phrase, "To the maximum extent possible," which, to me, sounds like we gave you discretion on hardship cases like this, where it

may be technically 20 miles away, even though this is longer than 20 road miles away. It seems like you would have some discretion to make exceptions or to understand the hardship that you'd be causing on people to close the office. Did you make any exceptions for anyone in the country?

Secretary VILSACK. We've not made exceptions as of today, Senator. And the reality is that I think probably every single member of Congress and every Senator could probably make a good persuasive local case for why a particular office should stay open and not be closed. This is a very difficult set of circumstances that we're confronted with. We have less money and we have substantially fewer people.

We've had a substantial increase in the number of retirements. In order to avoid substantial layoffs and furloughs, we had to have an early retirement, an early separation package, which in the last 15 months we've seen 7,000 of our most experienced people leave.

This is not an easy process. We have tried desperately to avoid furloughs and layoffs. That's basically where I'm coming from. And I'm not hiding anything here. We're doing everything we possibly can to try to squeeze out every buck that we can in a way that allows us to continue a record amount of activity.

Senator PRYOR. Thank you, Mr. Chairman.

Senator KOHL. Thank you.

Senator MORAN.

Senator MORAN. Chairman Kohl, thank you. Mr. Secretary, thank you for being here.

Mr. Secretary, you're going to be in Kansas in a few days, a couple of weeks, and I wanted to welcome you to our State. Very much appreciate you accepting the opportunity to speak at a Landon lecture in Manhattan, Kansas. Also want to thank you for your ongoing and continued support for the National Bio and Agri-Science Research facility and your efforts to see that it gets built.

I want to ask a couple of questions, and I'm going to try to ask them so I can get them both in in the 5 minutes that I'm allowed.

#### UNIVERSAL SERVICE FUND

Two different topics. First of all, Rural Utilities Service (RUS), it's a lending agency that you have a jurisdiction over. It provides loans for electric, water, sewer, and telecommunications. The telecommunications loan portfolio is more than \$4 billion. In October, the Federal Communications Commission (FCC) adopted an order that significantly modifies the Universal Service Fund and inter-carrier compensation formulas. On February 15, I wrote you a letter. I'm not yet complaining that it hasn't been responded to, but I've raised this topic with USDA, with you, in particular, trying to discover what your analysis is about the impact of the FCC's Universal Service Fund and inter-carrier compensation order, what the consequences are to the RUS loan portfolio, as it relates to telecommunications.

Are you concerned with that order? If so, what's RUS USDA doing to explain to the FCC and within the administration? I'm worried that the potential now exists for significant loan defaults of RUS, because one of the main features by which a rural telephone company has to repay their loan to RUS is Universal Service

Fund dollars that no longer will be flowing to those telephone companies.

Secretary VILSACK. Senator, I'm not sure if that's one question or two.

Senator MORAN. That was one question.

Secretary VILSACK. Okay. Do you want to ask the second one?

Senator MORAN. Thank you very much for that opportunity, if the chairman will let me get by with that.

#### LEAN FINELY TEXTURED BEEF

The second one is certainly a different topic, but Kansas is certainly a beef State. And lean finely textured beef has been front and center in the last few weeks. If lean finely textured beef is no longer used, it will take 1.5 million more head of cattle to make up for the lost beef, and the cost to producers is estimated to be about \$15 a head.

You said yesterday, and this is your quote, "Let me reiterate, without any equivocation, something that we have said hundreds of times, this product is safe, and there's no question about it." I would like to make certain that that's a statement that you believe to be true. And isn't it true that finely textured beef is just beef?

I notice that one of the newspapers today called it filler. There's nothing to this product except beef. And I would like to give you the opportunity to have you explain to us, but to the consumer the safety of this product.

#### UNIVERSAL SERVICE FUND

Secretary VILSACK. Okay. Senator, let's talk about the Rural Utilities Service first. That was your first question. When the FCC proposed its initial order, we did, in fact, communicate with the FCC about the fact that rural utility providers count on the Universal Service Fund. They count on inter-carrier rates. They also count on the infrastructure assistance that we can provide at USDA. Those three are three sort of pillars upon which the whole system operates.

And we expressed to them the need for them to consider, as they put together this proposal, enough flexibility to be able to address the need for expanded broadband, which we support. At the same time, recognize that there may be circumstances and situations where that order may have an impact on a particular carrier, that we would have to work with those carriers, and they need to give us the flexibility to do so.

We have asked the folks that we are currently doing business with to basically give us more information on the specifics as it relates to their individual operation, so that we have a better understanding on an individual basis how they see the potential impact.

We have asked the FCC, as they are flushing out this process, and it still has not been completed. We've asked them to take a look at the waiver system that's in place, to give us that flexibility that we've asked for, and if we have it, then I think we can make adjustments. We're also aware of the fact that the regression factor that they're using to calculate various fees and so forth is also being looked at.

So, this process is not complete. We have weighed in and asked for an understanding of its impact on individual operations. We've asked those individual operations to provide us with information so we could do an appropriate analysis, and we've also begun our process of figuring out precisely how we will approach things differently if this ultimately comes to fruition.

So, we are aware of it. We've engaged in it. We continue to engage in it. We are sensitive to the concerns that you've expressed. And we are hopeful that the FCC, with the waiver process, will give us enough flexibility to be able to address any anomalies or any concerns that might arise.

#### LEAN FINELY TEXTURED BEEF

We appreciate the fact that folks are now joining us in a discussion of lean finely textured beef. We have been talking about this issue, Senator, for a number of weeks. Sometimes we have been the only ones talking about it. So, we appreciate your question.

It is beef. And it is safe. And it's got less fat. It's something we've been saying for literally almost a month now.

I can't tell you how many times USDA, myself, Dr. Hagen, and other members of the FSIS family have been quoted or alluded to in reports, and articles, and broadcasts, and in news radio interviews about the safety of this product.

We have two issues, two responsibilities to USDA. One is to attest to the safety of a product. The other is as a purchaser of items for school lunch and school breakfast programs. In that context, we have to be responsive to our customers. We're not in the position to mandate that people do a certain thing or buy a certain thing, or have a certain thing.

Several hundred school districts have contacted us asking for choice. We have to be responsive to our customers. We've provided that choice. But we want to make sure that if they make that choice, they're making it based on the facts, and that they're not making it on the assumption or belief that this product is unsafe, because it is not.

Senator MORAN. Mr. Secretary, thank you very much. And if you'd ask somebody in your office to take a look at my February 15 letter to you in regard to RUS, I'd appreciate it.

Thank you.

Senator KOHL. Thank you very much.

Senator Brown.

Senator BROWN. Thank you, Mr. Chairman. Mr. Secretary, thank you. Again, thank you for your trip to Ohio recently, and the contribution you made there.

#### AGRICULTURAL RESEARCH FACILITIES

We've talked a lot about agriculture research, and I appreciate the work you've done in Wooster to help us after the tornado there. Agriculture is my State's—as the case in just about everybody here, I think—number one industry. Both the Center for Innovative Food Technologies—near Toledo, and you met some people from there—and Ohio State University's Agricultural Research Service (ARS) research station in Wooster have conducted groundbreaking research in many ways.

Last year, several of the ARS stations, including the North Appalachian Experimental Watershed Research Station in Coshocton, Ohio, eastern Ohio, were slated for closure. The facility provides valuable information on how farming practices affect water quality, data that is important, particularly important, given the algal blooms in the Western Lake Erie basin, which we discussed, and you learned even more about than you already knew the other day.

This subcommittee provided USDA with the option of transferring the land and the facility slated for closure at certain other institutions. Could you just give me sort of an update? To what extent is USDA open to partnering with eligible institutions to develop and implement a use for these facilities? How do you plan to move forward on that, inform us, and let us know sort of every step of the way, as you go forward?

Secretary VILSACK. ARS basically has got to follow a certain set procedure, which we are in the process of doing. We are certainly amenable to working with partnerships, land grant universities, and others. In fact, in some of the facilities that are slated for closure, those discussions, negotiations have already taken place, and are taking place.

#### BEGINNING FARMERS

I will say that, if I can take your question to a slightly different place, not only should we think about the partnerships with universities, but we have a real problem in terms of beginning farmers in this country, in terms of how young people, who might be interested in farming, could get into farming and be able to afford to get into farming.

To the extent that the Federal Government is the owner of land, or finds itself with land that it needs to dispose of, we might want to give consideration to expanding the opportunities available to ARS to basically lease or sell to beginning farmers, at a reasonable price that land, to make it a little bit easier to get young people engaged in farming. The average age of the farmer today, I'm guessing, is close to 60 years of age now. And I think it's something that we really need to be sensitive to.

So, Senator, we are following the rules as the statutes and regulations require. We are making efforts to reach out and find out if there is interest. And if there is interest, under what circumstances the arrangements could be made for the transfer.

We understand that there are restrictions on what that land can be used for, and we will follow those prescriptions and those restrictions.

Senator BROWN. Thank you. And I think that your point about beginning farmers will pique a lot of interest in a lot of places in Ohio, and we've discussed that. I think your idea is a good one there, and we will pursue that.

#### BROADBAND ACCESS

Let me follow-up with a slightly different twist on what Senator Moran said about broadband. Yesterday, I did my fifth annual, since 2008, my second year in the Senate, I bring college presidents from around Ohio to the Capitol for a day, and we had about 50, 55 of them yesterday. At the dinner the night before, a number of

them were talking about broadband access or the lack of broadband access. One college president said he believes about 29 out of Ohio's 88 counties don't have full broadband access. Only one county has none, until a local community action agency applied for one of the first ever USDA rural development broadband grant. What you-all did, and what we did together in the Recovery Act for the \$7 billion, and a good amount of that went to USDA, and that helped a lot in my State, but it's still not enough.

We must ensure the funding through the rural broadband loan program; the community connect programs ensure that funding provides it direct to the most underserved areas in the most rural communities.

Tell me what you're doing to ensure that the program integrity there in bringing services, especially to those underserved low-income and small communities that all of us represent.

Secretary VILSACK. With reference to the Recovery Act proceeds, that was the principal effort on the part of USDA, was to make sure that we had a focus on areas that were remote and rural. In some cases, those remote rural areas probably would not be in a position to support full-blown broadband. We looked at additional ways in which we could enhance technology and make it fiscally responsible and accountable. Part of the Recovery Act money was used to create satellite opportunities and an upgrade of technology. So, whether it's full-blown broadband or whether it was an upgrade, we did focus on remote and rural areas.

As it relates to our regular program, which we're now in the process of instituting, there's a very small part of what we get from the Congress that is in the form of grants, and it is specifically directed, and it is roughly \$13 million. It's not a great deal of money. It's specifically directed to trying to expand opportunities in remote and rural areas.

In addition to that, there's roughly \$25 million that's available for distance learning and telemedicine grant opportunities. Then, of the \$822 million that is in this pot of money for telecommunications, about \$94 million of it will be made available for loan guarantees for expansion in rural areas. So, there is a significant effort here, either through grants, loans, or the Recovery Act.

We have, in the last 3 years, funded roughly 600 projects. If you take the Recovery Act, the distance learning, the telemedicine, and the Connect program, we basically have funded roughly 600 projects. Now, it doesn't anywhere near address this from a national perspective, which is why the Commerce Department has a map that shows where the areas are that still need attention, and that should drive additional decisions and future decisions.

Senator KOHL. Thank you very much.

Senator Cochran.

Senator COCHRAN. Mr. Chairman, thank you for convening this hearing.

#### WATERSHED REHABILITATION PROGRAM

Mr. Secretary, I notice in the Department's budget request that we see described a budget summary of the Watershed Rehabilitation Program. We've had a good many problems in the lower Mississippi River Valley with flooding and challenges that have re-

sulted from erosion, and it has been clear that there's a lot of money that's going to be needed to repair and refurbish existing watershed programs, dams, and other impoundments that have reached the end of their design lives.

The budget request doesn't have a specific request for funding of any activity in this area, and I wonder what your suggestion is. Is there going to be a supplemental budget request submitted, or what is the intention of the administration in providing assistance to local and district-wide governments and associations to rehabilitate these structures that are in need of attention?

Secretary VILSACK. Senator, one of the reasons why there is not an appropriation amount is that at the time these facilities were constructed, I think there was a basic understanding that they became a local and State responsibility. Second, the amount of money that has been appropriated in that program is relatively small, given what could very well be a very significant national need.

So, if we're going to do this, I would say two things. One, it needs to be done on a much larger scale than this budget conversation we're having today. And two, if we're going to do it, it needs to be in conjunction with and in partnership with States and local governments, because they have at least an equal responsibility, if not a greater responsibility, given the fact that these structures are theirs.

#### CONSERVATION PROGRAMS

Having said that, we are investing a substantial amount of money in conservation and in landscape-scale efforts to try to avoid and to try to do a better job of controlling water. We still have a long way to go, but we're working on it. We have a record number of acres now enrolled in conservation, and the budget before you would allow us to add another 29–30 million acres to the 330 million acres that are currently enrolled of the 1.4 billion acres that could potentially be subject to conservation programs of the amount of farmland in this country.

So, I would say we'd be happy to work with you on a much larger, much, much larger infrastructure discussion. I mean, I think this is part of why there has been a suggestion for an infrastructure bank, why there's been a suggestion for a large-scale infrastructure appropriations, because when you talk about \$20 or \$30 or \$40 million, it really has very little impact on the overall problem that you're alluding to.

Senator COCHRAN. I appreciate your personal attention to the situation and your willingness to explore possibilities for providing some Federal assistance in this area.

#### CATFISH INSPECTION PROGRAM

One area of interest, too, that I wanted to mention at today's hearing involved our domestic fish program and the development of what has become a very substantial financial investment throughout the southern part of the country. Catfish inspection and expansion of markets, dealing with competition from overseas in the United States are all parts of this area of concern and interest.

I know that as we are preparing for this new farm bill that's being considered, there's an opportunity for defining some statutory responsibilities for inspection and standards.

Do you have any information that you can provide the subcommittee giving us a status report of where we are on developing an inspection program for domestically produced catfish?

Secretary VILSACK. Senator, can I offer some advice before I answer your question?

Senator COCHRAN. Sure.

Secretary VILSACK. If you work on this in the farm bill, to the extent that you can define what a catfish is, it would be helpful.

Senator COCHRAN. You can tell by looking.

Secretary VILSACK. That's what I thought, too, coming from Iowa, but I found out in this process that there are at least 39 different varieties, and depending upon where you are domestically, or where you are internationally, catfish is not necessarily a catfish, which is why we received a substantial number of comments to the proposal.

As you know, we asked for input from folks to give us a better understanding of precisely how the world defines catfish, and we're in the process of evaluating those responses. And literally, it is a very difficult circumstance and situation, because depending upon how narrow or how broadly you define that term, it impacts and affects quite a bit. So, we're in the process of trying to figure out precisely what was meant, and there's some conflict in terms of the congressional history of this. And so, it would be helpful if there was clarity from the Congress in terms of precisely what variety or type of catfish you were referring to, or maybe you're referring to all types of catfish.

Senator COCHRAN. We look forward to working with you on this issue. It is very important, and I think it needs our best efforts.

Secretary VILSACK. I understand, sir.

Senator KOHL. Senator Hoeven.

Senator HOEVEN. Thank you, Mr. Chairman. Mr. Secretary, good to see you again.

#### WATER BANK PROGRAM

I want to thank you for your help on the Water Bank Program, and your folks are working to implement it. We think that would be very helpful on Devils Lake. So I just want to thank you for that.

#### WIC PROGRAM

Also, I want to bring up the WIC program, specifically regarding potatoes. I and others feel potatoes need to be included with fruits and vegetables. Your thoughts?

Secretary VILSACK. Senator, the WIC program is basically a supplemental program. It's designed to supplement and to encourage nutritious eating. What we do in developing the package is we take a look at what people are already consuming, in terms of fruits and vegetables, and then what we try to do is to amplify or add to that. What we found from the review is that people are already consuming quite a bit of—the potatoes are not something that they don't consume. They consume quite a bit of that. What they don't

consume as much of are dark green, orange vegetables, things of that nature. So, the WIC program is designed to essentially complement what people are already deciding to do or already eating.

Senator HOEVEN. Are you willing to encourage that potatoes be included with the WIC supplemental nutrition program? I think there's a lot of people who feel that it should not have been left out, and we'd like to see it included. Are you willing to work towards that objective?

Secretary VILSACK. Senator, again, the purpose of this is to complement what people are already doing. If they're already consuming enough of one item, it would basically mean that we would have to reduce our commitment to some other item that they're not consuming a great deal of, and probably ought to, if they want to have a balanced and nutritious opportunity for their young children. So, this is a complementary. This is not a situation where people aren't eating any potatoes. These are situations in which people are eating quite a lot of potatoes, but they aren't eating a lot of the other types of vegetables and fruits. So what we want to do is make sure that they have access to those other options.

Senator HOEVEN. All right. I understand your point and would encourage its inclusion.

#### BLENDER PUMPS

But, I want to move to blender pumps. I believe that you've looked at funding blender pumps out of the Rural Energy for America Program (REAP). Is that correct?

Secretary VILSACK. That's right.

Senator HOEVEN. And in the President's budget, there's \$4.6 million in REAP funding. Give me your thoughts on what portion of that can and should go to blender pumps. I know you and I share a common belief that blender pumps are a good thing, can help give consumers more choice, better pricing, help stimulate renewable fuel, production, and distribution. What are your thoughts in terms of what you can put towards blender pump, promoting blender pumps and helping gas station owners get blender pumps on their premises?

Secretary VILSACK. I agree, Senator. And I may be misstating this, and if I have, I'll correct it. I believe we received instructions from the House that they were not particularly interested in us using monies for blender pumps. I'm not sure if there's a prohibition. I think there was at one point.

I don't know that I'd necessarily want to commit to a certain percentage, because there are an awful lot of good ideas that come out of the REAP program. We were a little concerned about the fact that it was substantially reduced in this current budget, which made it more difficult for us to do everything we'd like to do.

We've had 13,000 different projects, energy efficiency, anaerobic digesters, energy audits, windmill solar systems, as well as blender pumps. We've funded, I think, a couple hundred, maybe 250 blender pumps. We obviously want to do more than that. And depending upon the amount of resources that the Congress allocates to this program, we're going to continue to fund blender pumps, if there's not a prohibition restriction.

Senator HOEVEN. I know there's been some legislation offered that would restrict it. I don't know of any restriction in place. I mean last year, I think the funding was about \$3.4—

Secretary VILSACK. You mean in terms of what went to blender bumps, or the overall REAP money, because it was more than that.

Senator HOEVEN. Oh. Blender pumps. I think it was around \$3.4. Does that sound right?

Secretary VILSACK. You're probably right.

Senator HOEVEN. In any event, I'd like to work with you to see what we can do. I know there is some pushback on it, but look, I think in terms of renewable fuels, we're trying to find more market-based approaches to continue to develop renewables from the standpoint of giving customers choice and helping with pricing. I think blender pumps is the way to do it. So, I'm interested in working with you in the context of your budget as to how we can do more of it.

I thought REAP might be the best program. You may have other ideas. If so, I'd love to hear what they are.

Secretary VILSACK. To me, when you deal with the farm bill, you deal with rural development programs, and you deal with the energy title within the farm bill, to the extent that we can have flexibility, that's the key. We may have to have fewer programs, but if we have flexibility, we can use maybe the business and industry loan program to work with a consortium, for example, of convenience store owners to assist them in putting blender pumps in, as opposed to an individual grant to an individual business. Maybe that's a possibility. That's currently not necessarily a possibility under the business and industry loan program.

Senator HOEVEN. Who would we work with on your staff to really figure out what makes most sense, in terms of trying to develop this?

Secretary VILSACK. Sarah Bittleman. We'll get you her contact information, Senator.

Senator HOEVEN. Thanks, Secretary.

Secretary VILSACK. Thank you.

Senator KOHL. Thank you very much.

#### FOOD FOR PEACE TITLE II GRANTS

Mr. Secretary, we all know that many, many millions of people around the world suffer from chronic and acute hunger. We've seen how rising food prices have caused instability to some of the most vulnerable populations, and yet, the budget includes a decrease of \$66 million in the Public Law 480 program.

What is the rationale for cutting this program when the need for food assistance around the world is increasing? And if less funding is provided for this program, is this administration prepared to respond to an emergency, as we saw last year in the Horn of Africa?

#### INTERNATIONAL FOOD ASSISTANCE

Secretary VILSACK. Senator, we work with our sister agency, the U.S. Agency for International Development (USAID), to make sure that we're providing the assistance and help that's necessary. We have the Bill Emerson Humanitarian Trust, as you well know, that provides some degree of assistance and help, an entity that may,

for example, be utilized when North Korea is requesting food assistance. There's a possibility of that.

These are difficult times. If you say to add the money back that you reduced from that, then the question is, where does it come from? Does it come from the WIC program? Does it come from rural development programs? Does it come from the food safety program? Where does it come from? I mean the reality is we're dealing with constrained budgets. So, tough choices have to be made.

We think that there's a substantial amount of money that's committed to these programs. It's \$1.4 billion, plus the McGovern-Dole program, which we did maintain at a status quo funding. We think we're still in a position to help millions of people with this. And we also believe it's not just the United States' responsibility, which is why we've been working with General Assembly countries and the Group of Twenty (G-20) Agricultural Ministers to discuss a more coordinated and global response to these concerns. A discussion, for example, of developing virtual reserves, grain reserves, so that we're in a position to be able to respond internationally and in partnership in a collaborative effort. That's the reason why we have the Feed the Future initiative, which is not just designed to provide food assistance, but also to take a look at how we might make producers in other countries more productive, so that they can do a better job of meeting their own needs. So, we reduce the need for this kind of assistance.

So, I think you have to look at the totality of what we're proposing, and look at what we're doing internationally to try to stretch and leverage these resources.

#### ANIMAL AND PLANT HEALTH INSPECTION SERVICE FUNDING AND STAFFING

Senator KOHL. Mr. Secretary, the Animal and Plant Health Inspection Service (APHIS) promotes the health of animals and plants and guards against invasive species. The budget proposes 7-percent funding reduction as well as elimination of 151 employees. How do you plan to meet the responsibilities of APHIS with such severe cuts in funding and staff? Can you provide assurances that existing safeguards against intrusion of new invasive pests will not, in fact, be weakened?

Secretary VILSACK. Senator, what we have done is we've, first of all, engaged in a fairly significant process improvement initiative within APHIS, so that we can do our job in a quality way, in a better way, and spending less time. There are a number of permitting regulatory and licensing responsibilities that APHIS has, where we have substantially reduced the amount of time. We can provide you and the subcommittee with a copy of our process improvement manual that shows the number of days that we've saved from biotechnology reviews, et cetera. That's one strategy.

[The information follows:]

#### STREAMLINE DECISIONS FOR GENETICALLY ENGINEERED PLANTS

While maintaining strong oversight to ensure the safety of genetically engineered (GE) products, APHIS is reforming its processes so that the time it takes to consider petitions for deregulating the use of GE crops will be cut in half, reducing to 13-

16 months the potential adoption of new seeds with traits that can deliver a variety of improvements such as improved yields or reduced inputs. APHIS announced the start of this process in November 2011 as part of other streamlining improvements. APHIS reviewed its approval process using Lean Six Sigma's business process improvement strategy and identified a number of areas that could be improved, leading to a more timely, predictable and higher quality process. APHIS has improved the overall timeline significantly by standardizing and streamlining process steps. APHIS will also be soliciting public input on pending petitions earlier in the review process, enabling the agency to improve the quality of its environmental analyses. By taking these steps, APHIS believes it can deliver to its customers and the public a more predictable process for considering and acting on product deregulations. Once the agency implements all of these business process improvements, a more predictable timeframe will enable developers to bring products granted nonregulated status to market more quickly and provide growers with more choices and access to new technologies sooner, while enabling APHIS to maintain its mission to protect U.S. agriculture and the environment from plant pests. In calendar year 2011, USDA made 10 determinations on petitions for nonregulated status for genetically engineered crops. That is the most determinations in a single year in more than a decade.

#### STREAMLINE VETERINARY BIOLOGICS LICENSING PROCESS

To ensure the best use of resources and work toward meeting the demand of the biologics industry, APHIS is conducting a business process improvement review of work flow at the agency's Center for Veterinary Biologics with the objective of decreasing turnaround times for veterinary biologics license submissions, reducing the overall time it takes to process a complete license application by about 100 days, a savings of 20 percent. Making certain we meet our responsibility of ensuring that veterinary biologics are pure, safe and effective has always been the strongest consideration during this process. APHIS broke the larger licensing process up into smaller, multiple projects creating a group of projects that will ultimately speed up overall licensing times. Some of the process improvements include the electronic workflow of documents and moving from a four-tier labeling system to a single-tier labeling system. The four-tier labeling system required a significant amount of information to be printed on product packages. Rather than have more information on the label, the proposal is to require a label statement referring the user to a Web site where basic information regarding efficacy and safety for the product may be viewed. From this information, the end-user can use personal judgment in determining which product to use to meet his/her particular circumstances/needs. The user may also compare efficacy results from several firms with like products. APHIS projects additional savings from reductions in reagent/reference production, laboratory testing, and animal use.

Additional examples of process improvements can be found at USDA's Web site on the Blueprint for Stronger Service ([www.usda.gov/strongerservice](http://www.usda.gov/strongerservice)). A summary of some other APHIS actions is included in the fact sheet for Marketing and Regulatory Programs and a blog on February 24, 2012, by Administrator Parham.

Secretary VILSACK. The second strategy is that we have taken a look at the pest and diseases that we are currently managing and asking the question, Is the strategy that we are using with reference to specific diseases and pests the appropriate strategy? Do we have an eradication strategy when, in fact, a maintenance strategy might be more appropriate and probably more feasible? Are there circumstances where good practices by producers will be sufficient to protect against a reemergence of a particular disease or pest?

As a result of all of those steps, we feel that we can still do the job that we are required to do and should do in order to increase and maintain agricultural productivity, even though we're faced with, again, some difficult budget discussions and decisions.

The 151 employees, this is basically, we worked our way through an attrition program. We have a workforce where 50 percent is probably within 5 to 10 years of retirement, and in many cases, well over the normal retirement age. We're seeing a lot of folks be-

ginning to retire. So, we're trying to manage this in a way that allows us to do our job, do it well, but perhaps do it quicker, more efficiently, and more effectively.

Senator KOHL. All right. Senator Blunt.

BROADBAND PROGRAM RULE

Senator BLUNT. Thank you, Chairman. Mr. Secretary, both Senator Moran and Senator Brown talked about broadband. My biggest question on broadband continues to be the balance between the underserved and the unserved. In fact, Senator Brown used the phrase, "The most underserved," which I assume the unserved, would be the most underserved.

Talk to me a little about the new rule, and concerns I would have, without knowing a lot about the rule until you explain it to me, that we're continuing to encourage competition, where people have taken their own money and created a network that somebody's decided is underserved, because there's no competition, rather than really focusing on the 15 percent of Missourians that are unserved.

Secretary VILSACK. Senator, I want to make sure I understand your question. When you talk about the rule, you're talking about the FCC rule, or are you talking about the rule that we have for the administration of our broadband program?

Senator BLUNT. I'm talking about the new RUS rule.

Secretary VILSACK. Okay. What we are attempting to do is to respond to the concerns that folks have expressed about the fact that we are not directing our resources in the appropriate way and in the right way. I think what you'll see from us is a focus on those unserved.

Senator BLUNT. Unserved is what I want to say.

Secretary VILSACK. Unserved areas. Having said that, there are times when because of the remoteness of it or the population of a particular area, it may be difficult to have the highest level of broadband capacity, because you may not be able to sustain it with a customer base. So, it is, I think, important for us to continue to look for ways in which we can improve access and connection to telecommunications, without necessarily creating a circumstance where we're setting somebody up for failure.

I think the FCC rule does have some play here, because I think the FCC is under the belief that if they empower some of the larger operators to become more interested in these unserved areas, that they'll do a better job than they've done in the past of trying to respond to the needs of those unserved areas.

Let me also say that I think that there are new technology opportunities that we haven't had a chance to discuss today. I should have brought my prop with me today. At USDA, we are engaged in experimenting in the State of Hawaii with a technology that basically is about as big as this card, and it's about that thick, and four or five of these items placed on a tall building or on a hill will provide access for miles and miles of coverage, without the necessity of tens-of-thousands of dollars of infrastructure.

We are operating these units to develop a 4G network in Hawaii, using it for public safety purposes, and to provide interoperability. So, a month or so ago, I was sitting in my office in DC, in the Agri-

culture building in DC, talking to our chief information officer, who was on the big island in Hawaii, and we were talking to an ambulance that was driving on another island, by virtue of these little square boxes. As I understand it, they are several hundred dollars, not several thousand dollars, in cost. So, it is conceivable that we are on the cusp of new technology that will make it easier to get to those remote areas, and still make it financially feasible for them to have the technology. It's a combination of our programs, the FCC trying to help the Verizons and the AT&Ts of the world be more responsive to these needs, and new technology advancements that might make it less expensive to do it.

Senator BLUNT. That sounds good. It doesn't surprise me at all that the technology is getting smaller and more available, and I encourage you to continue to stay focused, as you obviously are, on that. It does bother me when we use tax dollars to create a competitor to somebody that has created a service without tax dollars, particularly, when there are still people who have no service of any kind.

Secretary VILSACK. I agree, and I think that's the reason why when we did the Recovery Act we made a real effort to avoid that criticism and that concern. So you'll see a lot of where we're working on the unserved areas, and in some cases, very remote areas.

#### RESEARCH LAB CLOSURES

Senator BLUNT. Right. I appreciate that. On the extramural grants, when we close research labs, what's the cost of moving that program somewhere else? And did the cost in fiscal year 2012 meet your expectations for the fiscal year 2012 cost of the labs we're currently in the process of closing and moving that work somewhere else?

Secretary VILSACK. We're still in the process of doing that, Senator, so it may very well be that a more definitive response can be given to you in a couple of months.

Senator BLUNT. Would you do that?

Secretary VILSACK. Sure.

Senator BLUNT. Go ahead and do what you can today, but I'll just ask right now.

Secretary VILSACK. Absolutely.

Senator BLUNT. When you get more information on that, I'd like to see it.

[The information follows:]

The fiscal year 2012 agriculture appropriations conference report agreed with the ARS proposal to close 12 laboratories. Research activities at the 12 laboratories have ceased and were not relocated elsewhere. The one-time costs associated with the relocation or separation of affected personnel and the disposal of property are estimated at \$39 million in fiscal year 2012.

Secretary VILSACK. I have requested from ARS an outline of what their plans are. There are certain timelines, certain restrictions, certain communication requirements that they are going through, and they are going through with each individual location. In some cases, it obviously costs a little bit more upfront, and the savings occurs down the line.

I don't know that I've been apprised at this point that any of the estimates are totally inaccurate. Sometimes it does depend on the

relationship and the deal that's made with the university, in terms of rehabilitation, in terms of environmental cleanup, that type of thing, but I have not been advised as of today that there is a significant difference between our estimates and what we actually will incur.

As far as the programming is concerned, let me say that what ARS has done, at my request, is they have looked at every single facility in our portfolio, more than 100 of these locations, and if you can conceptualize in your mind a grid, it is basically divided into four quadrants. In this quadrant at the top right-hand are those facilities that are in very good shape, from a maintenance standpoint, and are also high-priority research.

The lower right-hand quadrant are high-priority research, but in facilities that are not in particularly good shape. The upper left-hand quadrant are low-priority research and facilities that are in pretty good shape, and then over here, low-priority research and facilities that are in bad, bad shape.

So as we look at this quadrant, we're going to be in a position to know, as resources get tight, where the priority research is and where the good facilities are, and we have to make sure that we do the best job we can to match those up, and that's essentially what we're doing.

If we close a facility, and the research is high priority, it gets transferred to another facility. If it's research that is of a lower priority, it may have to be assumed by someone else. I mean the reality is we're dealing with a different day here, a different day, and that day is that we will have and have had less money in many of these areas, and that's the consequence of having less money. You've got to prioritize. And when you prioritize, you basically prioritize, and you draw a line where the money runs out, and everything below that line has got to go in some way, or shape, or form.

Senator Hoeven knows about this. Maybe he doesn't, because he's always dealt with surpluses, but those of us who are not fortunate enough to have been Governor of North Dakota understand that. And if you want to take something from the bottom of the pile and take it to the top of the pile, and then something from the top of the pile has to come down, because you've only got so many dollars.

Senator BLUNT. My understanding is the surpluses got a lot greater after Senator Hoeven became Governor, so maybe they didn't always have them, but they did have them when he left.

On that regard, as long as I don't have to explain what was in every quadrant, I'm okay, but I think I've kind of followed the quadrants, as you explained them.

Do you have any idea how ARS, rather, arrived at the decision as to where to make the cuts? It did seem they fell very heavily on the research outside of ARS, the extramural, the campus-based research, as opposed to research that was more inside the department.

Secretary VILSACK. I think I would have to provide a more detailed explanation, but I don't want to misstate something, and I'll be happy to provide that to you, but I will tell you that given where we see this headed, with various discussions and decisions you-all

have to make about reducing budgets significantly, we want to be prepared to be able to do this in a thoughtful and strategic way. As a result of this approach that I've just outlined, we're now in a position to do that. And I think, if there are criticisms, I'd be happy to visit with you about—

Senator BLUNT. Yes. If you can get a little more of that information to our staff, that would be great. I would like to look at that, because it does seem to me that the campuses, particularly, have a lot of resources included, and student labor, and other opportunities that aren't available in other places. And I think that campus-based research has always been pretty cost-effective, but these closures appear to be heavily focused on that kind of research versus research that's fully funded by the Federal Government.

Secretary VILSACK. It may be the age of the facilities. It really may be the priority of the research itself. It could be the fact that it duplicates research that's being done in other locations more effectively and more efficiently. I mean it could be a combination of all those factors, Senator.

[The information follows:]

The temporary budget reductions to ongoing ARS programs in fiscal year 2012 are necessary to finance the one-time costs associated with the closure of 12 ARS laboratories. ARS sought to balance the impact on intramural and extramural programs through an across-the-board reduction of intramural research, a hiring freeze, and extramural funding reduction. Together, these actions will finance the one-time costs to ARS for facility closures without terminating other ARS research projects and continuing research with ARS extramural partners.

Senator BLUNT. I want to talk more about that, and we can.

Thank you, Chairman.

Senator KOHL. Senator Pryor.

#### FARM SERVICE AGENCY OFFICE CONSOLIDATION

Senator PRYOR. Thank you, Mr. Chairman. And I would like to follow-up on something Senator Blunt said a few moments ago about broadband, and Senator Moran and Senator Brown mentioned it as well.

In terms of closing some of these offices, these FSA offices in Arkansas, if you look on a map, where we have the least amount of broadband, that's where you tend to be closing these offices. It's in the most rural and sometimes most challenging parts of the State. And I know a lot of people do business online today, but these farmers who are out there in these parts of the State, they're not going to be able to go online.

Let me ask about another FSA office in Arkansas, and I'm sure this is true in other places. In Lafayette County, it's spelled Lafayette, but we pronounce it La-fay-ette in our State, there's Lewisville, Arkansas. It is 22.86 Euclidean miles away from the closest FSA office, which is in Hope. And what I would like to do, if possible, is get an understanding from you, because your people say it is only 14.9 Euclidean miles away.

Secretary VILSACK. Senator, if we've made a mistake, we obviously have to acknowledge that, and we'd be happy to work with you and your staff to make sure that either we're right or you're right, and if we're wrong, we'll need to correct that.

Senator PRYOR. Here's a map of it right here. Is it possible that I could send one of my staff members over either today or tomorrow to sit down with your people and look at your software? This software that we have right here, we couldn't get from you. We requested several times to give us a copy of what you have, and to show us how you're doing it. You wouldn't do it. We were going on Google. We were going on MapQuest, whatever else. Finally, we figured out that we actually have the software that you use at the Geographic Information office in Little Rock, so we understand we're using the exact same software you are. Could we send a staff person over there to sit down with your people and confirm that—

Secretary VILSACK. Sure.

Senator PRYOR. We're right on our numbers? Thank you.

In Faulkner County, which is Conway, we have a situation where there's 136,000 total reported planted acres in Conway. You have what we call a one-stop shop. I think you guys may call it a service center, where you have lots of different government offices there, where everybody can come in, and it's something that I know in recent years USDA and others have bragged about, because it makes it very convenient for the citizens of the State. This is another example where if we were using the road miles versus the Euclidean miles, this one wouldn't be closed. Do you take into consideration the convenience here that, in effect, what you're doing is you're breaking out of this one-stop shop for people? Did you-all take that into consideration when you looked at it?

Secretary VILSACK. We were aware of the fact that some of these facilities were collocated, Senator, but to get back to the comment that I made earlier, the options are not good. None of the options are good. And eventually, the options were creating greater inconvenience for a lot more people and a lot more offices. I mean, if you furlough people or you lay people off, that's going to create more concerns in a lot more offices. So, that's what we're faced with.

#### BLUEPRINT FOR STRONGER SERVICE

These are not easy decisions, trust me. We did not take these lightly. Just in the same way that we're not taking lightly internally what we're trying to do within USDA to figure out how we might be able to provide more efficient service, save money, and not have to close offices in the future. This administrative services process, I'm not sure how familiar you and your staff are with it, but we'd be happy to brief you on it. I think you will find that we are looking very carefully at our own internal activities, taking a look at whether or not we could be better off with regional centers for some of the work that we do, figuring out whether or not there are centers of excellence or shared service centers that might allow us to do a better job of human resources, or civil rights, or IT, the things that are common to every mission area.

We are looking at every aspect of this, because we recognize you-all have tough decisions to make, you're going to make those tough decisions, and we're going to have less money.

## FARM SERVICE AGENCY OFFICE CONSOLIDATION

Senator PRYOR. I mentioned that we have 10 FSA offices in Arkansas that closed, and I promise you this will be the last one I mention. This is the fourth out of the 10. And we could go through all 10, but we won't today.

In Clarksville, Arkansas, there's one, and it's within the 20 miles of Paris, Arkansas. But, you also have Paris on the closure list. So, that means that there will not be one for the folks in Clarksville, in that county, so they're going to have to go to Ozark, which is farther than 20 miles. Did you take that in consideration when you were doing this? That, to me, seems inconsistent with the statute.

Secretary VILSACK. Let me say that we asked the State folks to verify and to weigh in on the decisions that were specific to the State of Arkansas.

Senator PRYOR. Right. But there again, this is another map of it. That seems inconsistent with the statute, because what they're left with is, they're left with traveling farther than the 20 miles that's in the statute to get to an FSA office. I mean this is more of an interpretative issue, I think, with USDA rather than your local people in Arkansas issue.

Secretary VILSACK. It isn't, though, sir, because of the way in which these decisions were developed. They were developed primarily from instructions in DC, implemented, if you will, at the State level, so the State folks were the ones who gave us the recommendations for which offices needed to be closed. So, if we've made mistakes, we obviously have to own up to those mistakes.

Senator PRYOR. Right.

Secretary VILSACK. There's no question about that.

Senator PRYOR. But, wouldn't you say that this might be a mistake, too?

Secretary VILSACK. I don't know, because—I mean, I don't know this particular situation. The first example that you gave me was, I think, a little clearer in my mind, and it may be that I need to—I can't see that map, frankly, Senator.

Senator PRYOR. Okay. We certainly can—

Secretary VILSACK. My eyes aren't that good. I wish they were.

Senator PRYOR. In fact, maybe this afternoon or tomorrow, when I send my staff person over to meet with your people, they can talk about this one, too, because basically the bottom line is, these folks in Clarksville, the net effect is they will have to drive farther. They will have to drive much farther than 20 miles to get to an FSA office.

Actually, my last question on this line, Mr. Chairman, is, I know that you slated 131 of these for closure, and you had several public meetings. Did any of these public meetings change your mind at all on these 131?

Secretary VILSACK. Senator, these are tough decisions, and obviously, people are going to come and they're going to talk very passionately about the need for their individual office. And you could basically find a reason to keep every single one of them open, but the reality is we don't have the resources or the people to do that. That's number one.

## RURAL DEVELOPMENT

Number two, my view of this is that we really need, perhaps, at USDA to do an even better job than we've done, even though we've helped more than 50,000 small businesses in the last 3 years, which is a record number. We really need to figure out how we can generate a lot of private sector activity in these communities so that there are options for jobs and for better incomes. Many of these communities rely, to a great extent, on publicly supported institutions, and really, we need to figure out how to do a better job of creating private enterprise, so that folks have more job opportunities than they have from trying to keep a post office, or an FSA office, or a school open. Those are really important, but we haven't done a good enough job, I guess, in getting factories opened there so that folks have options.

Senator PRYOR. Thank you, Mr. Chairman. I actually have a few more questions. Are we going to have a third round?

Senator KOHL. Certainly.

Senator PRYOR. Thank you.

Senator KOHL. Mr. Hoeven.

Senator HOEVEN. Thank you, Mr. Chairman. I can defer, if you just have a question or two to finish up, Senator. Are you sure? Okay.

## AGRICULTURE RESEARCH FUNDING

I actually want to follow-up on a question that Ranking Member Senator Blunt asked you, and it's about the agriculture research funding, and it's the extramural program funding. At North Dakota State University, they're doing a lot of work on the U.S. Wheat and Barley Scab Initiative, and also on the Ug99 barley stem rust research program. Both of those have seen administrative reductions of about 30 percent. And at the State level we've put a lot of funding into our agriculture research greenhouse at North Dakota State University, and so I understand that you have to find ways to save, but could you go into a little bit of how you're making that analysis?

And I know that Senator Blunt was asking the same question, but through the university system, and in States like ours, we're willing to try to design programs to maximize the leverage on that research. So, we need to understand how you're approaching that, so that we can, I guess, do the best job possible of attracting those dollars into programs like these two, which are very important to us.

Secretary VILSACK. Roughly 51 percent of the resources go into crop and animal production protection and productivity. Roughly 18 percent or so goes into environmental stewardship and the importance of maintaining water quality and quantity. A percentage goes into some of the other areas that are outside of agriculture, specifically in terms of nutrition, food safety, and things of that nature. So, it's a broad base of responsibilities we have from a research perspective. I get a little confused, because when we talk at USDA about external and internal, we often refer to the external as the competitive grant program.

Our belief is that we have got to do a better job on two fronts. First, we have to do a better job of continuing to leverage the resources that we have more effectively. The competitive grant process allows us that opportunity to fund the best projects possible, and to really force and compel people to really think about what research they're doing and how they're doing it.

Second, as great as the university systems are, and they are, and I appreciate Senator Blunt's acknowledgement of our 150th anniversary, and that of the Morrill Act, there is no overarching process that establishes the national research goals that would allow us to avoid duplication and replication of research that's taking place in many land grant universities across the country. So it's going to be important, I think, for us to have a conversation in a time of limited resources, either at the State level or at the Federal level, to do what we're doing at the global level.

We have the Global Research Alliance, where we're dealing with 30 different countries on climate issues, and we're saying let's not replicate or duplicate research, let's make sure the right hand knows what the left hand is doing. I have to feel that there's probably some duplication that's taking place across the country, and maybe we're not investing our research dollars, whether internally or externally, as efficiently as we can. So, somewhere there's got to be a process, the competitive grant process is one way of compelling collaboration, and which is working. We're making grants now to a university, but that university may have six or seven different other universities that they're partnering with. So, I think there's a lot of work in this area.

The last thing I would say, we don't have the advantage that other research areas have, the National Science Foundation, the National Institutes of Health. Our funding has been flat-lined, for the most part. It hasn't been increased dramatically. We don't have outside foundations or resources that would allow us to supplement our resources. So, I think there's a lot of opportunity in this space for us to do a better job.

Senator HOEVEN. I do want to emphasize those two programs to you, U.S. Wheat and Barley Scab Initiative, also, the Ug99 Barley Stem Rust Research Program, because both saw 30-percent reduction, administratively applied reduction, which I think is significant.

Secretary VILSACK. Senator, can I ask, when you say administrative, so I know what you mean, I think I know what I would mean by that, but what do you mean by that?

Senator HOEVEN. Essentially, reduction in this year's funding for those programs, for those research programs, in terms of what came out to the university to deduct.

Secretary VILSACK. I think there has been an effort on our part to make sure that we're not overfunding the administration of grants, as opposed to the actual research. There's a difference between how much money goes to the university to sort of administer the university versus how much money actually goes to the research project itself.

Senator HOEVEN. No. I'm talking about research for those specific programs, research dollars for those specific programs.

Secretary VILSACK. But I'm saying, within that grant, there's a certain allocation for administration and a certain allocation for the actual research, and I'm not sure if that's where we're having a communication issue.

Senator HOEVEN. No. When I say administratively reduced, I mean USDA actually coming in on a discretionary basis, reducing actual research dollars for that research. And this is something that I'll be working with Senator Blunt and others on, because I mean this is something that, obviously, we're very interested in and think that this is critically important.

The other thing is, in terms of the, and I say this a lot of times, I've got one more question. I can certainly defer for the third round. I know that's what Mark did. Maybe it's best I do that.

Senator KOHL. Go ahead.

#### CROP INSURANCE

Senator HOEVEN. Okay. Just in the overall budget, the administration's budget, they reduced crop insurance by almost \$8 billion. I'm on the Agriculture subcommittee as well, and that's not the direction we're going. Clearly, we're not going to have direct payments. And so, what we're trying to do is find ways to enhance crop insurance. I'm on legislation with Senator Conrad, Senator Baucus, and others, and there are other bills as well. But crop insurance is going to be more important, in terms of a cost-effective safety net.

Just give me your thoughts here, because my sense is you're sympathetic to the tremendous importance of crop insurance, particularly in the situation of tight dollars. That's going the wrong direction. Just your thoughts.

Secretary VILSACK. It depends. It depends on where the money is coming from. I mean clearly, let me state unequivocally that crop insurance is the linchpin of the safety net. But, there are three components to the crop insurance. There's the amount the insurance company gets. There's the amount the agent gets. And there's the amount that the farmer pays. And all of those are basically supplemented, if you will, by Government assistance.

We've done an analysis of what insurance companies currently are getting in terms of the return on investment, and how much it would take for those insurance companies to be able to maintain the integrity of crop insurance. What we found was a 12-percent return on the money would be sufficient to maintain the integrity.

Even in a year that was extraordinary, last year, crop insurance companies are still going to net about \$1.5 billion, I'm told, of profit. So right now, they're getting 14 percent. So, the question is: Is there any adjustment in these tight times between 14 and 12 that could be made that doesn't compromise the process of the crop insurance program at all? Number one.

Number two, I think agents, on average, get somewhere around \$1,000 per policy for selling a policy, a slight adjustment to that, given the fact that 15 years ago when crop insurance was sold, it was quite difficult to sell the concept to farmers. Today, it's not at all difficult, because most farmers want it, and most bankers require it. Can there be a slight adjustment there?

Then the third component of the President's proposal is crop insurance is a partnership between the Government and farmers. Some commodities, we are actually subsidizing the premium by 60 to 65 percent. Maybe a 50–50 partnership is fair. So those three areas do not compromise the capacity for us to have crop insurance, nor does it compromise our capacity to expand the number of products available to cover more crops as we've done. So, I don't know that you necessarily equate reductions in Government subsidy with not supporting the program. It depends on where the money comes from.

Senator HOEVEN. There was \$6 billion taken out of crop insurance, in terms of what goes to the insurers in the past year. And crop insurance is going to have to carry a lot more of the load. So, separate and apart from what you're saying, in terms of the actual program and how we make sure we have a safety net for farmers, we're going to need to emphasize crop insurance, which is going to take more funding in that part of the program, not less.

Secretary VILSACK. Not necessarily, Senator, because with the money that was taken, insurance companies were generating 17, in some cases as much as 26-percent return on their money annually.

Senator HOEVEN. But, remember, we took \$6 billion out of the program already.

Secretary VILSACK. This brought it down to 14—\$2 billion went back into various programs to help the farmers.

Senator HOEVEN. And now you've got crop insurance picking up some of the help that was formerly provided by other parts of the program. Crop insurance is going to have to pick that up. So, there's a lot more to it than just the one piece you're talking about.

Secretary VILSACK. Unless you amplify crop insurance with another program, which a lot of folks are talking about, which the President recognized in his budget of providing additional resources for "a disaster program of one kind of another."

Senator HOEVEN. There'll be some of that, but we're still going to need to have to emphasize crop insurance.

Thank you.

Senator KOHL. Good. Senator Pryor.

#### AGRICULTURAL RESEARCH SERVICE LAB CLOSURES

Senator PRYOR. Thank you, Mr. Chairman. Let me ask about an ARS issue, about a 30-percent cut to extramural ARS activities.

As I understand it, in fiscal year 2012, ARS proposed to close 12 laboratories. However, USDA did not submit a budget request to the Congress that included all the costs associated with closing these facilities, including the closure of labs, relocating employees, et cetera. As a result, ARS was \$38 million short for these activities after the appropriation bills were signed into law. Is that right? Do I have that right?

Secretary VILSACK. Senator, you may very well be right, and that's basically what we have to do is when that happens we've got to figure out how to absorb that cost.

Senator PRYOR. And that seems to me to be a budget mistake on USDA's part for not budgeting properly last year.

Secretary VILSACK. I'd like to think that you-all would have given us that money, but I'm not sure that's the case, given the fact that you've been cutting ARS the last couple of years.

Senator PRYOR. My understanding was that it wasn't part of your request, that you thought you had adequate funds to do the changes.

Secretary VILSACK. We have to absorb that, Senator.

Senator PRYOR. And that's my point. You're absorbing it at our expense. I mean, in effect, we're paying for the mistake. Aren't there other ways to find that money to absorb that \$38 million?

Secretary VILSACK. There are other ways. You could appropriate money. I mean a supplemental appropriation. We could transfer money, but in which case you'd then be asking me why we were transferring resources from another program that you like to another program that you like. I mean these are tough issues, Senator. These are tough issues, and when the Congress is basically telling us, as we have heard repeatedly, that we're going to have less money, and when we're talking about a \$1.5 trillion cut that's forthcoming, these are hard decisions. There's no easy answer.

And I will tell you, I hear a lot of folks talk about waste, fraud, and abuse is the answer. Well, there's always going to be better ways to do things, but at the end of the day, with the kind of cuts we're talking about, and that we've dealt with, we're dealing with real difficult decisions. I think it's important for people to understand that.

Senator PRYOR. I do have some more questions along those lines, but I don't want to try the subcommittee's patience. So, let me ask about one more thing.

#### AGRICULTURAL RESEARCH SERVICE GRAZING RESEARCH

It seems like Arkansas got a lot of focus over at the USDA when they looked at cutting their budget this year. You've decided to close the Dale Bumpers Small Farms Research Center in Booneville. In light of the closure of the Brooksville, Florida, facility in 2011, and the expected closures of Watkinsville, Georgia, and Beaver, West Virginia, by June 1, 2012, where will the ARS conduct grazing research for the Eastern part of the United States?

Secretary VILSACK. There are three areas that will pick up some of the work that was done in Arkansas. They are Nebraska, Oklahoma, and Texas.

Senator PRYOR. And they'll be looking at the grazing aspect of it.

Secretary VILSACK. Yes, sir.

Senator PRYOR. Because I know that part of what Booneville was doing is they were doing long-term, like a 20-year study on watersheds and the impact livestock have on those.

Secretary VILSACK. The fact is that the priority research is going to continue. It may continue in a facility where the maintenance costs over time will be less. It may continue at a facility that is actually doing this work as well, to avoid duplication.

Senator PRYOR. And actually, this Dale Bumpers facility actually meets one of the criteria you talked about earlier, because it is hard for young people to get into farming. And here, they focus on small farms, and startups, and how you can get into certain type of farming activities and actually make a go of it.

## AGRICULTURAL RESEARCH

I think that on this, and maybe some of these other facilities that we've talked about today, they focus on long-term basic research that actually helps farming, helps agriculture, and helps that be a core strength in the U.S. economy. So, are you-all just going to be getting out of the research business? Is that where you're headed?

Secretary VILSACK. Senator.

Senator PRYOR. I'm asking.

Secretary VILSACK. We have over 100 facilities that will still be operating, and we've asked for additional resources in the Agriculture and Food Research Initiative (AFRI) portion of the budget, \$60 million-plus additional above and beyond what was appropriated last year. We've been advocating for more research opportunities. It doesn't necessarily mean that we have to have more facilities. It means that there is a number of different ways in which we can embrace additional research.

So, it's unfair to suggest that we're trying to get out of the research business. But, it is fair to point out that the Congress has provided less money in several areas of our budget, and we have to deal with that. I'm not going to whine about it. I'm not going to complain about it. I'm going to manage it. But I have to have the capacity to manage it. I have to have the capacity to make choices. And sometimes those choices are difficult.

If it doesn't come from one source, it's got to come from another source. That's the reality of less money, and we are in that position and circumstance where every single entity, every single agency of the Government is going to have to go through this.

## BLUEPRINT FOR STRONGER SERVICE

Frankly, it's a difficult process, but it's an important process, because it really allows you to think carefully and very strategically about what we ought to be doing, where we ought to be doing it, and how we ought to be doing it. Which is why we just didn't focus on office closings, we just didn't do what a lot of people do when they're faced with less money, is just to do a blanket across-the-board cut in workforce, which would have disrupted services in a lot of different areas. We took a strategic approach. We said, Less travel, less supplies, less conferences. We said, Are there ways in which we can do civil rights, IT, budget and finance, human resources, security, property management, and procurement more effectively and efficiently? Yes—379 different set of recommendations that we're now in the process of implementing.

We looked at a Voluntary Separation Incentive Pay and Voluntary Early Retirement Authority (VSIP/VERA) process, so that we didn't have to be unfair to the people who had worked and dedicated their life to USDA, by giving them an opportunity for early retirement or for a buyout, so that we could keep a lot of our young people that we have been hiring over the course of the last several years, to maintain a good diversity in our workforce.

We looked at office closings. We looked at lab closings. We looked at the entire process, which is what you have to do. If you could tell me we're not going to be faced with tough budget times in the next couple of years, that's great, but everything I read suggests

that we're going to have to hunker down here. That's why I managed the change, rather than be managed by the change.

#### AGRICULTURAL RESEARCH

Senator PRYOR. That's why I asked about research, because under the Budget Control Act, it's going to be tougher in the next few years. And I'm trying to get a sense from you. You say you want to spend more in research, but you're going to have to be cutting other places. I'm just trying to get a sense of where you think the USDA is going over the next several years.

Secretary VILSACK. The research that we see is the best way to use scarce resources, is to do it in a competitive way, that compels land grant universities and other universities that are engaged in research to collaborate, to avoid duplication, to avoid replication of research. That's why we think that the AFRI process and National Institute of Food and Agriculture (NIFA) is a good way to approach this and get the biggest bang and the largest stretch for our dollar.

There have been those that have suggested that we need to complement that with the establishment of a foundation. I'm all for that. I think that's great. We don't have that in agriculture. We have it in a lot of other areas, and those areas have seen significant improvements in research. So, there are multiple ways in which we are going to be supportive of agricultural research. Make no mistake about that. Make no mistake about that. Because there is a direct correlation between agricultural productivity and research. The charts are very clear.

Senator PRYOR. I agree. I agree. And that's why I was asking that. I hope one thing you'll consider is taking these old facilities and research you're not using, and not going to fund any more, and possibly see if you can turn those over to some land grant universities so they can use those for research.

Secretary VILSACK. We are required to do that, in the sense that we're required to reach out to our land grant university partners and say, "Are you interested in having this facility? And if you are, what would you be willing to do with it, and can we enter into an agreement where you would commit it to agricultural activities for a period of time?" We're required to do that, and we will follow through with that.

Senator PRYOR. And would there be any funding stream that would go along with that for research?

Secretary VILSACK. That would, I suppose, depend on whether or not they'd like to participate in the competitive grant process under NIFA and the AFRI program.

#### CIVIL RIGHTS

Senator PRYOR. Mr. Chairman, the last thing I will say, and I'm sorry for trying the subcommittee's patience here. I know you've made a lot of progress in the last few years on civil rights, but there is still one major problem, I think, that exists, and that is USDA has no deadline for civil rights intake process or responding to civil rights complaints. And we have several folks in our State, and I'm sure others do as well, that are hanging out there in limbo for sometimes years at a time, waiting for responses from USDA.

Secretary VILSACK. Senator, I don't think that's correct. I just don't think that's correct. In fact, I get a quarterly report on both internal and external complaints against USDA by mission area. We have a response time within 180 days. I will get to your staff the list that I get, and it will show you that there is no claim that's currently before the USDA that is over the time period that the statute of limitations has expired since we started this process and started keeping track.

[The information follows:]

The attached table is the color coded list that USDA uses to track the progress of pending complaints that raise claims under the Equal Credit Protect Act (ECOA). The table tracks the number of days left before the statute of limitations runs on ECOA claims. USDA's civil rights managers at every level meet once a week to review progress on these claims and take steps to expedite or remove road blocks as necessary.

Most ECOA claims in inventory fall under a 2-year statute of limitations. This means that 2 years from the date of the incident alleged to be discriminatory, complainants lose the right to pursue the claim in court. More recent claims may benefit from the 5-year statute of limitations extended by the Dodd-Frank Act. This administration inherited a backlog of over 1,000 uncatalogued complaints that did not identify ECOA claims or track the date of the applicable statute of limitations.

USDA civil rights staff inventoried the backlog and identified complaints raising ECOA claims. Based on that information, USDA created the attached table to track processing time against the deadline created by the statute of limitations for each complaint. The table identifies complainants' names (redacted); the number of days remaining until a 2-year statute of limitations would expire; the date on which the 2-year statute of limitations would expire; the status of each complaint; OASCR staff assigned to process the complaint; and other relevant information.

An ECOA committee representing staff at every stage of complaint processing continues to meet regularly to maintain and update the table. New complaints raising ECOA claims are immediately added to the list. USDA civil rights managers at every level meet once a week to review progress on these pending claims and take steps to expedite or remove road blocks as necessary.

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No.	Days remaining until 2 years from incident date	2 years since incident date	USDA rovd date	Agency	Case #	Status	Investigator adjudicator	Pending review OASCR	Program name	Corresp date	Days elapsed (from incident date)	Current date	Actual incident date	Initial incident date	Date ECOA letter mailed
1	32 .....	4/30/2012	10/1/2010	FSA .....	11-4279	Adjudication ..	MB, WS ..	OASCR .....	Farm Operating Loan (FSA).	9/14/2010	698	3/29/2012	5/1/2010	5/1/2010	10/13/2010
2	55 .....	5/23/2012	5/25/2010	FSA .....	10-3929	Adjudication ..	SF, WH, EP.	OASCR .....	FSA-Guaranteed Loan.	5/24/2010	675	3/29/2012	5/24/2010	5/24/2010	.....
3	58 .....	5/26/2012	7/28/2010	FSA .....	10-4133	Adjudication ..	RC, HR ...	OASCR .....	Farm Service Agency (FSA).	7/22/2010	672	3/29/2012	5/27/2010	5/27/2010	9/23/2010
4	100 .....	7/7/2012	7/27/2010	RD .....	11-4412	Adjudication ..	CB, KC ...	Adjudication ..	SFH—Rural Housing Direct Loans (RD).	7/29/2010	630	3/29/2012	7/8/2010	12/21/2010	12/29/2010
5	155 .....	8/31/2012	7/27/2010	RD .....	11-4338	Investigation ..	SF .....	Investigation ..	SFH—Rural Housing Direct Loans (RD).	9/29/2010	575	3/29/2012	9/1/2010	9/1/2010	12/2/2010
6	168 .....	9/13/2012	10/4/2010	FSA .....	11-4283	Adjudication ..	HR, RC ...	OASCR .....	Direct Operating Loan/Guaranteed Operating Loan (FSA).	9/27/2010	562	3/29/2012	9/14/2010	9/14/2010	11/5/2010
7	188 .....	10/3/2012	1/31/2011	RD .....	11-4704	Adjudication ..	CB, JE ....	Adjudication ..	SFH—Rural Housing Direct Loans (RD).	3/25/2011	542	3/29/2012	10/4/2010	10/1/2010	3/25/2011
8	213 .....	10/28/2012	7/27/2010	RD .....	11-4515	Adjudication ..	KCB, LR	OASCR .....	SFH—Rural Housing Direct Loans (RD).	10/29/2010	517	3/29/2012	10/29/2010	10/29/2010	12/15/2010
9	228 .....	11/12/2012	11/23/2010	FSA .....	11-4443	Adjudication ..	MB, LR ...	Adjudication ..	Farm Operating Loans (FSA).	11/13/2010	502	3/29/2012	11/13/2010	11/13/2010	1/12/2011

10	265	12/19/2012	1/10/2011	FSA	11-4609	Investigation ..	MB	Investigation ..	Farm Operating Loans (FSA).	12/22/2010	465	3/29/2012	12/20/2010	12/20/2010	2/7/2011
11	289	1/12/2013	1/7/2011	RD	11-4606	Investigation ..	MP	Investigation ..	SFH--Housing Repair & Rehabilitation Grant/Loan.	2/24/2011	441	3/29/2012	1/13/2011	1/13/2011	2/24/2011
12	303	1/26/2013	2/1/2011	FSA	11-4687	Investigation ..	WH	Investigation ..	Farm Operating Loan (FSA).	3/14/2011	427	3/29/2012	1/27/2011	1/27/2011	3/14/2011
13	330	2/22/2013	11/4/2011	FSA	12-5519	Investigation ..	TA	Investigation ..	Farm Operating Loans (FSA).	10/17/2011	400	3/29/2012	2/23/2011	2/23/2011	11/29/2011
14	345	3/9/2013	9/22/2011	FSA	11-5359	Investigation ..	TA	Investigation ..	Farm Ownership Loans (FSA).	10/19/2011	385	3/29/2012	3/10/2011	3/10/2011	10/19/2011
15	352	3/16/2013	4/11/2011	FSA	11-4845	Investigation ..	SA	Investigation ..	Farm Operating Loans (FSA).	4/5/2011	378	3/29/2012	3/17/2011	3/17/2011	6/17/2011
16	377	4/10/2013	10/1/2010	FSA	11-4280	Adjudication ..	AG	Adjudication ..	Farm Operating Loans (FSA).	9/29/2010	353	3/29/2012	4/11/2011	4/11/2011	10/15/2010
17	377	4/10/2013	4/21/2011	FSA	11-4887	Adjudication ..	JE, MP	Adjudication ..	Farm Ownership Loans (FSA).	4/14/2011	353	3/29/2012	4/11/2011	4/11/2011	5/13/2011
18	395	4/28/2013	3/2/2011	RD	11-4828	Investigation ..	MB	Investigation ..	SFH--Rural Housing Loan (RD).	4/29/2011	335	3/29/2012	4/29/2011	4/29/2011	7/18/2011
19	395	4/28/2013	3/25/2011	FSA	11-5093	Investigation ..	EP	Investigation ..	Farm Operating Loan (FSA).	4/29/2011	335	3/29/2012	4/29/2011	4/29/2011	8/15/2011
20	412	5/15/2013	8/19/2011	RD	11-5227	Investigation ..	TA	Investigation ..	SFH--Guaranteed Loan.	8/4/2011	318	3/29/2012	5/16/2011	5/16/2011	10/7/2011
21	414	5/17/2013	9/20/2011	FSA	11-5348	Investigation ..	AG	Investigation ..	Farm Operating Loans (FSA).	9/30/2011	316	3/29/2012	5/18/2011	5/18/2011	9/30/2011
22	421	5/24/2013	9/7/2011	RD	11-5316	Investigation ..	MP	Investigation ..	SFH--Rural Housing Direct Loan (RD).	8/25/2011	309	3/29/2012	5/25/2011	5/25/2011	10/27/2011

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No.	Days remaining until 2 years from incident date	2 years since incident date	USDA rovd date	Agency	Case #	Status	Investigator adjudicator	Pending review OASCR	Program name	Corresp date	Days elapsed from incident date)	Current date	Actual incident date	Initial incident date	Date ECOA letter mailed
23	433	6/5/2013	6/20/2011	FSA	11-5046	Investigation ..	CB	Investigation ..	Farm Operating Loans (FSA).	6/12/2011	297	3/29/2012	6/6/2011	6/6/2011	9/26/2011
24	442	6/14/2013	5/4/2011	RD	11-4937	Investigation ..	MP	Investigation ..	SFH—Rural Housing Direct Loans (RD).	4/25/2011	288	3/29/2012	6/15/2011	6/15/2011	6/23/2011
25	450	6/22/2013	7/5/2011	RD	11-5098	Adjudication ..	SA, LR	Adjudication ..	SFH—Rural Housing Guaranteed Loan (RD).	6/28/2011	280	3/29/2012	6/23/2011	6/23/2011	7/28/2011
26	456	6/28/2013	7/19/2011	FSA	11-5132	Investigation ..	KCB	Investigation ..	Farm Operating Loan (FSA).	7/14/2011	274	3/29/2012	6/29/2011	6/29/2011	8/8/2011
27	475	7/17/2013	8/15/2011	FSA	11-5215	Investigation ..	LJ	Investigation ..	Farm Operating Loan (FSA).	7/18/2011	255	3/29/2012	7/18/2011	7/18/2011	11/9/2011
28	500	8/11/2013	11/8/2011	FSA	12-5524	Investigation ..	LJ	Investigation ..	Farm Operating Loan (FSA).	10/19/2011	230	3/29/2012	8/12/2011	8/12/2011	11/18/2011
29	500	8/11/2013	9/30/2011	FSA	11-5392	Investigation ..	EP	Investigation ..	Farm Operating Loans (FSA).	9/15/2011	230	3/29/2012	8/12/2011	8/12/2011	10/21/2011
30	542	9/22/2013	11/8/2011	RD	12-5527	Investigation ..	NA	Investigation ..	SFH—Rural Housing Direct Loans (RD).	10/29/2011	188	3/29/2012	9/23/2011	1/27/2010	11/22/2011
31	553	8/29/2013	10/24/2011	RD	12-5497	Fact-Finding ..	FF	Fact-Finding ..	SFH—Rural Housing Loan.	10/24/2012	177	2/23/2012	8/30/2011	8/30/2011	2/13/2011

32	580	10/30/2013	1/9/2011	FSA	12-5699	Fact-Finding ..	FF .....	Fact-Finding ..	Commodity Def. Loan (FSA).	12/28/2011	150	3/29/2012	10/31/2011	10/31/2011	3/16/2012
33	609	11/28/2013	1/18/2012	RD	12-5715	Fact-Finding ..	FF .....	Fact-Finding ..	SFH—Other (Mortu- torium).	12/20/2011	121	3/29/2012	11/29/2011	11/29/2011	2/28/2012
34	616	12/5/2013	1/20/2012	FSA	12-5740	Fact-Finding ..	FF .....	Fact-Finding ..	Farm Operating Loan (FSA).	1/10/2012	114	3/29/2012	12/6/2011	12/6/2011	2/28/2012
35	624	12/13/2013	11/23/2011	RD	12-5576	Fact-Finding ..	FF .....	Fact-Finding ..	SFH—Rural Housing Direct Loans (RD).	1/23/2012	106	3/29/2012	12/14/2011	12/14/2011	1/23/2012
36	687	2/14/2014	3/2/2012	FSA	12-5864	Fact-Finding ..	FF .....	Fact-Finding ..	Farm Operating Loans (FSA).	2/21/2012	43	3/29/2012	2/15/2012	2/15/2012	3/16/2012
37	950	11/4/2014	2/26/2010	RD	10-3706	Adjudication ..	FF .....	Adjudication ..	SFH—Other (RD) ...	11/19/209	875	3/29/2012	11/5/2009	11/5/2009	.....
38	1047	2/9/2015	8/16/2010	RD	10-4155	Adjudication ..	FF .....	Adjudication ..	Rural Development (RD).	4/25/2010	778	3/29/2012	2/10/2010	2/10/2010	10/1/2010
39	—103	12/17/2011	5/13/2010	FSA	10-3906	Adjudication ..	OASCR ...	Adjudication ..	Farm Operating Loan (FSA).	5/27/2010	833	3/29/2012	12/17/2009	7/15/2010	5/27/2010
40	.....	.....	6/22/2010	FSA	10-4017	Adjudication ..	OASCR ...	Adjudication ..	Farm Operating Loan (FSA).	6/16/2010	.....	3/29/2012	TBD	TBD	8/24/2011
41	—412	2/11/2011	3/4/2009	FSA	09-2297	Adjudication ..	OASCR ...	Adjudication ..	Farm Operating Loans (FSA).	2/11/2009	1142	3/29/2012	2/11/2009	2/11/2009	4/16/2010
42	0	1/22/2012	2/18/2010	FSA	10-3681	Settlement completed with com- plainant.	.....	.....	Farm Operating Loans (FSA).	2/8/2010	797	3/29/2012	1/22/2010	1/22/2010	9/1/2010
43	42	5/10/2012	5/18/2010	FSA	10-3933	F 2/29/2012 ..	.....	.....	Farm Operating Loan (FSA).	5/18/2010	688	3/29/2012	5/11/2010	5/11/2010	6/22/2010

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No.	Days remaining until 2 years from incident date	2 years since incident date	USDA rovd date	Agency	Case #	Status	Investigator adjudicator	Pending review OASCR	Program name	Corresp date	Days elapsed from incident date)	Current date	Actual incident date	Initial incident date	Date ECOA letter mailed
44	218	11/2/2012	2/15/2011	FSA	11-4729	F 2/29/2012			FSA—Farm Operating Loan.	4/8/2011	512	3/29/2012	11/3/2010	4/8/2011	
45	93	6/30/2012	9/22/2010	FSA	10-4242	F 2/29/2012			Farm Operating Loans (FSA).	8/27/2010	637	3/29/2012	7/1/2010	7/1/2010	10/20/2010
46	34	5/2/2012	6/2/2010	FSA	10-3988	NF 3/8/2012			Operating Loan (FSA).	5/25/2010	696	3/29/2012	5/3/2010	5/25/2010	7/7/2010
47	0	2/22/2012	3/2/2010	RD	10-3719	Closure Withdrawn 1/30/2012.			SFH—Rural Housing Direct Loans (RD).	2/22/2010	766	3/29/2012	2/22/2010	2/22/2010	9/9/2010
48	0	8/31/2011	1/20/2010	FSA	10-3593	NF 3/8/2012			Farm Operating Loans (FSA).	12/30/2009	941	3/29/2012	8/31/2009	5/1/2009	
49	0	5/13/2012	6/8/2010	RD	10-3966	NF 1/12/2012			RD (loan)	5/24/2010	685	3/29/2012	5/14/2010	5/14/2010	6/25/2010
50	0	8/18/2012	7/27/2010	FSA	11-4445	Closure 8/19/2011.			Farm Operating Loans (FSA).	8/22/2010	588	3/29/2012	8/19/2010	8/19/2010	12/15/2010
51	0	7/11/2013	7/20/2001	RD	11-5143	Closure 11/03/2011.			SFH—Rural Housing Guaranteed Loan (RD).	7/12/2011	261	3/29/2012	7/12/2011	7/12/2011	8/12/2011

52	0	2/8/2012	3/1/2010	FSA	10-3707	NF 12/22/2011				Direct Operating Loan/Guaranteed Operating Loan (FSA).	2/24/2010	780	3/29/2012	2/8/2010	2/8/2010	7/19/2010
53	0	11/9/2011	4/29/2010	FSA	10-3873	NF 11/10/2011				Outreach & Assistance for Socially Disadvantaged Farmers.	4/25/2010	871	3/29/2012	11/9/2009	4/7/2010	4/30/2010
54	0	11/9/2011	4/29/2010	FSA	10-3872	NF 11/09/2011				Outreach & Assistance for Socially Disadvantaged Farmers.	4/25/2010	871	3/29/2012	11/9/2009	4/7/2010	11/5/2010
55	0	12/2/2011	3/18/2010	RD	10-3766	NF 10/24/2011				SFH—Rural Housing Direct Loans (RD).	3/8/2010	848	3/29/2012	12/2/2009	12/2/2009	2/11/2011
56	0	10/22/2011	9/15/2010	FSA	10-4218	NF 10/21/2011				Operating Loan (FSA).	9/7/2010	889	3/29/2012	10/22/2009	5/3/2010	.....
57	0	11/1/2011	5/27/2010	FSA	10-3942	NF 10/24/2011				Farm Operating Loan (FSA).	5/21/2010	879	3/29/2012	11/1/2009	11/1/2009	Pending discussion
58	0	2/29/2012	7/28/2010	RD	10-4099	Closed 10/19/2011.				Rural Development (502/504 loan grant).	7/20/2010	759	3/29/2012	3/1/2010	3/1/2010	6/1/2010
59	0	3/9/2012	10/28/2010	RD	11-4469	Closed 10/21/2011.				SFH—Rural Housing Direct Loans (RD).	2/11/2011	750	3/29/2012	3/10/2010	3/10/2010	6/1/2010
60	0	5/31/2012	7/20/2010	FSA	10-4102	Closed 8/15/2011.				Emergency Loan (FSA).	7/12/2010	667	3/29/2012	6/1/2010	.....	9/27/2010
61	0	11/14/2012	5/4/2011	RD	11-4941	Closed 10/5/2011.				SFH—Rural Housing Loan (RD).	4/12/2011	500	3/29/2012	11/15/2010	.....	7/8/2011

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No.	Days remaining until 2 years from incident date	2 years since incident date	USDA rovd date	Agency	Case #	Status	Investigator adjudicator	Pending review OASCR	Program name	Corresp date	Days elapsed from incident date)	Current date	Actual incident date	Initial incident date	Date ECOA letter mailed
62	0	10/9/2011	10/27/2009	FSA	10-3304	NF 9/30/2011			Farm Operating Loans (FSA).	10/26/2009	902	3/29/2012	10/9/2009	10/9/2009	5/5/2010
63	0	11/18/2011	1/26/2010	FSA	10-3633	NF 9/29/2011			Farm Ownership Loans (FSA).	1/27/2010	862	3/29/2012	11/18/2009	11/18/2009	5/18/2010
64	0	2/26/2012	2/26/2010	FSA	10-3689	Closed—No Jurisdiction.			Farm Ownership Loans (FSA).	2/26/2010	762	3/29/2012	2/26/2010	2/26/2010	2/11/2011
65	0	6/30/2012	8/25/2010	FSA	10-4181	Adjudication Closed—Filed in Federal Court.			Disaster Loan (FSA)	8/25/2010	637	3/29/2012	7/1/2010	7/1/2010	10/4/2010
66	0	9/1/2011	7/20/2010	FSA	10-4083	NF 8/31/2011			Farm Operating Loans (FSA).	7/12/2010	940	3/29/2012	9/1/2009	9/1/2009	.....
67	0	10/14/2011	10/21/2009	FSA	10-3312	NF 8/26/2011			Farm Operating Loans (FSA).	10/14/2009	897	3/29/2012	10/14/2009	10/14/2009	5/20/2010
68	-616	7/22/2010	12/15/2008	FSA	09-2094	Investigation (Held in Abeyance).			Farm Operating Loans (FSA).	12/9/2008	1346	3/29/2012	7/22/2008	7/22/2008	4/15/2010
69	-626	7/12/2010	7/31/2008	FSA	8-1642	Investigation (Held in Abeyance).			Farm Operating Loans (FSA).	7/31/2008	1356	3/29/2012	7/12/2008	7/12/2008	4/30/2010

70	0	.....	7/4/2012	7/27/2010	RHS	10-4092	Closure 8/23/2011.	.....	.....	Rural Development (RD).	7/20/2010	633	3/29/2012	7/5/2010	7/5/2010	8/27/2010
71	0	.....	12/2/2011	1/12/2010	FSA	10-3558	Adjudication Not ECOA.	.....	.....	Farm Operating Loan (FSA).	1/4/2010	848	3/29/2012	12/2/2009	12/2/2009	12/2/2009
72	0	.....	12/11/2011	12/30/2009	FSA	10-3546	Removed Not ECOA.	.....	.....	Farm Ownership Loans (FSA).	12/11/2009	839	3/29/2012	12/11/2009	12/11/2009	9/3/2010
73	0	.....	9/1/2011	4/7/2010	FSA	10-3827	Closure 8/17/2011.	.....	.....	Farm Operating Loans (FSA).	3/21/2010	940	3/29/2012	9/1/2009	9/1/2009	5/27/2010
74	0	.....	1/1/2012	10/6/2010	RD	11-4468	Closure 8/17/2011.	.....	.....	SFH—Rural Housing Direct Loans (RD).	2/11/2011	818	3/29/2012	1/1/2010	1/1/2010	5/14/2010
75	0	.....	1/14/2012	4/5/2010	RD	10-3813	Removed Not ECOA.	.....	.....	Rural Development	3/24/2010	805	3/29/2012	1/14/2010	1/14/2010	5/13/2010
76	0	.....	7/24/2011	9/4/2009	FSA	09-3073	F 7/25/2011 ..	.....	.....	Farm Operating Loans (FSA).	8/27/2009	979	3/29/2012	7/24/2009	10/1/2009	.....
77	0	.....	7/28/2011	8/14/2009	RD	09-2948	NF 7/28/2011	.....	.....	SFH—Rural Housing Guaranteed Loan (RD).	8/7/2009	975	3/29/2012	7/28/2009	7/28/2009	4/16/2010
78	0	.....	7/29/2011	1/8/2008	RD	8-0907	NF 7/28/2011	.....	.....	SFH—Rural Housing Direct Loans (RD).	1/6/2010	974	3/29/2012	7/29/2009	7/29/2009	.....
79	0	.....	10/26/2011	10/26/2009	FSA	10-3260	Removed Not ECOA.	.....	.....	Farm Operating Loans (FSA).	10/26/2009	885	3/29/2012	10/26/2009	10/26/2009	5/20/2010
80	-253	.....	7/20/2011	9/11/2009	FSA	09-3087	Closure/File in Federal Court (KCB).	.....	.....	Farm Operating Loans (FSA).	7/20/2009	983	3/29/2012	7/20/2009	7/20/2009	.....
81	0	.....	7/21/2011	11/7/2009	FSA	10-3332	Closure 7/20/2011.	.....	.....	Farm Operating Loans (FSA).	10/7/2009	982	3/29/2012	7/21/2009	7/1/2009	5/20/2010

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No.	Days remaining until 2 years from incident date	2 years since incident date	USDA rovd date	Agency	Case #	Status	Investigator adjudicator	Pending review OASCR	Program name	Corresp date	Days elapsed from incident date)	Current date	Actual incident date	Initial incident date	Date ECOA letter mailed
82	0	10/31/2011	10/9/2009	FSA	10-3343	Closure 6/27/2011.			Farm Operating Loans (FSA).	9/29/2009	880	3/29/2012	10/31/2009	10/31/2009	7/1/2010
83	0	2/26/2012	4/2/2010	RD	10-3810	Closure 6/24/2011.			Denial of Loan (RD)	2/26/2010	762	3/29/2012	2/26/2010	2/26/2010	9/3/2010
84	0	2/23/2012	7/27/2010	FSA	10-4090	Closure 6/23/2011.			Farm Operating Loans (FSA).	4/27/2010	765	3/29/2012	2/23/2010	2/23/2010	4/30/2010
85	0	7/13/2011	7/30/2009	FSA	09-2919	NF 7/12/2011			Farm Operating Loans (FSA).	7/24/2009	990	3/29/2012	7/13/2009	7/13/2009	5/5/2010
86	0	7/8/2011	3/5/2009	FSA	09-2294	NF 7/5/2011			Farm Operating Loans (FSA).	2/25/2009	995	3/29/2012	7/8/2009	5/18/2009	4/16/2010
87	0	7/14/2011	4/6/2009	FSA	09-2482	Removed			Farm Ownership Loans (FSA).	4/3/2009	989	3/29/2012	7/14/2009	7/14/2009	4/30/2010
88	0	7/6/2011	7/29/2009	FSA	09-2904	NF 7/1/2011			Farm Operating Loans (FSA).	7/9/2009	997	3/29/2012	7/6/2009	7/6/2009	4/16/2010
89	0	6/26/2011	7/30/2009	RD	09-2899	NF 6/27/2011			Rural Business Enterprise Grant (loan) (RBS).	7/28/2000	1007	3/29/2012	6/26/2009	6/26/2009	7/19/2010
90	0	6/17/2011	5/28/2009	FSA	09-2668	Closure 5/26/2011.			Farm Operating Loans (FSA).	5/18/2009	1016	3/29/2012	6/17/2009	4/24/2009	5/20/2010



USDA—OFFICE OF THE ASSISTANT SECRETARY FOR CIVIL RIGHTS—OFFICE OF ADJUDICATION—EQUAL CREDIT OPPORTUNITY ACT CASES STATUTE OF LIMITATION NOT EXPIRED—Continued

No.	Days remaining until 2 years from incident date	2 years since incident date	USDA rovd date	Agency	Case #	Status	Investigator adjudicator	Pending review OASCR	Program name	Corresp date	Days elapsed from incident date)	Current date	Actual incident date	Initial incident date	Date ECOA letter mailed
102	0	5/13/2011	3/5/2009	RD	09-2311	NF 5/13/2011			SFH—Rural Housing Guaranteed Loan (RD).	2/16/2009	1051	3/29/2012	5/13/2009	5/13/2009	4/23/2010
103	0	5/5/2011	5/27/2009	FSA	09-2646	NF 5/4/2011			Farm Operating Loans (FSA).	5/4/2009	1059	3/29/2012	5/5/2009	5/5/2009	5/20/2010
104	0	4/30/2011	6/10/2009	FSA	09-2726	NF 5/2/2011			Farm Operating Loans (FSA).	6/5/2009	1064	3/29/2012	4/30/2009	6/5/2009	4/16/2010
105	0	5/1/2011	3/4/2009	FSA	09-2302	NF 5/2/2011			Farm Operating Loan (FSA).	7/7/2009	1063	3/29/2012	5/1/2009	5/1/2009	.....
106	0	4/23/2011	5/6/2010	RHS	10-3898	F 4/25/2011			504 Loan Grant/ Loan (RD).	4/28/2010	1071	3/29/2012	4/23/2009	4/23/2009	5/20/2010
107	0	8/1/2011	11/17/2009	FSA	10-3367	Admin Closure			Farm Operating Loans (FSA).	11/12/2009	971	3/29/2012	8/1/2009	8/1/2009	5/5/2010
108	0	5/7/2011	5/27/2009	RD	09-2667	Admin Closure			SFH—Rural Housing Guaranteed Loan (RD).	5/7/2009	1057	3/29/2012	5/7/2009	5/7/2009	5/20/2010
109	0	4/1/2011	6/12/2009	RD	09-2815	Admin Closure			Rural Housing	6/24/2009	1093	3/29/2012	4/1/2009	4/1/2009	4/23/2010
110	0	4/8/2011	4/21/2009	FSA	09-2501	F 4/8/2011			Farm Operating Loans (FSA).	4/15/2009	1086	3/29/2012	4/8/2009	4/8/2009	4/16/2010

111	0	4/9/2011	5/6/2009	FSA	09-2580	NF 4/11/2011						1085	3/29/2012	4/9/2009	4/9/2009	4/16/2010
112	0	6/1/2011	10/14/2010	FSA	11-4379	Status Change No Longer ECoa (RC)						1032	3/29/2012	6/1/2009	6/1/2009	2/3/2011
113	0	4/17/2011	4/30/2009	FSA	09-2560	Admin Closure						1077	3/29/2012	4/17/2009	4/17/2009	Request to withdraw ltr. Was mailed to Comp. on 040610
114	0	5/18/2011	5/27/2009	FSA	09-2651	Admin Closure						1046	3/29/2012	5/18/2009	5/18/2009	Need ECoA ltr. Gave to TNU on 051910
115	0	4/2/2011	4/26/2009	RD	09-2568	NF 4/4/2011						1092	3/29/2012	4/2/2009	4/2/2009	4/16/2010
116	0	4/15/2011	4/22/2009	FSA	09-2524	Admin Closure						1079	3/29/2012	4/15/2009	4/15/2009	.....
117	0	3/19/2011	6/5/2009	FSA	09-2729	NF 3/21/2011						1106	3/29/2012	3/19/2009	3/19/2009	6/15/2010
118	0	4/30/2011	5/13/2009	RD	09-2622	Admin Closure						1064	3/29/2012	4/30/2009	4/30/2009	5/24/2010
119	0	3/6/2011	4/7/2009	RD	09-2438	Adjudication Admin Closure.						1119	3/29/2012	3/6/2009	3/6/2009	6/15/2010
120	0	2/4/2011	6/30/2008	FSA	8-1537	Settlement 2/4/2011.						1149	3/29/2012	2/4/2009	2/4/2009	4/15/2010

USDA—OFFICE OF THE ASSISTANT SECRETARY FOR CIVIL RIGHTS—OFFICE OF ADJUDICATION—EQUAL CREDIT OPPORTUNITY ACT CASES STATUTE OF LIMITATION NOT EXPIRED—Continued

No.	Days remaining until 2 years from incident date	2 years since incident date	USDA rovd date	Agency	Case #	Status	Investigator adjudicator	Pending review OASCR	Program name	Corresp date	Days elapsed (from incident date)	Current date	Actual incident date	Initial incident date	Date ECOA letter mailed
121	0	2/5/2011	2/9/2009	FSA	09-2233	NF 2/7/2011			Farm Operating Loans (FSA).	1/15/2009	1148	3/29/2012	2/5/2009	2/5/2009	4/16/2010
122	0	1/8/2011	2/24/2009	FSA	09-2273	NF 1/10/2011			Farm Operating Loans (FSA).	1/27/2009	1176	3/29/2012	1/8/2009	1/8/2009	4/16/2010
123	0	1/21/2011	1/6/2009	RD	09-2164	NF 1/20/2011			SFH—Rural Housing Direct Loans (RD).	12/21/2008	1163	3/29/2012	1/21/2009	1/21/2009	4/16/2010
124	0	7/7/2011	7/22/2009	RD	09-2861	Adjudication Admin Closure.			SFH—Housing Repair & Rehabilitation Loan (RD).	7/16/2009	996	3/29/2012	7/7/2009	7/7/2009	4/30/2010
125	0	1/6/2011	1/29/2009	FSA	09-2210	NF 1/6/2011			Farm Operating Loans (FSA).	1/8/2009	1178	3/29/2012	1/6/2009	1/6/2009	4/23/2010
126	0	12/21/2010	2/2/2009	RD	09-2226	NF 12/21/10			RBP—Business & Industry Guaranteed Loans (RD).	1/20/2009	1194	3/29/2012	12/21/2008	12/21/2008	4/16/2010
127	0	12/20/2010	11/13/2008	FSA	8-1651	NF 12/20/10			Farm Operating Loan (FSA).	11/3/2008	1195	3/29/2012	12/20/2008	12/20/2008	4/23/2010
128	0	12/20/2010	8/5/2008	FSA	8-1660	F 12/20/10			Farm Operating Loans (FSA).	8/1/2008	1195	3/29/2012	12/20/2008	12/20/2008	4/15/2010
129	0	11/29/2010	1/7/2009	RD	09-2129	NF 11/26/10			SFH—Rural Housing Direct Loans (RD).	12/27/2008	1218	3/29/2012	11/27/2008	11/27/2008	4/23/2010

130	0	11/13/2010	12/23/2008	RD	09-2118	NF						12/4/2008	1232	3/29/2012	11/13/2008	11/13/2008	4/23/2010
												SFH—Rural Housing Direct Loans (RD).					
131	0	11/1/2010	10/29/2008	FSA	09-1973	NF 10/28/10						10/18/2008	1244	3/29/2012	11/1/2008	11/1/2008	4/15/2010
												Farm Operating Loans (FSA).					
132	0	9/17/2010	12/15/2008	FSA	09-2095	NF 9/16/10						12/5/2008	1289	3/29/2012	9/17/2008	9/17/2008	4/23/2010
												Beginning Farm loan denied (SOL).					
133	0	8/13/2010	8/20/2008	RD	8-1715	NF 8/12/10						8/14/2008	1324	3/29/2012	8/13/2008	8/13/2008	4/23/2010
												SFH—Rural Housing Direct Loans (RD).					
134	0	8/19/2010	8/27/2008	FSA	8-1744	F 8/19/10						8/20/2008	1318	3/29/2012	8/19/2008	8/19/2008	4/15/2010
												Farm Operating Loans (FSA).					
135	0	6/14/2010	6/21/2008	FSA	8-1269	NF 6/11/10						6/9/2008	1384	3/29/2012	6/14/2008	6/14/2008	5/27/2010
												Farm Operating Loans (FSA).					
136	0	5/16/2010	5/14/2008	FSA	7-0270	F 5/17/10						5/16/2008	1413	3/29/2012	5/16/2008	5/16/2008	4/27/2010
												Farm Storage Facility Loans (FSA).					
137	0	5/6/2010	5/20/2008	RD	8-1416	F 5/10/10						5/15/2008	1423	3/29/2012	5/6/2008	5/6/2008	4/19/2010
												SFH—Rural Housing Direct Loans (RD).					

Current date: 3/29/2012.  
 Priority 1 = 180 days from 2-year incident date.  
 Priority 2 = 181-365 days from 2-year incident date.  
 Priority 3 = 366 days from 2-year incident date.  
 Cases SOL TBD.  
 Cases held in abeyance.  
 Cases resolved prior to SOL expiration.

		Name		Title		Initial	
Tonya Ahmed				Investigator		TA	
Sterling August				Investigator		SA	
Karen Bascombe-Cleaver				Investigator		KBC	
Moses Brown				Investigator		MB	
Cinnamon Butler				Investigator		CB	
Roberto Contreras				Investigator		RC	
Michele Ferreira				Investigator		MF	
Shawney Fox				Investigator		SF	
Alpha Griffin				Investigator		AG	
William Henry				Investigator		WH	

Name	Title	Initial
Loretha Johnson	Investigator	U
Minh Pham	Investigator	MP
Edward Profit	Investigator	EP
Carleeta Watkins	Investigator	CW
Kristine Yen	Investigator	CY
Barrett Carne	Adjudicator	BC
Leila Levi	Adjudicator	LL
Carla Quincy	Adjudicator	CQ
William Reid Strong	Adjudicator	RS
Pilar Velasquez	Adjudicator	PV
Millie West-Wiggins	Adjudicator	MWW
Tyson Williams	Adjudicator	TW
Keyo & Judy	Adjudicator	K&J
Heather	Adjudicator	H&N
Lawrence Rudden	Adjudicator	LR
Neema G.	Adjudicator	NG

UPDATE STATUS CODES

	Codes
Program Intake Div	PI
Program Investigations Div	PID
Program Adjudications Div	PAD
Fact Finding	FF
Transfer	T
Admin Closure	AC
Actual Incident Date Change	AIDC
Finding	F
No Finding	NF
EEOA Compliant Addition	ECA
Assignment	ASMT
Pending	P
Status Change	SC
Closure	C

Secretary VILSACK. We are now in a process of knowing. We've got a red, green, yellow system, and if it's a red, it tells us that within a certain period of time we've got to get a response, otherwise their claim expires. We have not let that happen.

Senator PRYOR. That's great. I know you have been improving this, but I met with a fairly large group in Arkansas, 3 or 4 months ago, I don't remember exactly when it was, and that was one of the concerns that pretty much everybody in the group had.

Secretary VILSACK. They don't know what the system is, Senator. I mean that's just not accurate.

Senator PRYOR. Okay. We have one claim, apparently, that's 2 years old, that they haven't gotten a response from you guys yet. I'll tell you what. We'll sit down after this. I'll send my folks over, or you can send your folks over. We can talk about it.

Secretary VILSACK. I'm happy to talk to you about it, but sometimes it turns out that there's more to the story than either you or I are getting, and if we have a claim that's more than 2 years old, I'm happy to personally get that rectified. But, I will tell you that we are very focused on this, because we are not interested in giving rise to the tens-of-thousands of lawsuits and claims that I've been working on for the last couple of years to get resolved.

[The information follows:]

In 2009, USDA discovered more than 14,000 documents that had been classified as civil rights program complaints filed against the Department between 2001 and 2008 that had barely been looked into. Many of these documents in fact turned out to be complaints, alleging discrimination under a variety of laws, including title VI, section 504 of the Rehabilitation Act, the Food Stamp Act, and the Equal Credit Opportunity Act (ECOA). The delayed and minimal processing of complaints during the previous Administration was particularly troubling for those cases that fell under the ECOA. The ECOA, which prohibits discrimination in lending, is distinct from other civil rights laws because under the ECOA, the Government can be held liable by a court for compensatory damages. In addition, the USDA has the authority to provide monetary relief to resolve an administrative complaint of lending discrimination against the Department provided the complainant could still go to court on that claim (e.g., the statute of limitations is not expired). For incidents of discrimination that occurred before July 21, 2009, the statute of limitations for ECOA claims is 2 years.<sup>1</sup>

The administration proposed \$40 million in the fiscal year 2013 President's budget request for the purpose of settling written claims filed under the ECOA from July 1, 1997, to October 31, 2009. This funding would be subject to authorization by Congress to allow USDA to waive the statute of limitations to settle these claims.

A farmer or other customer with an ECOA claim does not have to file a complaint with USDA; they have the right to proceed directly to court. However, litigation can be a costly alternative to the administrative process. When the backlog was discovered, the typical processing time for a civil rights complaint was 4 years, with many cases taking much longer, which meant that by the time a decision was rendered on a complaint, no monetary relief could be provided by USDA where discrimination and resulting economic harm was found. To ensure that a backlog like the one encountered did not occur again, the Department set a policy to resolve all ECOA complaints either in formal closure and/or a settlement before the expiration of the statute of limitations. To achieve this goal, the Office of Civil Rights doubled the number of investigators and adjudicators working on program complaint processing, and instituted a Lean Six Sigma process improvement initiative to streamline the complaint process and reduce processing time. Since the new complaint staff have been recruited and trained, every ECOA complaint filed with the USDA has been resolved before the expiration of the statute of limitations. The typical processing time for new civil rights program complaints has been reduced from 4 years to 18 months. Processing time for one component of the complaint process, complaint intake, has been reduced from an average of 90 days to an average of 28 days to de-

<sup>1</sup>The Dodd Frank Financial Reform Act extended the statute of limitations to 5 years, but the extension was not retroactive.

termine jurisdiction and intake a complaint in 2012. Despite the extension of the ECOA statute of limitations to 5 years in the Dodd Frank Financial Reform Act, the Office of Civil Rights is pressing forward to further reduce processing time for complaints. Just this year, the Office of Civil Rights debuted a single, USDA-wide form that USDA customers and program participants can use to file a civil rights complaint. By capturing all of the information needed to accept a complaint, the form will reduce the time it takes to process complaints. The form helps to simplify and expedite the process for those who believe they have been discriminated against. The Department knows how important it can be to customers to receive a decision on their civil rights case and is committed to making that happen as quickly as a fair, thorough, and just decision can be reached.

Senator PRYOR. Like I said, I think you deserve a lot of credit for the progress you've made in that area, because it's been something that's been neglected for a long time.

Thank you.

#### ADDITIONAL COMMITTEE QUESTIONS

Senator KOHL. Thank you very much, Senator Pryor, and we thank you-all for being here today, particularly Secretary Vilsack, for your very strong testimony.

We'll keep the record open for 1 week.

Secretary VILSACK. Thank you.

[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

##### FIELD OFFICE CLOSINGS

*Question.* What is the current status of the Farm Service Agency (FSA), Natural Resources Conservation Service (NRCS), and Rural Development office closings that were recently announced?

*Answer.* As of March 29, 2012, Rural Development (RD) closed 20 of the 43 offices with plans to close the remaining office by the end of fiscal year 2012 and NRCS plans to close or consolidate 24 offices by the end of fiscal year 2012. At this time none of the NRCS offices have been closed or consolidated. The 2008 farm bill (Public Law 110-246) requires that FSA take no action toward final approval of the office consolidation proposal until at least 90 days after the Secretary of Agriculture notified Members of Congress of his proposal. This notification occurred on February 27, 2012.

[Clerk's note: Subsequently, on May 29, FSA announced its decision to consolidate 125 of the 131 offices originally proposed for consolidation with other USDA Service Centers, consistent with provisions of the 2008 farm bill.]

*Question.* What will be the total costs of closing offices in fiscal year 2012?

*Answer.* The total estimated costs for the Department in fiscal year 2012 will be approximately \$44.5 million.

*Question.* What do you estimate to be the total savings of these closings in fiscal year 2013?

*Answer.* Total annual savings for all closures is approximately \$58.7 million, already reflected in the budget.

##### FOOD SAFETY AND INSPECTION SERVICE

*Question.* The Food Safety and Inspection Service (FSIS) is responsible for ensuring that the Nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and correctly labeled and packaged. This is accomplished through inspection and regulation of the products by agency personnel. The budget calls for a \$13 million cut in funding associated with implementing new methods of poultry inspection and reducing staff by 500 employees.

Have you begun negotiations with your unions on implementation of the new inspection process?

*Answer.* We are currently conducting pre-decisional involvement (PDI) sessions with the union that should be completed by June 2012. In PDI, we work with representatives of the union by sharing information about the proposed poultry slaugh-

ter process and asking the union to identify its concerns. We have tried to find solutions to the union's concerns to limit the scope of bargaining should we decide to go forward with the final rule. PDI is essentially pre-negotiations.

*Question.* The \$13 million in fiscal year 2013 savings assumes implementation of the new inspection method by October. Is it realistic to think you can obtain industry buy-in, successfully complete union negotiations, and implement new procedures in such a short time?

*Answer.* Our timeline is very ambitious, and there are of course some things beyond our control. However, FSIS is committed to implementing on schedule. We understand that most large and small plants favor the proposed change, so industry will likely seek to participate shortly after a final rule is published. As stated above, we are conducting pre-decisional involvement sessions with the union. We are hopeful that these sessions will limit the scope of any necessary bargaining, assuming that the agency decides to finalize the proposal. When the agency makes a final decision on how to proceed, we hope to conduct any negotiations with the union, possibly in late summer. Our experience with the Hazard Analysis and Critical Control Point (HACCP)-based Inspection Models Project gives us some understanding of the implementation tasks we face and will help us manage the conversion should we decide to adopt the rule. Finally, our estimate was based on spreading implementation over about 9 months, so FSIS does not expect to have to convert a large number of plants immediately in order to achieve our estimated savings.

We are currently conducting PDI sessions with the union. In PDI, we work with representatives of the union by sharing information about the proposed poultry slaughter process and asking the union to identify its concerns. We have tried to find solutions to the union's concerns to limit the scope of bargaining should we decide to go forward with the final rule. PDI is essentially pre-negotiations.

*Question.* How do you plan to purge 500 employees from your roles next year?

*Answer.* FSIS' goal is to ensure that every employee affected by this proposed change is given an opportunity to remain with the agency. We plan to accomplish most of the reductions through attrition and reassignment to vacancies in other parts of the agency.

#### NON-O157

*Question.* In September 2011, FSIS published a "Final Determination" that six additional strains of E. coli would be deemed adulterants in certain beef products.

Please detail the process and scientific evidence on which this determination was made.

*Answer.* FSIS developed a risk profile to examine the risk of non-O157 Shiga toxin-producing Escherichia coli (STEC) as an emerging food safety hazard associated with beef consumption in the United States. This risk profile provides an in-depth review of the relevant science to assess public health risk. The conclusions reached in the risk profile include that raw non-intact beef products and raw components of those products may harbor non-O157 STEC; that pathogenic non-O157 STECs are injurious to human health; that ordinary cooking practices, which include rare cooking, may be insufficient to destroy all cells of the pathogen in beef; and that a low dose of a non-O157 STEC can induce illness. In fact, the Centers for Disease Control and Prevention estimate that each year, non-O157 STEC serotypes cause nearly 113,000 foodborne illnesses in the United States. Moreover, while more than 100 STEC serotypes have been associated with human illness, these six serogroups cause between 70 and 83 percent of the confirmed non-O157 STEC illnesses. Thus, combating these six serogroups can have a significant beneficial public health impact.

For these reasons, FSIS announced a final determination that raw, non-intact beef products, or raw, intact beef products that are intended for use in raw, non-intact product, that are contaminated with STEC O26, O45, O103, O111, O121, and O145, are adulterated, per 21 U.S.C. 601(m)(1) and (m)(3).

*Question.* What are the implications on the industry and on our international beef trading partners of this determination?

*Answer.* FSIS will launch its non-O157 E. coli testing program on June 4, 2012, which will allow establishments time to validate their test methods. FSIS will initially test raw beef manufacturing trimmings (the major component of ground beef), and then expand testing to other raw ground beef product components. FSIS will apply the new tests to samples already being tested for other pathogens, so this policy will ensure a safer, more reliable food supply with minimal additional cost to the agency or to industry.

Foreign countries that export FSIS-regulated products to the United States must maintain a food safety system equivalent to that of the United States. Therefore,

in February 2012, FSIS contacted foreign governments already approved for the export of raw beef to the United States and informed them that FSIS would make a limited amount of reagents used in the FSIS laboratory method for non-O157 STEC serogroups available to a foreign government if that government wanted to conduct a comparative analysis of its methods with test kits assessed by FSIS.

#### AGRICULTURAL RESEARCH SERVICE

##### *2013 Budget Resource Reallocation*

*Question.* The Agricultural Research Service (ARS) is the flagship in-house research agency of the Department.

This budget proposes to redirect over \$70 million in resources from “lower priority programs” to higher priority research activities. Please explain your process to determine the priority of research initiatives, and how decisions were made to reallocate resources.

*Answer.* Focusing on the need to reallocate limited resources to address high-priority initiatives, all research programs were systematically evaluated based on relevance, quality, impact and cost effectiveness. The fiscal year 2013 budget recommends selected high-priority initiatives which address the administration’s science and technology priorities and the Department’s strategic goals. The reallocation of these resources would allow Congress to fund higher priority agriculture research identified in the fiscal year 2013 budget.

*Question.* Is the redirection of \$70 million in resources in 1 year normal for your research portfolio or is this unusually high?

*Answer.* The reduction of \$70 million is not unusually high. In fiscal years 2009 through 2012, the President’s budget for ARS proposed reductions and/or terminations of research activities ranging from \$39 million to \$146 million to help offset proposed initiatives.

##### *Agricultural Research Service Lab Closures*

*Question.* This budget proposes to close five laboratories within existing facilities, and to close one facility entirely. Please explain how these decisions were made.

*Answer.* Decisions regarding which programs to propose for termination or closure are always difficult but necessary, given the ongoing budget constraints and changing priorities of research endeavors. These research laboratories proposed for closure met one or more of the following criteria:

- Considered by the administration to be of lower priority;
- Mature where the research objectives have been mainly accomplished;
- Duplicative or can be accomplished more effectively elsewhere in ARS;
- Marginal or below threshold funding for program viability or sustainability;
- Conducted in substandard or inadequate infrastructure and future costs are prohibitive;
- Lacking a critical mass of scientists/support personnel for an effective program;
- or
- Are carried out by other research institutions.

*Question.* What will happen to the employees at these locations?

*Answer.* USDA will strive to place all impacted permanent Federal employees in suitable jobs where ARS position vacancies exist and for which the employee is qualified. While every effort will be made to identify a position for all impacted employees, USDA cannot guarantee that all employees will be placed. In the event that a placement cannot be identified for an impacted employee, the Department will ensure that the individual is provided all the entitlements and protections available under prescribed personnel procedures and programs.

*Question.* How much will it cost to close these labs in 2013?

*Answer.* The estimated cost to accommodate the impacted employees and dispose of the real property ranges from \$10 million to \$12 million. These costs may be spread over 2 fiscal years, depending on how quickly the real property assets can be disposed.

*Question.* When do you expect to begin realizing savings from these closures?

*Answer.* Beginning in fiscal year 2013, the \$17 million associated with the research activities at the six laboratories will be reallocated to high-priority research in other ARS laboratories. After all costs have been expensed, the closure of these laboratories will allow ARS to achieve significant cost avoidance in the capital improvement and repair/maintenance of these facilities beginning in 2014.

*Budget Reductions*

*Question.* The Animal and Plant Health Inspection Service (APHIS) promotes the health of animal and plant resources to facilitate their movement in international markets, and works to ensure abundant agricultural products for U.S. consumers. These responsibilities include monitoring plant and animal health, working to eliminate or control invasive pests, facilitating safely bringing benefits of genetic research into the market place, providing diagnostic laboratory activities, assisting developing countries improve their safeguarding systems, and protecting and promoting animal welfare. However, the budget proposes a 7-percent funding reduction, and elimination of 151 employees.

How do you plan to meet these responsibilities with such severe cuts in funding and staffing?

*Answer.* The 2013 budget identified several ways for APHIS to operate more efficiently, allowing APHIS to maximize its resources to carry out its mission. APHIS has implemented a variety of changes in its operations that will result in cost-savings for fiscal year 2013, including the consolidation of information technology customer service support and switching telecommunications technology. In addition, APHIS has identified other areas where a shift in methodology can allow savings and still achieve the agency's goals. For example, APHIS has developed several statistical and epidemiological methods to increase the efficiency of animal health surveillance while continuing to meet international standards, saving \$9 million. APHIS also is implementing business process improvements that will result in savings in areas such as licensing of veterinary biologics products, import and export reviews, and reviews of petitions to determine the regulatory status of genetically engineered crops. The agency's budget request reflects the implementation of the identified efficiencies and changes in strategies without compromising our mission and services.

APHIS is also proposing further reductions in the agency's contributions towards domestic and international efforts to allow those who benefit from our services to contribute, or to scale back the Federal role when a pest or disease is simply too widespread. We will continue to place high priority on protecting the health and value of American agriculture by focusing on those pests or diseases that pose the greatest risk and facilitating safe agricultural trade.

*Question.* The Animal and Plant Health Inspection Service promotes the health of animal and plant resources to facilitate their movement in international markets, and works to ensure abundant agricultural products for U.S. consumers. These responsibilities include monitoring plant and animal health, working to eliminate or control invasive pests, facilitating safely bringing benefits of genetic research into the market place, providing diagnostic laboratory activities, assisting developing countries improve their safeguarding systems, and protecting and promoting animal welfare. However, the budget proposes a 7-percent funding reduction, and elimination of 151 employees.

Can you provide assurances that existing safeguards protecting against intrusion of new invasive pests into the United States will not be weakened?

*Answer.* APHIS uses a comprehensive set of measures to safeguard the United States against the introduction of foreign pests and diseases. These measures include assessing and reducing threats overseas through information collection and collaborating with foreign governments, and implementing regulatory import policies designed to facilitate trade while excluding high-risk products. The agency also works with the Department of Homeland Security's Customs and Border Protection to enforce these regulations, monitoring for introductions of high-risk pests and diseases in the United States and maintaining emergency response capabilities to respond when outbreaks occur.

In developing its fiscal year 2013 budget proposal, APHIS carefully examined its programs and operations to determine where we could gain efficiencies while maintaining focus on the areas that pose the highest risks. For example, APHIS has proposed decreases related to changes in epidemiological methods for swine and cattle disease surveillance. These changes will allow the agency to realize savings while still meeting international standards. In other cases, APHIS identified efficiencies that could be gained in telecommunications and information technology that will have little or no effect on program operations and reduce overall costs. Other reductions target programs for pests and diseases that are already established in the United States, such as emerald ash borer (EAB), and focus resources on those programs where they could make a difference. Despite intensive efforts by APHIS and cooperating States to address this pest, we lack the tools needed to control it. APHIS will continue to work on tools to manage EAB over the long term and protect

U.S. forests and urban landscapes. The overall proposed reduction is the result of our efforts to identify targeted changes and reduce costs while focusing on the highest risk areas.

*Question.* The Animal and Plant Health Inspection Service promotes the health of animal and plant resources to facilitate their movement in international markets, and works to ensure abundant agricultural products for U.S. consumers. These responsibilities include monitoring plant and animal health, working to eliminate or control invasive pests, facilitating safely bringing benefits of genetic research into the market place, providing diagnostic laboratory activities, assisting developing countries improve their safeguarding systems, and protecting and promoting animal welfare. However, the budget proposes a 7-percent funding reduction, and elimination of 151 employees.

Much of this savings assumes State-cooperating agencies accept higher costs. Have you discussed with your State partners their willingness to take on these higher costs? What are the implications of States being unable to pay more for these activities? Do you have a back-up plan?

*Answer.* Most of APHIS' plant and animal health programs are cooperative efforts with State and local partners, and we understand that our budget proposal affects them. In developing the agency's budget request, we had to make difficult choices to enable us to best protect the health of American agriculture while balancing the President's priority of reducing the deficit. Under the reality of current resource limitations, it is reasonable to share with cooperators the costs of programs for which they will receive a benefit.

When addressing pests and diseases of national concern, the Federal Government's role traditionally is to coordinate and manage program efforts, and ensure that we apply program methods and technologies consistently in all affected States and areas. Since these pests and diseases have a direct impact on State and local conditions and since States and localities are beneficiaries of the actions, it is expected that all parties will devote available resources to the effort. While there may not have been agreement to the level of contributions for each pest and disease program, it is reasonable to expect all parties to contribute some level of resources towards these cooperative programs that, in most cases, have been in place for several years. These decreases will result in a more appropriate allocation of funding responsibility given the budget realities we face, and a transparent level of Federal contribution will allow cooperators to plan for future needs. The agency's budget request is presented more than 6 months in advance of when it will become effective, which allows time for program partners to develop their spending plans in the coming year. The agency will continue to conduct pest and disease programs based on the total available resources while considering the highest priorities for the program. We will continue to work cooperatively with our State partners on these programs and use available resources as effectively as possible.

#### ANIMAL WELFARE

*Question.* Animal Welfare has been a high priority of this administration. In past years the Department transferred funds from other accounts to supplement these activities. However, this budget cuts Animal Welfare funding by over 11 percent (larger than the overall reduction to the agency). What has caused this change in the administration's priority toward Animal Welfare responsibilities?

*Answer.* Animal Welfare still remains a high priority of the administration. APHIS recognizes that we need to do our part in helping to reduce Federal spending. As such, we are scaling back operations as a cost-savings measure, including our priority areas such as animal welfare inspection and enforcement. Even with the proposed budget in 2013, the Animal Welfare program remains a priority and will be comparable to the adjusted fiscal year 2011 funding level, including the re-programming of \$2.5 million in funding.

Additionally, APHIS will continue its focus on the most egregious violators of the Animal Welfare Act (AWA) while seeking ways to operate more efficiently in fiscal year 2013. The agency has implemented measures to enhance its animal welfare inspection and enforcement efforts in recent years. These measures include identifying potential regulation changes related to commercial dog breeders and dealers, re-evaluating the current methodology for calculating the frequency of inspection, and developing and sponsoring meetings and trainings aimed at increasing compliance with the AWA. APHIS also conducted a business process improvement analysis of its enforcement activities, including animal welfare enforcement. After identifying more than 80 recommendations for streamlining its processes and improving timeliness, the agency pilot tested several recommendations with considerable success.

These business process improvement efforts will allow quicker and more effective actions that require fewer resources.

#### LACEY ACT

*Question.* One of the rare increases in this budget is for implementation of Lacey Act responsibilities. In fact, the budget seeks to double Lacey Act spending by 50 percent, to \$1.5 million. Please describe what the Department is doing this year regarding its Lacey Act responsibilities. In your view, do you think this USDA effort is successful? What do you plan to do with the 50-percent increase? Could these responsibilities be more efficiently handled outside the Department?

*Answer.* As amended in the 2008 farm bill, the Lacey Act prohibits the importation of any plant, with limited exceptions, taken or traded in violation of domestic or international laws. The amendments were designed to address illegal logging in other countries. Illegal logging is environmentally destructive and undermines markets for wood products produced in the United States, affecting businesses and jobs. Among other things, the Lacey Act requires a declaration for imported shipments of regulated products. This declaration must contain the scientific name of the plant, the importation value, the quantity of the plant, and name of the country where the plant was taken.

APHIS began phased-in enforcement of the Lacey Act in May 2009 and currently receives about 10,000 declarations per week. Approximately 10 percent of these are submitted on paper forms that require significant resources to analyze and store. Currently, electronic declarations can only be made through licensed Customs brokers. In 2012, APHIS has \$775,000 available for activities conducted under the amendments to the Lacey Act. The agency is using these funds for a dedicated staff, secure document storage, and outreach activities to inform the various industries and importers affected by the Lacey Act amendments. The program selects 1 percent of the declarations at random for a cursory review and stores the remaining documents. The Department of Homeland Security's Customs and Border Protection collects the electronic declarations and sends them to APHIS on a weekly basis. For 2013, the agency is requesting an additional \$725,000 for a total funding level of \$1.5 million. With these additional funds, the program would work toward providing an easier electronic means for collecting and maintaining declarations to help eliminate the need for paper-based declarations. This will provide another alternative to importers for filing declarations (as importers currently must go through a licensed customs broker or fill out a paper declaration) and allow APHIS to be more responsive to importers' needs. In addition, APHIS would utilize additional staff to assist with Lacey Act activities and expand outreach efforts to affected industries so they better understand the act's requirements. With the requested increase in 2013, the program anticipates selecting an increased share of the declarations for a review.

APHIS is working within an interagency group representing the U.S. Forest Service, U.S. Department of Homeland Security's Customs and Border Protection (CBP), U.S. Trade Representative, U.S. Department of Justice, U.S. Department of State, U.S. Fish and Wildlife Service, the Council on Environmental Quality, and the U.S. Department of Commerce, to implement the Lacey Act provisions and review the program. The interagency group represents a broad range of viewpoints on how to implement the act. Because of APHIS' regulatory role and interaction with the importing community as well as its ongoing joint efforts with CBP through the Agriculture Quarantine Inspection program, the agency is well positioned to implement the act. APHIS will continue working with its partners to administer the Lacey Act in the most efficient manner possible given the volume of declarations and products covered.

#### BIOTECHNOLOGY REGULATORY SERVICES

*Question.* In the past, this subcommittee has provided increased funding for Biotechnology Regulatory Services to support an effective biotechnology compliance program for genetically engineered organisms. Private sector demands on these services continue to expand. Currently, the agency currently faces litigation due to its inability meet its regulatory responsibilities in a timely manner. However, this budget reduces this funding by 8 percent. How do you plan to improve this unfortunate situation with a large funding cut?

*Answer.* I appreciate the subcommittee's support for APHIS' Biotechnology Regulatory Services (BRS) program. BRS is integral to the process of ensuring that genetically engineered (GE) crops under development can be safely tested and brought to market. After a careful evaluation of the nonregulated status petition review process, APHIS has identified several process improvements that are expected to achieve the goal of reducing the overall length and variability of the time it takes

for the petition process. Once complete, this effort is expected to reduce review time by more than 50 percent (average review times will decrease from about 3 years to just over 1 year). For instance, APHIS has eliminated unnecessary steps, clarified and simplified responsibilities, and put into place time frames for completion of individual steps while maintaining appropriate safeguards. Additionally, a portion of the program's \$5 million increase in fiscal year 2012 will be used for one-time legal fees related to litigation over GE alfalfa. The remaining portion will be used to hire additional staff and enter into contracts for environmental analysis to support the improvements to the petition review process. While we are proposing a small decrease in fiscal year 2013, biotechnology remains a priority for the agency. Even with the proposed reduction, the BRS funding level would increase more than 25 percent from the fiscal year 2010 level of \$13.3 million to the fiscal year 2013 request of about \$16.8 million.

#### AGRICULTURAL MARKETING SERVICE

##### *Microbiological Data Program*

*Question.* The fiscal year 2012 House report did not include funding for the Microbiological Data Program. The conference report included the following statement:

"The statement of the managers remains silent on provisions that were in both House Report and Senate Report that remain unchanged by this conference agreement, except as noted in this statement of the managers."

Please explain why this program was zeroed out in the budget even though no funding was provided in fiscal year 2012.

*Answer.* The Microbiological Data Program (MDP) was continued in 2012 because the funding reduction in the Consolidated and Further Continuing Appropriations Act, 2012 for Marketing Services (which includes MDP) could not be positively identified. While the House provided \$77,500,000 for Marketing Services, accompanied by Appropriations Committee report language that denied funding for MDP, the Senate and final Appropriations Act provided \$82,211,000. Both the Senate committee and conference reports were silent on the matter. The program was zeroed out in the fiscal year 2013 proposed budget due to budget constraints. In developing the fiscal year 2013 budget, we took a hard look at activities which support AMS' core mission. The fiscal year 2013 budget eliminates funding for MDP, which saves about \$4.3 million. This reduces discretionary funding while focusing Marketing Services resources on AMS' core mission. AMS is not a food safety agency and MDP is not closely aligned with AMS's core mission to facilitate the competitive and efficient marketing of U.S. agricultural products.

#### PESTICIDE RECORDKEEPING PROGRAM

*Question.* The budget proposes to terminate the Pesticide Recordkeeping Program. Currently, 27 States and 2 territories are reimbursed to conduct federally recognized State pesticide recordkeeping requirements. This program has been in place since 1992.

Please explain the rationale for terminating this program in light of ever-shrinking State budgets.

*Answer.* We continue to take practical steps to control expenditures and optimize organizational structure to more effectively manage current and future resources. In making budget determinations we are focusing on AMS' core mission to facilitate competitive and efficient marketing of U.S. agricultural products.

*Question.* Since this program has been operating for 20 years, why does AMS now believe it is no longer central to its core mission?

*Answer.* We took a hard look at activities that support AMS' marketing-based mission and Pesticide Recordkeeping is not as closely aligned with marketing as other AMS activities such as Market News or Transportation and Market Development. Although Federal monitoring and advisory services will be discontinued, applicators of restricted use pesticides will still be required to retain their records and provide access upon request to Federal and State agency representatives. Since the Federal program has been operating for 20 years, we have had the opportunity to educate a large number of private applicators of federally restricted use pesticides. More than 100,000 pesticide recordkeeping manuals, brochures and other outreach materials have been distributed each year by the program to producers.

#### CONSERVATION

*Question.* The budget proposes a decrease of \$2.5 million and 142 staff years for conservation technical assistance.

How does NRCS plan to provide important technical assistance with fewer funds and fewer staff?

Answer. NRCS will continue to provide important technical assistance to landowners in addressing their resource issues and concerns. This will be accomplished through the use of improved delivery and streamlining processes such as the Conservation Delivery Streamlining Initiative (CDSI), expanding the role of Technical Service Providers (TSPs), and continuing to build strong conservation partnerships with local, State, and Federal entities as well as with the private sector.

*Question.* Please describe what organizational improvements NRCS plans to implement.

Answer. In coordination with the USDA Blueprint for Stronger Service, NRCS is taking a holistic look at our entire organization to ensure we are well prepared to meet our mission now and in the years to come. NRCS currently has teams working on 17 major efforts that will result in a streamlined, efficient organization to transform NRCS into a 21st century, multi-billion dollar agency that can adapt to change while delivering exceptional conservation assistance to private landowners. The information is provided below.

The efforts are organized into five categories:

—*Conservation Delivery Streamlining Initiative (CDSI).*—This effort will result in new and innovative technology that will support conservation assistance process online, streamline service delivery, and will give landowners 24/7 access to their conservation information. It will allow conservationists to spend more time in the field while enabling administrative experts to handle the administrative tasks of programs and applications.

In fiscal year 2012 through fiscal year 2013, CDSI will implement a national strategy to realign field positions through the establishment of program support specialist position. This position will reduce the administrative burden on the technical field employees and enable a more streamlined and efficient approach to the delivery of conservation support.

—*Science Efforts.*—NRCS launched efforts to gain agency-wide efficiencies by sharing resources, reducing duplication of effort, and enhancing our role as a leader in conservation science while addressing decreased operating budgets. Efforts include:

- Consolidate Soil Survey offices and provide shared services across larger geographic regions;
- Reduce duplication of effort and streamline our system of developing and maintaining conservation practice standards and associated guidance;
- Improve our capacity to support complex engineering needs across the country; and
- Create more effective and efficient systems for conservation technology acquisition, development, and support to the field.

In fiscal year 2012 and fiscal year 2013, NRCS will implement the consolidation of the Soil Survey offices, beginning with the 24 office closures identified by Secretary Vilsack.

—*State Efforts.*—NRCS is also working on State level improvement efforts to coordinate, centralize, and streamline State processes and needs.

- States are charged with finding ways to increase direct technical service and increase resource sharing across State boundaries. Selected States in each region will test models where they reduce duplication by sharing services such as contract management and technical expertise;
- NRCS is also evaluating the benefits of centralizing support for quality assurance, equitable relief, and legal appeals at national headquarters to reduce burdens on State and field staff.

In fiscal year 2012, NRCS kicked off the multi-State servicing pilot that is testing a comprehensive approach to identifying areas for State-sharing, analyzing the option, and implementing long-term strategies for sharing resources.

—*Administrative Efforts.*—NRCS is taking a comprehensive approach to analyze administrative efforts; specifically NRCS is focusing on four key administrative functions or areas:

- Budget and financial management;
- Human resources;
- Procurement; and
- Property functions within NRCS.

NRCS is determining short-term solutions to position NRCS to best integrate the USDA Administrative Solutions Project and deliver the best support to the field.

In fiscal year 2012, NRCS will be moving forward with the development of a new administrative operating model that will focus on streamlining processes,

developing virtual teams, and enhancing standardization. NRCS will develop and implement the new operating model throughout fiscal year 2013 and this will result in increased capacity for administrative services and will position NRCS for improved performance.

—*Modernization Efforts.*—Modernization efforts across NRCS will look at IT, Public Affairs, and Outreach to identify ways to improve the delivery of communications and information services to our internal and external customers.

In fiscal year 2012, NRCS began the modernization of the public affairs and IT organizations. Public Affairs implemented the redesign of the external Web site and engaged with GovDelivery for modernization of communications delivery. Public Affairs is also underway with a comprehensive redesign that is currently in the baseline assessment stage and will result in fiscal year 2013 with additional improvements to the Public Affairs function at NRCS. The IT assessment is currently underway as well; an organization redesign is expected in fiscal year 2013. This effort will help to improve IT delivery, enhance oversight, and enable increased service delivery across NRCS.

#### RURAL DEVELOPMENT

##### *Broadband*

*Question.* This subcommittee has provided substantial support for expanding high-speed broadband service to remote rural areas. The Federal Communications Commission (FCC) is now engaged in revising access to the Universal Service Fund, on which the bulk of Rural Development broadband loans rely for a portion of their income. Reducing Universal Service Fund payments to rural providers will place Rural Development's loan portfolio in severe jeopardy.

Please discuss how USDA is working with the FCC to ensure that rural broadband providers are not treated unfairly under the new FCC requirements.

*Answer.* Throughout the years, Rural Development and FCC have worked closely to uphold the universal service provisions in the 1996 Telecommunications Act as Congress had intended. Those provisions ensure that rural America has access to advanced telecommunications services at rates and at levels of service that are comparable to those offered in urban America. Prior to implementing the new Universal Service Fund (USF) Reform Order, Rural Development consulted with FCC on numerous occasions to help ensure that this important statutory objective was fulfilled. Rural Development has provided briefings and data to the FCC on its portfolio and on the impacts of revenue reductions to RD's borrowers. The USDA also worked with the FCC in developing a national broadband strategy published in 2009, as required by the 2008 farm bill.

*Question.* What is USDA doing in the short run to protect existing broadband borrowers and their rural customers?

*Answer.* In the short run, Rural Development is analyzing its portfolio to determine the impacts of reduced USF and intercarrier compensation revenues on rural telecommunications providers serving rural high-cost communities. Rural Development has conducted a series of listening sessions with borrowers, financial experts, and other segments of the rural infrastructure sector to fully comprehend the impact on rural America. Rural Development is keenly focused on making sure that rural America continues to receive affordable, high-speed broadband service required for economic development and job creation.

*Question.* Is the Department experiencing reduced loan demand due to the uncertainty of looming changes to FCC requirements? If so, does that affect the Department's broadband loan request for fiscal year 2013?

*Answer.* The Rural Utilities Service (RUS) and the telecommunications industry continue to evaluate the impact of the FCC revisions in USF, ICC, and local rates. While the level of uncertainty caused by the order may delay project consideration, the agency fully supports the proposed funding levels for fiscal year 2013. The broadband infrastructure needs across rural America were demonstrated by the tremendous response to the Recovery Act's Broadband Initiatives Program (BIP). There were many valuable projects which simply could not be funded. We are hopeful that some BIP applicants will apply for regular RUS loan programs to further extend existing broadband networks to rural areas. We are also hopeful the FCC will consider the needs of RUS borrowers who are actively investing in rural broadband networks made possible through the Recovery Act by reestablishing the regulatory and financial certainty that is needed for rural telecommunications investment to continue.

*Question.* When the FCC announced plans to reform the Universal Service Fund, what changes did the Department make to its broadband loan underwriting criteria to reflect this new uncertainty?

Answer. Even before FCC published its proposed USF Reform Order, Rural Development revised its underwriting criteria in both our infrastructure and broadband programs to determine reliance on USF and the impact of reduced revenues. Only loans which meet more rigid underwriting standards advance through this process to loan approval. The agency further enhanced its underwriting criteria after the first USF order was published and will continue to make changes to ensure any taxpayer investments are secured.

#### HOUSING

*Question.* This budget calls for a 27-percent reduction in your flagship direct single family housing loan program.

Is demand for this program going down?

Answer. The USDA budget proposal reflects the efforts of this administration to do more with less and to make tough decisions where necessary. Historically, the direct single family housing program has helped low- and very-low-income borrowers to obtain homeownership. Our budget proposal will refocus the direct single family housing program to serve low- and very-low-income borrowers, and will target a portion of the funding to help attract a new generation of bright, young teachers to our rural schools.

Over the past decade, Rural Development has increasingly relied upon guaranteed loans to cost effectively provide for the credit needs of rural America. In fact, during this administration alone, funding for the guaranteed single family housing program (excluding Recovery Act funding) has quadrupled from about \$6.2 billion to \$24 billion in 2011. This funding has helped to fill a critical need for credit in rural America, and importantly, this level of assistance is being provided at no subsidy cost to taxpayers.

*Question.* What is the current backlog of applications and pre-applications for these loans?

Answer. As of March 29, 2012, the total number of Section 502 Direct Loan applications on a waitlist pending processing due to the lack of available funds is 11,398.

*Question.* Is there any other Federal direct loan program that provides home-ownership assistance for low- and very-low-income rural residents?

Answer. There is no other Federal direct loan program similar to the Section 502 Direct Loan program. The Section 502 Direct Loan program provides mortgage financing for low- and very-low-income rural Americans unable to get credit from other sources. The program includes a payment assistance feature to reduce the borrower's housing cost for principal, interest, taxes, and insurance to approximately 24 percent of income. The other fundamental difference in program administration between USDA and other Federal housing programs such as Housing and Urban Development (HUD) programs is USDA's field staff, which allows USDA to maintain a local presence in the rural communities it serves.

*Question.* Why are you seeking such a drastic cut in the program?

Answer. Some of the same rural residents with low- and very-low-incomes who qualify for loans under the single family housing direct loan program can also qualify for the single family housing guaranteed loan program. The primary difference between the two programs is that the direct loans are made and serviced by USDA and in some instances contain an interest subsidy. The guaranteed loans are made and serviced by a bank or other commercial lender at the current market interest rate and guaranteed by the Federal Government. Unlike the direct program, the guaranteed program is provided at no subsidy cost to taxpayers.

*Question.* Please discuss the requested set-asides for rural teachers and self-help housing program participants. Why did you elevate the priority of those applicants above others, including healthcare workers, police and fire workers, daycare workers, etc?

Answer. The budget proposes to set aside a small portion of the direct single family housing program funding for teachers and beneficiaries of the Mutual and Self-Help Grant Program for a portion of the fiscal year, after which the funds will be available for all applicants.

The decision to set aside funding for the Mutual and Self-Help Grant Program ensures that adequate loan funds are available to support the grant funding provided by Congress. Without sufficient loan funding we would be unable to fulfill the intent of Congress with respect to self-help housing.

Rural Development remains committed to the support of all low- and very-low-income families, regardless of their profession. Set aside funding for teachers, however, would help address the shortage of teachers willing to work in rural areas that lack affordable housing. Teachers are a key factor in creating sustainable rural communities. By targeting a portion of this assistance to teachers, we hope to encourage

many bright, young, and enthusiastic college graduates to consider returning to rural America to begin their professions as teachers.

*Question.* This budget seeks to eliminate the multi-family housing direct loan program (section 515). The stated justification for this elimination is that the guaranteed multi-family housing loan program (section 538) also provides construction financing and more funds are needed in the multi-housing revitalization program to maintain existing projects.

How effective is the guaranteed loan program in promoting construction in small towns and not just in larger communities?

*Answer.* The Multi-Family Housing (MFH) Guaranteed Rural Rental Housing Program (section 538) is very effective in promoting construction and preservation in rural areas. Like the MFH direct loan program (section 515), the section 538 program is restricted to areas of no more than 20,000 in population, unless eligible under a statutory exception. Approximately 50 percent of the loans guaranteed under section 538 preserve existing affordable properties in rural areas, most notably section 515 properties. For new construction, financial tools, including section 515 and section 538 loans, are more efficient for properties with more units of affordable housing, so nearly all of the new construction activity is in rural areas with populations between 10,000 and 20,000.

*Question.* How effective is the guaranteed program in offering affordable rents for very-low-income households?

*Answer.* The MFH Guaranteed Rural Rental Housing Program is very effective in offering affordable rents to very-low-income seniors, families, and individuals. The vast majority of tenants are under 80 percent of the area median income. More than 70 percent of all properties financed in the past several years using the section 538 program also have low-income housing tax credits (LIHTC), which impose lower income thresholds for tenants to qualify under the LIHTC program. Under the LIHTC program tenants must be very-low-income (50 percent of area median income) or low-income (less than 80 percent of area median income) families. In the last 3 years alone, the MFH Guaranteed Rural Rental Housing Program provided financing to build or preserve approximately 200 apartment buildings with 11,100 apartments, of which more than 9,400 are rented to very-low-income or low-income seniors, families or individuals.

*Question.* What is the total funding needed for the revitalization program?

*Answer.* We believe the budget request provides adequate funding for the Revitalization Program.

#### COMMUNITY FACILITIES

*Question.* This budget requests a \$2 billion Community Facilities Direct Loan Program (CF) level, up from \$1.3 billion in fiscal year 2012.

Is there demand for a \$2 billion annual loan program?

*Answer.* As a result of the credit crisis, one of the biggest issues facing rural communities today is the lack of access to capital. In recent years, the agency has seen an increase in funding requests for projects that are larger in nature, scope, and complexity. Accordingly, we believe the proposed program level reflects the sizable demand that exists for infrastructure financing in rural areas.

*Question.* What is the current backlog of applications and pre-applications?

*Answer.* As of May 2, 2012, the Community Facilities Program has a total backlog of about \$1.8 billion. This includes approximately 635 direct loan applications for \$1.6 billion, over 900 grant applications for \$51 million, and 27 guaranteed loan applications for \$131 million.

*Question.* Why is the guaranteed loan program eliminated?

*Answer.* The guaranteed loan program originated as an inexpensive alternative to the direct loan program and was designed to stimulate additional assistance to moderate income communities in rural areas. The default rate for the program, however, has been much higher than originally projected; in effect, this has made it more expensive than the direct loan program. The proposed increase in the direct loan program will more than offset the effects of the guaranteed loan program termination.

#### RURAL JOBS ACCELERATOR

*Question.* We have recently become aware of a new initiative, the Rural Jobs Accelerator, which apparently will be a joint effort among USDA, the Economic Development Administration, the Delta Regional Commission, and the Appalachian Regional Commission.

Please explain the purpose of this initiative and how it is designed to work?

*Answer.* The programmatic guidelines and goals of the Rural Jobs and Innovation Challenge (RJA) are very similar to those of the regular RCDI; RJA merely empha-

sizes building regional capacity. To be eligible for RJA, applicants must be eligible for the regular RCDI program.

RJA is a coordinated interagency funding opportunity designed to promote accelerated job creation and community and economic development in rural regions through regional collaboration. The RJA will provide resources to support economic development in the areas of renewable energy, food production, rural tourism, natural resources, and advanced manufacturing. The RJA will also assist distressed rural communities in accelerating job creation by leveraging local assets, building stronger economies, and creating regional linkages. The Funding Partners include USDA, the Department of Commerce's Economic Development Administration (EDA), the Appalachian Regional Commission (ARC), and the Delta Regional Authority (DRA). This coordinated, integrated, interagency initiative offers applicants the opportunity to submit a single project narrative to access multiple funding sources that collaboratively support regional development in rural communities.

*Question.* What are the performance measures you will use to gauge the initiative's success?

*Answer.* Applications will be evaluated based on their ability to satisfy core evaluation criteria. This includes building community and regional capacity, linking to regional clusters and opportunities, integrating and building regional partners, and utilizing multiple resources to meet project objectives and promote substantive economic growth in the region and rural communities. Grant recipients will identify project milestones and submit reports throughout the project period, along with a final project performance report. Success will be gauged by the degree to which grant recipients achieve their project milestones.

*Question.* What administrative and programmatic resources have you committed in fiscal year 2012, and what resources do you hope to use in fiscal year 2013, to support the initiative?

*Answer.* The Rural Jobs Accelerator will be administered using existing USDA staff for fiscal years 2012 and 2013. Approximately half (\$2.49 million) of the funding available for use in fiscal year 2011 and half (\$1.81 million) of the funding available for use in fiscal year 2012 for the Rural Community Development Initiative (RCDI) will be used to support this initiative. The remaining \$4.33 million in RCDI funding was announced under a separate notice of funding availability on March 21, 2012.

*Question.* Will USDA's support in fiscal year 2012 require a transfer or reprogramming of funds?

*Answer.* No. USDA is using existing authorities and a portion of the existing appropriations for the Rural Community Development Initiative (RCDI) to fund our portion of the Rural Jobs Accelerator. The projects funded by USDA must meet all existing RCDI funding criteria and would be eligible for RCDI assistance regardless of their participation in the Rural Jobs Accelerator. However, by employing a "whole-of-government" approach through the Rural Jobs Accelerator we can significantly enhance the prospects for job growth in the selected regions.

#### NUTRITION

##### *Equipment Grants*

*Question.* In 2009, this subcommittee provided \$100 million through ARRA for grants to allow schools to purchase and renovate their food service equipment. The fiscal year 2013 budget for Child Nutrition Programs includes \$35 million for this same activity. In February 2012, USDA's Office of Inspector General (OIG) issued a report criticizing FNS' management of these ARRA funds. According to the OIG report, FNS "did not create adequate, proactive controls to ensure that grants were awarded based on Recovery Act criteria and accurate data."

If funding is provided in fiscal year 2013, what assurances can FNS provide to this subcommittee that funds will be managed appropriately?

*Answer.* USDA believes that the ARRA grant award process in its totality was highly effective and met the goals set forth by the Recovery Act to effectively and timely distribute funds to low-income schools that clearly demonstrated need. The OIG audit did not identify any instances of improper use of the ARRA funds, but it did identify some areas for process improvement, and FNS will address these issues where needed. FNS' oversight of the State agencies which operate the school meals program will focus on ensuring that the processes used to distribute grant funds meet all appropriate requirements and ensure that funds are used for their intended purpose. As the audit report notes, OIG has accepted FNS' plan to implement additional internal controls within its standard competitive grant award processes, identifying areas that can be strengthened for future grant awards. I am con-

fidet that FNS would appropriately manage another round of school equipment funding.

Moreover, it is critically important to recognize that there remains significant unmet funding need for schools to replace out-dated equipment and help schools meet our new, updated standards for school meals. These standards represent the first update to school meals in over 15 years, emphasizing fruits, vegetables, and whole grains. Schools need modern, appropriate equipment to help them serve healthy meals. Only about 22 percent of the school districts who requested ARRA funds received them. So, the present \$35 million request for the School Meals Equipment Grants is critical to providing support to help fund equipment purchases for school districts that did not receive Recovery Act funding.

*Question.* How do you envision these grants being allocated?

Answer. FNS would award equipment assistance funding to State agencies using a competitive process, and the State agencies would then build on the Recovery Act of 2009 criteria, which targeted low-income districts with the greatest need. When developing the specific competitive grant process that States would use when awarding these grants to school districts, FNS would also consider how to best meet the needs of school districts as per the requirements associated with the \$35 million school meals equipment grant funding request.

*Question.* What changes to your grant process will be made in response to OIG's recommendations and concerns?

Answer. FNS will use management evaluations and/or targeted reviews to determine State agency compliance with the grant application and award processes. As part of these reviews, if FNS reviewers determine that (1) exceptions to the grant application were made during grant execution; and (2) potential grant awards to the State are pending, FNS will develop appropriate corrective action plans which could include submission of documentation for selected future grant awards to FNS for review and approval prior to implementation. This documentation may include applications (RFAs) and grant award evaluation processes prior to the States releasing the applications to potential subgrantees.

#### CIVIL RIGHTS

*Question.* Can you explain to the subcommittee the status of the women farmers discrimination litigation against USDA, along with the status of the USDA's plans for a Women and Hispanic Farmers Claims Process?

Answer. I will provide an update of the civil rights discrimination litigation as well as USDA's plans for a Women and Hispanic Farmers Claims Process.

[The information follows:]

In 2006, the D.C. Circuit affirmed the district court's denial of class certification of plaintiffs' ECOA claims. *Love v. Vilsack*, 439 F.3d 723 (D.C. Cir. 2006). In 2009, the D.C. Circuit affirmed the district court's dismissal of the claims plaintiffs brought under the Administrative Procedure Act (APA), 5 U.S.C. sections 701-706, by female farmers in *Love v. Vilsack*, and remanded the cases to the district court on the named plaintiffs' individual claims under ECOA. *Garcia v. Vilsack*, 563 F.3d 519 (D.C. Cir. 2009). In January 2010, the Supreme Court denied plaintiffs' petitions for certiorari on the APA claims in *Love* and *Garcia*. 130 S. Ct. 1138 (Mem.) (2010). All appeals related to class certification have been decided in favor of USDA and the *Love* case is now limited to individual claims of credit discrimination. *Love* has been stayed while the voluntary Alternative Dispute Resolution claims process is being finalized by USDA.

In order to offer relief to female and Hispanic farmers who allege credit discrimination during the relevant statutory period, USDA developed an entirely voluntary ADR program to settle those claims without litigating them individually in court. This non-adversarial process will be administered by a third-party neutral, who will make individualized determinations based on the evidence presented by each claimant. Successful claimants will receive up to \$50,000 or \$250,000 each depending on the tier of relief chosen by the claimant, plus tax relief on their award and possible debt cancellation for certain outstanding farm loans. Whether any individual chooses to participate in the program is entirely up to the individual. Those farmers who wish to ignore the ADR process are free to do so.

The claims process has not yet started. On January 25, 2012, after hearing from members of Congress, community organizations, and farmers, the Department announced changes to the claims process framework. In May, USDA selected an independent Administrator/Adjudicator who is now preparing to implement the claims process. Claimants will not need to pay any filing fees to participate in the claims process.

*Question.* What is the USDA's outreach plan to spread the word to women farmers nationwide about the availability of the claims process? Who will conduct the outreach, what forms of outreach will be used, and how much money does the agency plan to spend on outreach? Is the Agency involving women's and farmers' groups in the development of the outreach plan?

*Answer.* USDA has engaged in outreach activities to inform potential claimants, including women farmers who have alleged past discrimination, about the claims process. As part of the outreach process, USDA has held numerous meetings and webinars with farmers and community organizations, including women's organizations. USDA will expend up to \$75,000 for outreach inclusive of staff travel and meeting space incidentals. In addition, USDA announced the claims process (including recent changes) through press releases and media interviews; and created a dedicated Web site with informational documents about the process such as a fact sheet and summary notice. USDA currently operates a toll-free call center to register individuals interested in participating in the process, allowing them to request a claims package.

USDA plans to continue to notify women and Hispanic farmers who allege past discrimination against USDA about the claims process requirements and the date on which the claims period will commence. Ongoing outreach to potential claimants will be conducted in a number of ways. USDA will use media to contact as many women and Hispanic farmers as possible about the claims process, including social media, press releases, Web sites, and posters, and USDA will hold additional webinars summarizing the program to stakeholders. USDA also plans to mail postcards directly to over 500,000 women and Hispanic farmers listed in USDA customer information systems about the claims process, plans to continue to hold meetings with farmers to notify them about the program, and plans to work with third-party organizations to reach out to potential claimants. Finally, USDA plans to enter into cooperative agreements with third-party organizations to educate potential claimants about the process.

*Question.* What, if any, specific program reforms is USDA implementing to prevent future discrimination against women farmers in particular?

*Answer.* To prevent future discrimination against women farmers, USDA has strengthened training, outreach, and policy efforts. At my direction, every political appointee in the Department has attended civil rights trainings and USDA has offered civil rights training to Farm Service Agency, Natural Resources Conservation Service, and Rural Development leadership and staff at State offices in more than a dozen select States that have a history of problems in this area. The States included Oklahoma and Arkansas, two of the States with the highest concentrations of female producers. The States selected for civil rights training for the Farm Service Agency State leadership accounted for a total of 40 percent of FSA program complaints in fiscal year 2008, and the States selected for Rural Development trainings represented 42 percent of RD program complaints in the same period.

We commissioned an independent assessment of civil rights in USDA's program delivery. We are working to implement the recommendations of this Cultural Transformation Assessment to help USDA improve field-based service delivery to minority and women farmers and ranchers, and communities that have historically not participated in USDA programs. The recommendations for the Farm Service Agency in the assessment included steps to provide better representation of women and minority farmers on county committees, to take prompt action to hold employees accountable for discrimination, and to institute outreach as a core mission of the Agency. To improve USDA programs' ability to serve all farmers, we analyzed the potential for new policies, rules and decisions to impact civil rights. Over 3 years the Office of Civil Rights recommended important changes on about 20 percent of all policies they reviewed. We also more than doubled the number of internal compliance reviews of USDA agencies to evaluate their civil rights policies, procedures and practices.

USDA is committed to reaching out to women farmers and involving new generations of female farmers in local and State USDA committees. The Farm Service Agency also recently designed a customer's guide to improve all producers' knowledge of farm loan programs.

In 2010 and again in 2011, USDA's FSA recorded the fewest number of customer civil rights complaints since the Department began keeping track, 37 complaints were filed in 2010 and 37 in 2011. We have also made changes to improve the processing of the complaints we do receive. Adding staff and conducting Lean Six Sigma process improvement have reduced the typical processing time for new civil rights program complaints from 4 years to 18 months.

## QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

## DIVERSITY OF RURAL ELECTRIC PROGRAMS

*Question.* The budget request for the Rural Utilities Service electric loan program provides specific set-asides for renewable energy plants and fossil fuel powered facilities that include carbon emissions reduction. As a result, the budget request puts traditional power plants sourced by fossil fuels, such as natural gas and coal, at a disadvantage in participating in the program.

While I appreciate the importance of renewable energy and carbon sequestration, Americans in rural areas rely on cheap, accessible electricity that demands a diversification of energy sources for affordable customer rates. Energy policy should have a balanced approach and not focus on one particular source.

Does USDA know the potential long-term economic effects if rural electric cooperatives are unable to utilize the loan program to construct natural gas and coal-fired power plants or to provide basic facility upgrades that do not specifically reduce emissions?

*Answer.* USDA has not calculated the long-term economic effects of limiting future investment in fossil fuel-fired power plants. However, by virtue of being located in rural America, the rural electric cooperatives are ideally situated to invest in many renewable energy technologies such as solar and wind power. By targeting future assistance to renewable fuel technologies the rural electric cooperatives have the opportunity to play a central role in this administration's "all-of-the-above" approach to energy independence.

*Question.* How will the recent EPA announcement on greenhouse gas emission limits affect participation in the electric loan program?

*Answer.* The Rural Utilities Service (RUS) is expecting an increase in demand for RUS loan funds as borrowers work to comply with the EPA greenhouse gas emissions limits. At this point in time, RUS does not know the amount needed for borrowers to comply with EPA. However, the estimates for environmental upgrades range from \$1 billion this fiscal year and reaching approximately \$3.5 billion by 2016 according to the Electric Program application pipeline and the National Rural Electric Cooperative Association's 10-year projections.

*Question.* Because the average natural gas powered electric plant has a CO<sub>2</sub> emissions level below the recently announced EPA guidelines, what is the reasoning for prohibiting their access to two-thirds of the funding in the rural electric program unless they include carbon capture sequestration systems?

*Answer.* This limitation is one of many ways to achieve energy independence and improve the environmental health of the Nation. The proposal does not preclude the ability of rural electric cooperatives from seeking other sources of financing to build or upgrade fossil fuel-fired power plants. Rather, it provides an opportunity for the rural electric cooperatives to be at the forefront of implementing renewable energy strategies that will power a greener tomorrow.

## FREE TRADE AGREEMENTS WITH COLOMBIA AND PANAMA

*Question.* Last year, Congress approved the trade agreements with South Korea, Colombia, and Panama. Implementation of all three of the trade agreements will increase U.S. farm exports by an additional \$2.3 billion—supporting nearly 20,000 American jobs.

The agreement with South Korea came into force earlier this month (March 15). However, the agreements with Colombia and Panama have not been fully implemented. Full implementation of these two agreements would increase farm exports by \$400 million and support approximately 4,000 jobs. It is important that these agreements are implemented expeditiously to open up these markets for our agriculture producers.

What is the current status of the free trade agreements with Colombia and Panama?

*Answer.* The United States-Colombia Trade Promotion Agreement will enter into force on May 15, 2012. The Department of Agriculture's Foreign Agricultural Service (FAS) worked closely with the Office of the U.S. Trade Representative (USTR) and stakeholders to establish effective mechanisms for ensuring market access under the terms of the agreement, particularly for tariff-rate quotas (TRQs). A range of issues will be resolved prior to implementation, including barriers to U.S. poultry and rice. Almost 70 percent U.S. exports to Colombia will become duty-free upon implementation, and most other tariffs will be reduced and eliminated over 5 to 10 years, with all Colombian tariffs on agricultural products duty-free in 19 years.

With respect to the United States-Panama Trade Promotion Agreement, discussions with Panama are currently focused on changes required in their laws and regulations in order to implement the agreement. FAS is working closely with USTR to ensure the mechanisms Panama will use to implement its agricultural TRQs will be ready when the agreement enters into force. Panama will be adapting its current auction system for some TRQs and establishing new licensing and first-come, first-served systems for others. FAS and USTR are working to ensure that these systems will be implemented in a way that is consistent with the provisions of the agreement and that will enable U.S. exporters to take full advantage of new opportunities.

*Question.* Is there an estimated date for implementation of these agreements?

*Answer.* The United States-Colombia Trade Promotion Agreement will enter into force on May 15, 2012. An implementation date for the United States-Panama Trade Promotion Agreement will be set once agreement has been reached on all of the implementation mechanisms. FAS is working with USTR to ensure the new market access opportunities established in the agreement will be available as soon as the agreement enters into force. In an effort to ensure the implementation of the agreement moves forward expeditiously, a team of FAS, USTR, and Customs officials will travel to Panama in the first week of May to assist the Panamanian Government as it develops its TRQ regulations.

#### AGRICULTURAL RESEARCH SERVICE LAB CLOSURES

*Question.* Consistent with the budget request, the fiscal year 2012 agriculture bill closed 12 Agricultural Research Service (ARS) labs. However, the budget request did not adequately budget for the expense of closing these labs, which turned out to be far more significant than either USDA or the subcommittee imagined.

How much do you estimate it will ultimately cost ARS to relocate staff and close all 12 labs in fiscal year 2012?

*Answer.* The termination of research activities at the 12 ARS laboratories affected 233 permanent ARS employees. The one-time costs associated with the relocation or separation of affected personnel and the disposal of property are estimated at \$39 million in fiscal year 2012.

#### EXTRAMURAL RESEARCH

*Question.* I understand ARS plans to reduce existing extramural research funding by 30 percent this year to find the additional funds necessary to close the labs.

How did ARS arrive at the decision to reduce extramural funding as opposed to other activities within ARS?

*Answer.* The temporary budget reductions to remaining ARS programs in fiscal year 2012 are necessary to finance the one-time costs associated with the closure of 12 ARS laboratories. The 30-percent reduction to extramural research supported by ARS resources is one of several measures necessary to finance the one-time costs. These measures also include restricted hiring and assessing all remaining ARS management units. As a result of these actions, only about half of the one-time costs to close the 12 laboratories will be financed by reductions to extramural supported research. Although ARS' mission is to conduct primarily intramural research, ARS along with other USDA agencies, such as the National Institute of Food and Agriculture (NIFA), will continue to support high-priority extramural research.

#### CAPITAL ASSET AND CONSTRUCTION PLAN

*Question.* The fiscal year 2013 budget includes a proposal to close six more labs.

Last year, the subcommittee requested a capital assets and construction plan from ARS. We have not received the capital asset plan. Without the benefit of this plan, how did USDA determine which labs would be closed?

*Answer.* ARS has completed a capital investment strategy for recapitalization and new research facilities based on facility condition, needs, and research program priorities. The report establishes criteria and processes for determining and recommending the appropriate level of new investments needed for USDA research facilities. The report's recommendations and overall strategy will inform and support the development of administration budget requests for research facilities in the out years.

During the process of evaluating all ARS research programs, and in conjunction with developing the capital investment strategy, ARS also developed a conceptual framework to determine its capital investment needs based on the relation between the condition of a facility to the priority level of a program. This methodology allowed ARS to determine, on a scale, which facilities are in the poorest conditions and housed the lowest priority programs. The six laboratories recommended for clo-

sure were identified after all evaluations were completed. The 2013 budget proposes reallocating these funds to facilities/programs that support higher priority initiatives.

#### CLOSING COSTS OF RESEARCH LABORATORIES

*Question.* Should the subcommittee agree with ARS's plan to close the labs, does the budget request adequately account for the cost of closing these labs?

*Answer.* The estimated cost to accommodate the potentially impacted employees and dispose of the real property ranges from \$10–12 million. If the fiscal year 2013 proposed budget reallocations are approved, ARS would be able to utilize the associated program funds to offset the facility closure costs.

#### BUDGET IMPACT OF SCHOOL MEALS REGULATIONS

*Question.* I have received a number of inquiries from schools across Missouri regarding the Department's new school meal regulations. I am deeply concerned about the unintended costs on public schools as a result of the Department's regulations.

With the price of food commodities rising, it looks like the impact of the regulations will result in an unfunded Federal mandate on Missouri schools. My constituents have said that the fruit, vegetable, and whole grain requirements will increase the cost of a school lunch by as much as \$0.28 per meal. The increase in funding provided in the reauthorization is set at \$0.06 per lunch, significantly less than the estimated actual cost of implementation.

These cost increases will be borne by local school districts, which will likely be forced to increase prices on paid lunches, resulting in a reduction in overall participation rates.

How does the Department plan to deal with rising food commodity costs?

*Answer.* Beginning October 2012, school food authorities that meet the new meal patterns will receive a \$0.06 lunch reimbursement rate increase authorized by the Healthy, Hunger-Free Kids Act of 2010 (HHFKA). Furthermore, the HHFKA requires that schools set an adequate price for paid lunches so that schools receive as much revenue from paid lunches as the Federal program provides for free lunches. The HHFKA also requires that schools set competitive prices for foods sold outside of the reimbursable meal so that revenues received from the sale of non-program foods equal the cost of obtaining them. When taken together, the additional Federal reimbursement provided for improved meals and the non-Federal revenue generated by the aforementioned provisions will, on average, make sufficient resources available for schools to meet the new meal requirements. Also, it is important to note that over 3,000 schools receiving the HealthierUS School Challenge (HUSC) awards report they have been able to achieve similar standards without significant cost increases. To date, 61 Missouri schools have been recognized as HUSC award winners, including 12 schools that were recognized at the Silver level.

In addition, one key way that USDA helps schools provide cost-effective, nutritious meals is by providing agricultural commodities in the form of USDA Foods. The USDA Foods program helps schools stretch limited food budgets by providing high-quality fruits, vegetables, meat, fish, poultry, dairy, and grains. School commodities, which represent approximately 15–20 percent of the food on the cafeteria serving line, now include more fruits and vegetables, more whole grains, and more food that is lower in sugar, salt, and fat than ever before. For example, USDA purchased nearly \$300 million in canned, fresh, frozen, and dried fruits and vegetables for schools through the USDA Foods program and the Department of Defense (DOD) Fresh Fruit and Vegetable Program in fiscal year 2011. The USDA Foods program is well positioned to help schools meet the new meal requirements and we are confident that most of the schools will continue to benefit from this program.

*Question.* Does the Department have a plan for dealing with increased costs and the burdens these costs will place on public schools?

*Answer.* Careful consideration of cost and logistical issues were an important part of developing the updated nutrition standards for the school meals programs. USDA is committed to ensuring that any such standards are practical and accompanied by extensive guidance and implementation assistance for our school partners. As part of the Healthy, Hunger-Free Kids Act of 2010, USDA built the new rule around recommendations from an Institute of Medicine expert panel, updated with key changes from the 2010 Dietary Guidelines for Americans. Getting the science right is critical to better nutrition and health for our children.

We received unprecedented public participation and input on the proposed standards, and made modifications to the proposed rule where appropriate. As a result, the final standards are much less costly than the proposed standards, provide addi-

tional time for implementation of some key changes, and better accommodate the administrative constraints facing schools and States. These responsible reforms do what is right for children's health in a way that is practical and achievable in schools across the Nation. USDA's estimate shows implementation of the new nutrition standards for school lunches and breakfasts will cost \$3.2 billion over the next 5 years. This is less than half of the proposed standards' originally estimated cost of \$6.8 billion.

In addition, we believe the \$0.06 lunch reimbursement rate increase authorized by the Healthy, Hunger-Free Kids Act of 2010 along with the revenue support provisions noted in the previous response such as the non-Federal revenue generated by schools setting an adequate price for paid lunches so that schools receive as much revenue from paid lunches as the Federal program provides for free lunches and the requirement that schools set competitive prices for foods sold outside of the reimbursable meal so that revenues received from the sale of nonprogram foods equal the cost of obtaining them, will make sufficient resources available for schools to meet the new meal requirements. Finally, we are working on technical assistance and menu planning materials to help schools plan and prepare nutritious meals in a cost-effective manner, and will make those materials available as soon as they are complete.

#### BUDGET IMPACT OF COMPETITIVE STANDARDS RULE

*Question.* It's clear from speaking to many of the schools in Missouri that they depend on revenue from foods sold outside of the National School Lunch & Breakfast Programs to give them greater ability to purchase healthier options for school meals.

There is a lot of anxiety in the school foodservice community over how new competitive foods' standards will impact this revenue stream, particularly at a time when school cafeterias are being asked to cut their budgets.

I understand that the Department believes schools should expect increased revenue from competitive foods lines as a result of the new standards.

What data you are basing this assumption on?

*Answer.* The Department projected increased revenue from competitive foods as a result of regulations implementing section 206 of the Healthy, Hunger-Free Kids Act of 2010 (HHFKA). The rule, published in the Federal Register on June 17, 2011 (76 FR 35301), requires school food authorities (SFAs) to set prices for nonprogram foods purchased with SFA funds, a subset of competitive foods, at a level sufficient to generate revenue proportionate to their share of SFA food costs. The Department estimated that HHFKA section 206 would generate \$7.3 billion in additional SFA revenue over 5 years. The primary source for that estimate was USDA's school year 2005–2006 School Lunch and Breakfast Cost Study. That study found that nonprogram foods generated revenue for SFAs equal to just 71.3 percent of their reported costs of production. Counter to common perception, on average, the revenue generated by program meals subsidizes the production of other SFA foods when labor and overhead costs are properly allocated to all foods prepared with SFA funds.

Elimination of that subsidy is the source of the revenue generated by HHFKA section 206—not nutrition standards for competitive foods, which are still under development. Whatever the ultimate impact of those nutrition standards on competitive food sales, section 206 ensures that competitive foods will not divert revenue from the production of reimbursable meals. Reforming SFA accounts in this manner frees up program revenue for the investments necessary to meet new meal standards.

*Question.* Do you plan to perform any sort of assessment on impact of the competitive foods standards on school cafeteria budgets?

*Answer.* Yes. The Department will begin data collection in school year 2014–2015 for a "School Nutrition and Meal Cost Study". That study will examine both the school nutrition environment and school foodservice operations. The study will assess the impact of nutrition standards on the content of reimbursable meals and competitive foods, and will compare the revenues generated by each of these to their allocated share of SFA costs.

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#### QUESTION SUBMITTED BY SENATOR TOM HARKIN

##### LEAN FINELY TEXTURED BEEF

*Question.* In the light of the large amount of press attention recently given to a product called lean finely textured beef (LFTB), I would like to clarify for the record some aspects of the situation. As I understand it, the Department of Agriculture was informed and reviewed the process and technology involved in producing lean

finely textured beef and did not raise problems with the process, nor did the Department indicate a problem with including it in what is sold as “ground beef” without any special labeling. It is also my understanding that the Food and Drug Administration allows the use of ammonia in food under a designation of “generally recognized as safe.” The factual circumstances seem to show that the company that developed the process felt it was applying an innovative technology and addressing food safety risks in doing so, again, with the knowledge of and effectively an OK from the Department of Agriculture. Now the company has suspended operations at several plants and jobs of hundreds of workers are in doubt.

My question is simply, does lean finely textured beef meet the applicable food safety standards and criteria of the Department of Agriculture?

Answer. Yes, lean finely textured beef (LFTB) products meet Federal food safety standards. The process used to produce LFTB is safe, and adding LFTB to ground beef does not make that ground beef any less safe to consume.

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QUESTIONS SUBMITTED BY SENATOR SUSAN M. COLLINS

FOOD SAFETY

*Question.* I understand that the Department of Agriculture (the Department) has announced that it is preparing to propose new regulations for the grinding of raw beef that would require additional recordkeeping to help the Department trace outbreaks back to their source. It has been reported that these new regulations, which have not yet been published, would require retail stores to keep detailed records identifying the supplier and the quantities of all source materials used in raw ground beef products. The Department has long encouraged retail stores to keep such detailed records, but has not required them to do so. The Department has indicated that it considers the use of beef trimmings without detailed recordkeeping as a “high-risk” practice.

What additional actions is the Department taking or proposing to take to improve its ability to prevent foods containing dangerous pathogens from ever leaving the slaughterhouse, processing facility, or entering the retail chain?

Answer. FSIS announced and asked for comment on a new “test and hold” requirement for the meat and poultry industry that, once implemented, will significantly reduce consumer exposure to unsafe food. When the policy is finalized, industry will be required to hold products that FSIS has sampled for microbiological testing until the test results are received. The product will be released if the results show that it is safe to move in commerce. This approach could have prevented 22 recalls during fiscal year 2009 and fiscal year 2010. Under this policy, FSIS expects fewer recalls by industry, fewer illnesses, and increased consumer confidence in the safety of the food supply. The agency is also announcing new procedures for tracing product that is positive for *E. coli* O157 to its supplier as well as actions that will strengthen its implementation of HACCP.

*Question.* What steps is the Department taking to educate consumers about the risks of food-borne illness, the dangers and avoidance of cross contamination, and the need to handle and cook meat properly to ensure it is safe for consumption?

Answer. On June 28, 2011, FSIS launched a joint national multimedia campaign with the U.S. Department of Health and Human Services to help families prevent food poisoning: The Food Safe Families—Check Your Steps campaign. The campaign urges consumers to remember four key steps to food safety: Clean (surfaces, utensils, and hands), separate (raw meat and poultry from other foods), cook (to a safe temperature), and chill (raw and prepared food). We have reached millions, in English and Spanish, using a variety of donated media, including television, radio, print media, social media tools, and the Internet.

On May 5, 2011, FSIS launched the Mobile Ask Karen application ([m.AskKaren.gov](http://m.AskKaren.gov) on your phone’s mobile browser), a Web-based smartphone application that gives consumers another way to access the only U.S. Government-sponsored food safety virtual-representative. Consumers can search by topic and products, send e-mails, or use the chat feature, all via their mobile devices. Thus, users can get answers to their food safety questions anywhere: At the grocery store, barbecue grill, and kitchen stovetop.

During fiscal year 2011, the USDA Food Safety Discovery Zone, a new and improved USDA Food Safety Mobile, visited grocery stores, schools, and local community events to educate consumers about food safety and to promote the Food Safe Families Campaign. The Discovery Zone improves consumers’ awareness of the risks associated with mishandling food and provides in-depth, hands-on demonstrations of the steps they can take to reduce their risk of contracting a foodborne illness.

## NATIONAL SCHOOL LUNCH PROGRAM

*Question.* Recently the Department purchased for use in the National School Lunch Program a product that is commonly referred to as "pink slime," known in the industry as "boneless lean beef trimmings" or "lean finely textured beef," as an additive in ground beef. This product is reportedly treated with ammonium hydroxide gas, suggesting that decontamination is necessary to ensure the product is safe to eat. What analysis has the Department done to determine whether this product is safe for consumption?

*Answer.* Ammonium hydroxide is used in the production of lean finely textured beef (LFTB) as a pH control agent to help reduce harmful bacteria. Ammonium hydroxide, produced by mixing anhydrous ammonia (ammonia gas) with the natural moisture in LFTB, was determined to be Generally Recognized as Safe (GRAS) by the Food and Drug Administration (FDA) in 1974, after extensive review and a rule-making process (21 CFR 184.1139). USDA, after consultation with FDA, determined that ammonium hydroxide is safe and suitable for use in the production of meat and poultry products (FSIS Directive 7,120.1).

*Question.* Have there been incidents of food-borne contamination in products containing pink slime?

*Answer.* Some ammoniated beef has been shown to be contaminated with *E. coli* O157:H7, and such product has been excluded or removed from commerce under the same procedures FSIS employs for any product it regulates.

*Question.* Parents in Maine have contacted school districts to inquire about the safety and wholesomeness of products containing this additive. Are there any health implications, particularly for school-age children, associated with consuming foods that have been treated with ammonium hydroxide?

*Answer.* No. Ammonium hydroxide is accepted as GRAS for this use.

*Question.* Does the Department plan to undertake any additional studies or actions to ensure that these products are safe for consumption by the public and by our Nation's school children?

*Answer.* No. No evidence has been presented or cited that would raise a question about the GRAS status of this use of ammonium hydroxide. However, based on requests from school districts across the country, USDA announced on March 15 that it would offer more choices in the National School Lunch Program in terms of purchases of ground beef products.

## LEAN FINELY TEXTURED BEEF

*Question.* I understand that the Department has recently announced it will give schools the choice of using products that do not contain pink slime.

What will the Department do with unwanted product that contains this additive that, in some cases, has already been delivered to school districts?

*Answer.* On March 30, a policy memo was sent to State distributing agencies (SDAs) and school food authorities (SFAs) that not only reaffirmed the safety of lean finely textured beef (LFTB) but also outlined the options available for the treatment of their current inventories if recipients chose not to utilize the product as intended. USDA does strongly encourage all SDAs and SFAs that have ordered donated beef products to use them as intended but understands the desires of certain recipient Agencies not to do so. However, USDA cannot provide entitlement credit or reimbursement for any processing-related fees or replacement product. If the SFA does not wish to use donated beef products that contain LFTB, the SDA must determine if the donated products can be reallocated to another SFA that is willing to use them. If donated beef products in SDA inventories cannot be reallocated to another SFA, the SDA must determine if they can be transferred to another SDA for distribution to SFAs in the National School Lunch Program, or if such foods can be transferred for use in the Emergency Food Assistance Program (TEFAP), or another eligible charitable institution. SDAs will be responsible for any transportation costs, and there will be no compensation to an SDA or SFA for lost entitlements.

USDA continues to affirm the safety of LFTB products. However, the Department was overwhelmed with inquiries from schools and parents who did not want it to be allowed as a component in the ground beef that USDA purchases. The schools are our customers and they were demanding choices. The decision was driven by customer demand.

*Question.* What is the estimated cost to the Department and to schools of choosing not to use products containing this additive?

*Answer.* AMS estimates that the cost of beef products that do not allow for the inclusion of LFTB could run 3 percent higher than the comparable LFTB-allowing beef product specifications. Depending on whether a school food authority is ordering donated products or using non-entitlement funds, selecting this option could ei-

ther result in them receiving a smaller volume of products or a higher cost. USDA does not expect there to be any increased direct costs to the Department from providing the option.

AGRICULTURAL RESEARCH SERVICE PROGRAM REALLOCATION

*Question.* In fiscal year 2012, and in the 10 previous fiscal years, ARS and the potato industry, through a potato research initiative, have cooperated to identify research projects that have scientific merit and address potato industry priorities. ARS researchers serve as the lead investigators on all projects and collaborate with land grant universities and other private entities to conduct this research.

The President's fiscal year 2013 budget request proposes to reallocate \$4.6 million to improve the control of diseases attacking small fruits, nursery crops, potatoes, and other crops, through the development of resistant varieties and disease management strategies. Preventing the damaging effects of pests and diseases requires the consistent application of sound pest management strategies, including the development of disease- and pest-resistant crop varieties. These strategies are the result of years of collaborative efforts among ARS, research institutions, private industry, and local producers that have resulted in better pest management, reduced environmental impact, improved quality, and increased yield. Can you explain how the Department's proposed reallocation will affect these partnerships? Is USDA committed to providing adequate funding for pest and disease management programs, including the development of pest and disease-resistant varieties through ARS that address the potato industry's identified research priorities?

How does the Department intend to fund and administer these programs, and what resources will USDA commit to these programs to ensure they are able to address evolving pest and disease management challenges facing producers?

Answer. USDA will maintain its strong partnerships with its cooperators, customers, and stakeholders, including agricultural producers and universities. These close working relationships are an integral part of plant breeding and pathology research programs nationwide, and the Department will use its dedicated resources to continue these partnerships that address producer priorities in plant production and protection.

Public plant breeding programs are crucial in meeting needs identified by the potato and other industries. Development of improved germplasm and varieties, as needed, with enhanced disease and pest protection is a high-priority research initiative within the Department.

USDA research will continue to address producer needs for plant health and sustainability. Research priorities will continue to be established through a continuing dialogue with customers and stakeholders.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE CROP PROTECTION PROGRAM

*Question.* The President's fiscal year 2013 budget proposes to consolidate several pest management programs into a single "Crop Protection" program and to provide \$29.1 million for that program in the next fiscal year. Integrated Pest Management (IPM) programs allow research universities to partner with State, local, and regional producers to conduct critical field work and research, perform field inspections, and provide producer notifications. These steps are critical to converting laboratory research into improved pest and disease management strategies that can be applied in the field to reduce pesticide application and improve crop quality and yield.

Please describe how the Department intends to administer these important programs should such a consolidation occur. How would the proposed consolidation affect ongoing partnerships with States and research universities to transfer laboratory research to the field? How much of the \$29.1 million that is requested would go to fund IPM programs, and specifically, potato IPM programs? How much of the requested funding under this proposed consolidation would go to Minor Crop Pest Management (IR-4) program efforts?

Answer. USDA is currently soliciting broad stakeholder input on the appropriate design of the Crop Protection Program in anticipation of funding in fiscal year 2013. Our goal is to improve the efficiency of the program and enhance NIFA's ability to support research, education, and extension activities needed to assist in global food security and respond to other major societal challenges.

[Additional information is provided below.]

The President's budget for fiscal year 2013 proposed the consolidation of six pest management budget lines into the Crop Protection Program. The budget proposal identifies five priority areas that will be supported by the new program:

—The development of crop protection tactics and tools;

- The development of diversified IPM systems;
- Enhancing agricultural biosecurity;
- Developing IPM for a sustainable society; and
- Developing the next generation of IPM scientists.

These priority areas encompass core research, extension and service activities supported by the six budget lines that will be consolidated. As we implement the new program, we will try to minimize disruption to ongoing efforts that are currently supported by the six budget lines, which includes the IR-4 program. We value the partnerships that have developed as a result of the Department's involvement with these pest management efforts over the past 50 years, and we remain committed to supporting critical research, extension and service efforts in fiscal year 2013 and beyond. We believe that the proposed budget consolidation and creation of the Crop Protection Program will strengthen these partnerships, and will result in the most effective and efficient use of Federal funding appropriated to the National Institute of Food and Agriculture for pest management efforts. Funding allocations for this competitive program will be determined when 2013 funding is provided.

#### NORTHEAST REGIONAL AGRICULTURAL RESEARCH

*Question.* One of the major strengths of American agriculture is the wide variety of crops grown, and the ability of different geographic regions to produce high-quality, often unique, agricultural products. USDA research activities through the ARS play a key role in leveraging departmental resources, academic expertise, and the input of regional producers to improve quality and expand production of many crops. The President's fiscal year 2013 budget proposes to close several ARS laboratories, including the New England Plant, Soil, and Water Research Center—the only ARS lab in the six-State New England Region that conducts crop, soil, water, environmental, and economic research.

The closing of ARS labs represents a significant loss not only for regional producers, but also for affiliated research universities that will lose critical staff and resources. These losses can jeopardize the ability of universities and industry to apply prior research and develop better pest and disease management strategies. Moreover, the closure of the only plant, soil, and water ARS laboratory in New England hardens the impression that the Department does not view the Northeast's agricultural sector as worthy of growth, improvement, or investment. Does the Department believe it is important to maintain an ARS laboratory research footprint in New England and other regions of the country? Has the Department analyzed the potential economic impacts of closing these labs on regional producers who may directly benefit from the applied research that these labs can generate?

*Answer.* ARS is a national research institution; although many ARS research laboratories address the needs of local producers, these laboratories also often serve as model systems. Thus, research conducted at many ARS locations yields benefits to producers in Maine and elsewhere. USDA believes that there are significant benefits to maintaining research facilities across the range of climatic, soil, and cropping systems represented in the United States. Though the Orono facility is proposed for closure, ARS is maintaining a comprehensive set of research laboratories in New York, Pennsylvania, Maryland, and West Virginia that continue to address the needs of producers in the northeast. Agriculture in the United States is seldom extremely location-specific. Although crops usually are particularly productive in certain combinations of soils and climate, those conditions can often be found at multiple locations. Taking advantage of the differences across the country contributes to the important characteristic of resilience leading to increased food security.

The Department has not undertaken a comprehensive economic analysis of the impacts on regional producers from the proposed closures. Aside from Orono, ARS conducts many research projects around the concept of Agricultural Systems Competitiveness and Sustainability at research locations in several States. In most instances, these projects address complete cropping systems relevant to various production areas across the country. For example, many research findings in sustainable potato production systems in Washington and Oregon benefit producers in the northeast. Although the research in those locations is by necessity conducted on local crops and soils, the principles that are developed are beneficial in a broad range of crops, soils, and climates.

## QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

## COMPETITIVE FOOD RULE

*Question.* Changes to the National School Lunch and Breakfast Programs have imposed new challenges and costs on schools in Kansas and across the country. While I am glad the implementation cost of the final meal pattern rule is lower than what was initially proposed, I am concerned about what the cost may be of the competitive foods rule USDA is currently working on. What assurances can you give me and school nutritionists in Kansas who are already having difficulty planning menus for next year that the forthcoming rule on competitive foods will not impose costs and compliance hurdles similar to those that were proposed in the initial meal pattern rule?

*Answer.* As you are aware, the Healthy, Hunger-Free Kids Act (HHFKA) requires that the USDA develop nutrition standards for foods sold in schools outside the National School Lunch Program (NSLP) and the School Breakfast Program (SBP). It also requires they be consistent with the most recent Dietary Guidelines for Americans and take a number of important issues into consideration, including the practical application of the nutrition standards in schools. A proposed rule to establish such standards is currently under development.

We are aware that school districts have concerns regarding the potential financial and logistical impacts associated with the implementation of these standards and have received extensive input from a variety of stakeholders on how to best address those concerns. As we continue our work to develop the proposed rule, a great deal of time has been spent analyzing current scientific information and school practices as well as voluntary standards for food sold outside of the NSLP and SBP that have been recommended by a number of nongovernmental organizations. We have also considered the costs associated with implementation of such standards for all foods sold to students in school. I am committed to ensuring that any such standards are practical and accompanied by extensive guidance and assistance for our school partners as implementation moves forward. In addition, I understand the need to aim for consistency with the NSLP meal pattern regulation in areas in which the regulations may overlap, particularly as a means to ensure the regulations do not place undue burden or complexity on school staff who operate food service under both standards. We look forward to receiving public comments once the proposal is published and want to assure you that such comments will be most carefully considered as we develop the final rule.

*Question.* Last year, in the Consolidated and Further Continuing Appropriations Act (Public Law 112-55), Congress expressed concern about sodium reduction targets specified in the proposed meal pattern rule. Is the Department taking these concerns about aggressive sodium reduction targets into account as it finalizes its proposed rule for competitive foods?

*Answer.* We understand the complexity of balancing ambitious approaches to improving the food intake of children with the needs of program operators and look forward to receiving public comments once the competitive foods proposal is published. I want to assure you that such comments will be carefully considered as we develop the final rule. We continue to be committed to ensuring a careful review of current science and technologies before implementing the ambitious, but important, sodium reduction targets included in the school meal patterns final rule and will apply these considerations to our work on competitive foods.

## QUESTIONS SUBMITTED BY SENATOR TIM JOHNSON

## OFFICE CLOSURES

*Question.* Let me first thank you for your February 13, 2012, response to the letter I sent with Senator Thune and Representative Noem concerning your January 9, 2012, announcement to close 259 USDA offices, facilities, and laboratories across the country, including four FSA offices in my home State of South Dakota. At the same time, I was disappointed that several of our questions were not addressed in your response. I recognize, as you have stated publicly multiple times, that the Department has been faced with difficult choices given reduced budgets, and that you faced a choice of either closing offices or instituting furloughs. The situation in which you find yourself is certainly unfortunate; the rush to cut Federal spending by some in Congress without regard for the impact has begun to show the consequences.

Recognizing these difficult circumstances, I would like to get a better idea of how you identified offices for closure. The 2008 farm bill directed you to use a specific

set of criteria. Specifically, my constituents would appreciate a better understanding of why the Department utilized “as the crow flies” rather than driving miles for determining the mileage between offices; this has been of significant concern for my constituents, because in multiple cases, the distance between offices in question is actually greater than 20 miles. As we stated in our letter, the Department utilizes miles driven when determining mileage for official Government travel with motor vehicles; particularly given the unique geographical characteristics of some of the affected offices, why did the Department utilize the “as the crow flies” standard?

Answer. USDA selected Euclidian miles because it represents a precise distance between two points which is not subject to interpretation.

Question. Additionally, some of the offices slated for closure, though minimally staffed at the time the decisions were made, have still had a significant workload. As we stated in our letter, using the actual number of employees in the office at any given time is an unreliable and inconsistent staffing measure as this number can vary greatly due to retirements and transfers. Why did the Department use the actual number of employees for determining whether county offices met this statutory guideline?

Answer. USDA used the number of staff currently employed in each office in order to strictly adhere to the criteria laid out in the 2008 farm bill.

#### HOUSE BUDGET RESOLUTION

Question. Can you outline what the impact will be of the budget resolution recently passed in the House of Representatives, if enacted on your ability to operate in the future, and in particular, the degree to which you may need to consider additional office closures?

Answer. The President’s budget request was fiscally responsible and included reductions in many discretionary programs. For any further reductions beyond the President’s budget we would need to further review our priorities and make appropriate adjustments.

#### COUNTRY OF ORIGIN LABELING

Question. Thank you for your continued efforts in defending our country-of-origin labeling (COOL) program. As you know, I’ve worked on this issue for many years, and I am pleased that USDA, under your leadership, has finally implemented the program. Additionally, I am very pleased that the administration will be appealing the World Trade Organization Dispute Settlement Panel’s decision concerning our COOL program. Can you provide a general timeframe for the appeals process moving forward and the role that USDA will play in the process?

Answer. The parties to the dispute have already filed all their submissions in the appeal. The WTO Appellate Body will hold the hearing in this appeal on May 2–3, 2012. A final decision is expected sometime during the summer of 2012. USDA’s COOL team of regulators, economists, trade policy experts and lawyers has been working closely with United States Trade Representative’s litigation team throughout this dispute, both at the Panel stage and at the appellate stage.

#### SUN GRANT INITIATIVE

Question. As you know, the Sun Grant Initiative is an important university research and education program that addresses national priorities to develop bio-energy and bioproducts at regional and local levels. The initiative broadens the role of land-grant universities to conduct research and educational programs that emphasize renewable energy systems based on agriculture and renewable resources. Particularly given the administration’s emphasis on the importance of the development of renewable energy, why does the administration’s budget propose zero funding for this nationally authorized program?

Answer. A decrease is proposed so funding can be redirected to support higher priority activities, and is consistent with the administration’s policy to redirect available resources, as appropriate, and consistent with the agency mission, from lower priority areas to other science and technology activities. Alternative funding from the Agriculture and Food Research Initiative and/or formula funding may be used to support aspects of the program deemed to be of priority at State and/or local levels. For example, the 2013 budget proposes reallocating funding within AFRI towards bio-based energy technologies, increasing funding towards this initiative by \$30 million.

## QUESTIONS SUBMITTED BY SENATOR MARK L. PRYOR

## AGRICULTURAL RESEARCH SERVICE FISCAL YEAR 2012 FUNDING

*Question.* It's my understanding that USDA's fiscal year 2012 budget request for Agricultural Research Service (ARS) underestimated the funding needed to close the 12 ARS laboratories that were proposed for closure in fiscal year 2012. As a result I see that ARS has taken action to find the needed \$38 million elsewhere in the budget. I note three things happened to make up this shortfall:

- All ARS programs were cut an estimated 0.7 percent;
- ARS has frozen all vacancies; and
- ARS has proposed to reduce all extramural activities by 30 percent.

Do these three rounds of cuts fully make up for the budgeting error?

*Answer.* I do not believe this was a budgeting error. ARS' fiscal year 2012 enacted level was \$43 million below what was proposed in the fiscal year 2012 President's budget and \$38 million below the fiscal year 2011 enacted. This permanent reduction eliminated ARS' ability to offset the costs of the closures with program funds associated with each of the 12 laboratories. The one-time costs associated with the relocation or separation of affected personnel and the disposal of property are estimated at \$39 million in fiscal year 2012. These one-time costs are being financed by temporary reductions to remaining ARS research programs. The resources accumulated from the temporary assessments will cover the one-time costs in fiscal year 2012.

*Question.* Why do these cuts, to make up for an ARS budgetary mistake, target extramural activities?

*Answer.* I do not believe this was a budgetary mistake. The permanent reduction of \$38 million from fiscal year 2011 levels required that all ARS research, not just sponsored extramural research, needed to be reduced to pay for the closures. USDA sought to balance the impact on intramural and extramural programs through an across-the-board reduction of intramural research, a hiring freeze, and extramural funding reduction. Together, these actions will finance the one-time costs to ARS for the facility closures without closing other ARS research projects and let ARS partners continue ARS extramural research with 70 percent of the funding. USDA will also continue to support high-priority extramural research through other USDA agencies, such as the National Institute of Food and Agriculture (NIFA).

*Question.* Why is the cut not across the board like the earlier 0.7-percent across-the-board cut and the freeze on all ARS vacancies?

*Answer.* The approach to financing the one-time costs seeks to minimize the impact to USDA personnel. Additional temporary reductions to in-house research supported by ARS personnel would potentially impact additional ARS employees and require significant reductions in ARS intramural research.

*Question.* Was there a measured approach used to evaluate productivity or performance?

*Answer.* To fund the one-time costs associated with closing the 12 laboratories, all of ARS research was reduced through an across-the-board reduction of intramural research, a hiring freeze, and an extramural funding reduction. This balanced approach to reductions did not evaluate productivity or performance.

*Question.* Who made this decision to cut extramural facilities on their expected fiscal year 2012 funds to cover the closure costs?

*Answer.* I made the decision to assess the funding for extramural-supported research, as well as ongoing in-house programs, based on recommendations from ARS and other staff.

*Question.* Is there an appeal process?

*Answer.* USDA has not established a process to appeal the temporary reductions necessary to finance the one-time costs associated with closing the 12 laboratories.

*Question.* What other sources of funding were under discussion to help cover the unit closure budget shortfall?

*Answer.* The Department's ability to finance the one-time costs is limited to the resources appropriated to conduct the agency's research programs. All funds appropriated to ARS are used to support the salaries of ARS personnel and other necessary expenses to conduct research, including cooperative agreements with our extramural research partners that contribute to specific ARS program objectives. Since 2010, the ARS Salaries and Expenses budget has been reduced by over 7 percent, while the need to invest in research continues to grow. Shared sacrifice has to be made given limited resources.

## DALE BUMPERS SMALL FARMS RESEARCH CENTER

*Question.* The fiscal year 2013 budget request includes a proposal to effectively close the Dale Bumpers Small Farms Research Center in Booneville, Arkansas, by redirecting all its funding elsewhere. I obviously do not support this proposal. In light of the closure of Brooksville, Florida, in 2011, and the expected closures of Watkinsville, Georgia, and Beaver, West Virginia, by June 1, 2012, where will ARS conduct grazing research for the benefit of the eastern United States if it closes Booneville, too?

*Answer.* Grazing research for the Eastern United States is conducted at ARS locations in University Park, Pennsylvania (Pasture Systems and Watershed Management Research Unit); Lexington, Kentucky (Forage Animal Production Research Unit); Madison, Wisconsin (U.S. Dairy Forage Research Center); Morris, Minnesota (North Central Soil Conservation Research Laboratory); Mandan, North Dakota (North Great Plains Research Laboratory); Tifton, Georgia (Southeast Watershed Research Unit); and El Reno, Oklahoma (Grazinglands Research Laboratory). The research at these units is done in cooperation with university and industry partners.

*Question.* Booneville is the home of unique long-term water quality research including a 20-year grazing study that began in 2003 using 15 small watersheds in Booneville, and a 10-year study on the effects of poultry litter application method on nutrient runoff to watersheds. Both of these studies promise answers to critical issues plaguing the entire region. What are your plans to continue this highly valuable research if Booneville is abandoned?

*Answer.* ARS maintains a nationwide network of research watersheds at 22 locations. Similar research is being conducted in watersheds at University Park, Pennsylvania; Beltsville, Maryland; Florence, South Carolina; Madison, Wisconsin; Tifton, Georgia; Fayetteville, Arkansas; Bushland, Texas; St. Paul, Minnesota; Mississippi State, Mississippi; Bowling Green, Kentucky; and Clay Center, Nebraska. The research is addressing animal production systems for cattle beef and dairy, swine, and poultry. The mitigation of poultry litter impacts is specifically addressed by research at University Park, Fayetteville, Mississippi State, and Tifton.

*Question.* Additionally, Booneville is home to the only dedicated ARS sheep and goat research program. Sheep and goats are an ideal enterprise for small farms for the production of meat, wool, or milk, and there is an exploding demand for these products in the United States. What are your plans for conducting research in this area if you abandon Booneville?

*Answer.* In addition to Booneville, ARS conducts research in sheep production at other locations—Clay Center, Nebraska (U.S. Meat Animal Research Center); Dubois, Idaho (U.S. Sheep Experiment Station); and El Reno, Oklahoma (Grazinglands Research Laboratory). Research at these locations is focused on the development of genetic resources for the sheep industry including an “easy care” genetic composite for small flock producers in the Midwestern and Eastern United States, and maternal and terminal lines adapted for large Western and Southwestern range flock production systems. This research program is also coordinated with the rangeland programs to examine the interaction between sheep and rangeland ecosystem services with specific focus on grazing and fire remediation, invasive weeds, and rangeland ecology. Additional research at the Grazinglands Research Laboratory is focused on grazing system forage using pastures and winter annual forages to reduce production costs and environmental impacts associated with grazing for both small and large animal ruminants. ARS is planning to initiate grazing goat research at El Reno in cooperation with the Langston University Goat Research Center. ARS is providing leadership for an international consortium which is developing a project to sequence the goat genome. This project is being developed by ARS scientists in Beltsville, Maryland, at the Beltsville Agriculture Research Center.

*Question.* In your fiscal year 2012 budget proposal, this same Center was proposed to be one of the sites for a major increase in funding as part of an ARS biofuels feedstock initiative. Now this year ARS is apparently targeting for elimination grazing research and research that benefits small producers. I understand the budget realities the agency faces, but the on-again, off-again, chaotic nature of selecting funding priorities is out of line with the normal activities of a research agency focused on long-term, basic research. Can you explain the rationale behind the changes in ARS priorities from year-to-year?

*Answer.* A portion of a President’s budget request for \$10 million in 2010, and \$6 million in 2011 to the USDA Regional Biomass Research Centers was designated for Booneville, but these funds were not appropriated. The Booneville location now has only three scientist positions. Because of the loss of critical mass of scientists, and adequate funding to support priority biomass research at Booneville, small ru-

minant research will be addressed at other ARS locations including applications to small scale producers for goats at El Reno, Oklahoma, and coordination of regional biomass research at Temple, Texas.

#### DELTA OBESITY PREVENTION UNIT

*Question.* USDA's fiscal year 2013 budget request proposes to eliminate funding for the Delta Obesity Prevention Research Unit in Little Rock, Arkansas. I am opposed to this proposed elimination. In previous years, ARS has proposed changing priorities for the Delta Obesity Prevention Research Unit. It was suggested by ARS that funding redirected from this unit would be used at AR Children's Nutrition Center, Tufts, and Houston to augment basic nutrition research that could be targeted to the Delta region. What happened to that proposal? This year's budget proposal simply proposes to terminate this funding and redirect "to more critical needs."

*Answer.* The President's budget for fiscal year 2012 proposed redirection of funds from the Delta Obesity Prevention Research Unit (DOPRU) to a study that would evaluate factors affecting adherence to the Dietary Guidelines for Americans. The funds for that study were to be reallocated to Beltsville, Maryland, but all six of the ARS Human Nutrition Research Centers were to participate in the research and would have received a share of those funds distributed from Beltsville. This proposed reallocation was never implemented since Congress, in the 2012 conference report, directed that the funds continue to support DOPRU. The proposed closure of DOPRU is part of the ARS proposed termination of several predominantly extramural research projects.

#### CATFISH INSPECTION

*Question.* With passage of the Food, Conservation and Energy Act of 2008 Congress shifted inspection and regulation of catfish from the Food and Drug Administration (FDA) to the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS). Since that time, USDA has undertaken a thorough process to implement this new responsibility, including issuing a proposed rule and completing the comment period on June 24, 2011. It has been almost 4 years since this responsibility was given to USDA-FSIS. When will the final rule be implemented?

*Answer.* Because there are many factors that influence rulemaking, it is difficult to estimate when the final rule is published, but FSIS will do so as soon as possible.

*Question.* What are the challenges with completing this rule?

*Answer.* As you know, the law provided that USDA define "catfish," which is not as simple as it may seem. In the taxonomy of fish, Siluriformes (the common name of which is "catfish") consist of 36 different families, among which are Ictaluridae (North American channel and blue catfish) and Pangasiidae (which are common to Asia). While some Siluriformes imported from Asia include those in the family Ictaluridae, much of the product is in the family Pangasiidae. Thus, there is a great deal of controversy surrounding the question of whether "catfish" should be defined narrowly or broadly.

*Question.* Will you commit to issuing this final rule this year?

*Answer.* FSIS will publish a final rule as soon as possible.

#### FARM SERVICE AGENCY OFFICE CLOSURES

*Question.* Do you foresee any need to take further action beyond the "Blueprint for Stronger Service" initiative to further reduce the number of Farm Service Agency (FSA) county offices?

*Answer.* There is currently no plan or proposal to close more than the 131 FSA county offices identified on January 9, 2012.

Over the last 2 years, FSA's salaries and expenses appropriation has been reduced by more than 5 percent. These reductions have necessitated significant reductions in administrative spending, a reduction in permanent staffing by 12.5 percent, and the proposed consolidation of 131 offices in 32 States. These actions were designed to bring the Agency's operating budget in line with the current and expected future funding levels. USDA will continue to do its best to serve America's farmers and ranchers within the funding level set by Congress.

*Question.* How could the process used to consider USDA field office consolidations be improved to involve stakeholders in the process before these proposals are officially announced?

*Answer.* USDA adheres to congressional notification requirements in the annual appropriations acts. For FSA, additional guidelines are laid out in the 2008 farm bill.

The proposal to close 131 FSA county offices remains the Agency's only proposal to close FSA offices. This proposal was announced on January 9, 2012. Over the following month, FSA held public meetings in each affected county and notified Congress of the proposed office closures on February 27, 2012. The public meetings enabled stakeholders to share their concerns with senior FSA leadership. FSA communicated about the circumstances that led to proposed county office closures—the need to manage the Agency under significantly reduced operational spending, 12.5 percent fewer permanent staff, and an ever-increasing workload, while continuing to deliver the best possible service to farmers and ranchers. FSA's approach to consultation adhered to statutory requirements, and provided a transparent and inclusive means to communicate with affected parties.

*Question.* With 2,800 NRCS offices and only 2,100 FSA offices remaining open across the country, how is USDA insuring that producers are being adequately serviced in locations without both agencies present?

*Answer.* We strongly believe that co-location is a great benefit to producers, and we will continue to offer these arrangements wherever possible. However, it is important to note that even before the proposed closures were announced, not all FSA offices had an NRCS presence. Further, we do not believe the proposed closures significantly undermine our efforts to co-locate FSA and NRCS offices.

FSA is modernizing IT and improving its business processes so that farmers will be able to do more of their business with FSA without having to visit an office. If the proposed consolidations occur, FSA will concentrate staff in its 2,113 remaining offices in order to provide consistent service in fully staffed, fully functioning offices.

If the proposed consolidations take place, producers may choose any county office that is convenient for them to conduct their FSA business.

*Question.* Recently there has been a lot of emphasis on reorganizing the field office structure of the Farm Service Agency in an attempt to provide better more timely service to the producers they serve. Most private businesses do not cut or make reductions at the customer level until a complete review of their structure has been completed above the field level. As I look at USDA's Blue Print for Success, it appears to me that you have not made any attempts to review FSA's structure above the field level to find needed savings. When does USDA plan on reviewing and reorganizing USDA/FSA above the field level? Does USDA have any plans to reduce the number of State offices?

*Answer.* FSA reviewed its operations at all levels to identify administrative efficiencies that resulted in significant savings. FSA also achieved needed savings by reducing staff levels in national, State, and county offices by 12.5 percent. There is currently no plan or proposal to close any offices other than the 131 FSA county offices identified on January 9, 2012.

*Question.* Under USDA's Blueprint for Success, a number of county offices met the criteria of two or fewer permanent full-time employees after VERA (voluntary early retirement program) and VSIP (voluntary incentive payment retirement program) programs in 2011. Some of these offices have the workload to support four or more employees and employed four or more FTEs when calendar year 2011 began. Because of VERA and VSIP, some of these offices were quickly reduced to two FTEs. When you looked at the number of employees for each office, did you take into account the previous workload of each office?

*Answer.* The VERA and VSIP opportunities were implemented in order to reduce staffing necessary to live within current and expected future budget realities. To identify FSA offices for consolidation, USDA followed criteria provided by Congress in section 14212 of the 2008 farm bill, which required, for any office closures, that the Secretary "first close any offices of the Farm Service Agency that—(a) are located less than 20 miles from another office of the Farm Service Agency; and (b) have two or fewer permanent full-time employees." In addition, FSA proposed for closure all offices with zero full-time, permanent employees regardless of the distance to another FSA office.

*Question.* Office closure language included in the 2008 farm bill called for offices located closer than 20 miles apart would be the first offices considered for closure/consolidation. Under USDA's Blueprint for Success, there are a number of cases where the navigable miles between the proposed office to be closed and the proposed receiving office is significantly more than 20 miles. You mentioned in a previous letter that USDA used Euclidian miles in order to be more objective. Why was it determined that 20 Euclidian miles were more objective than 20 navigable road miles when developing the list of offices proposed to be closed/consolidated?

*Answer.* USDA measured using Euclidian miles because Euclidean miles offer no advantages to any particular county. Euclidean miles are the most uniform and equitable unit of measurement for distance, regardless of geography or terrain.

*Question.* Since 1996, USDA has prided itself in using the Service Center for customers utilizing programs and services provided by any agency in USDA. Repeatedly, USDA has stated the importance of having all USDA agencies in a single location to provide maximum customer service. Knowing 131 of the 259 USDA offices being proposed for closure are FSA county offices, this will certainly cause the Service Center concept to be abandoned in many areas. How can USDA maximize customer service while abandoning the Service Center, causing USDA customers to visit separate locations to transact business?

*Answer.* It is important to note that even before the proposed closures were announced, not all FSA offices were Service Center locations. Further, we do not believe the proposed closures undermine the Service Center concept. However, we strongly believe the Service Center concept is a great benefit to producers, and we will continue to offer these arrangements wherever possible. We understand the concerns of producers who will have to travel to another location to conduct business with FSA once consolidations take effect. However, over the past 3 years, FSA has had to make tough decisions to be able to continue to operate within significantly reduced budgets.

FSA is modernizing IT and improving its business processes so that farmers will be able to do more of their business with FSA without having to visit an FSA office. FSA will concentrate staff in its remaining offices in order to provide consistent service in fully staffed, fully functioning offices. Producers affected by an office closure will be able to choose any county office that is convenient for them to conduct their FSA business.

#### SUBCOMMITTEE RECESS

Senator KOHL. And this hearing is recessed.

[Whereupon, at 3:53 p.m., Thursday, March 29, 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 2013**

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**THURSDAY, APRIL 19, 2012**

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, Collins, Moran, and Hoeven.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

STATEMENT OF DR. MARGARET HAMBURG, COMMISSIONER

ACCOMPANIED BY:

PATRICK MCGAREY, ASSISTANT COMMISSIONER, OFFICE OF BUDGET, FOOD AND DRUG ADMINISTRATION

NORRIS COCHRAN, DEPUTY ASSISTANT SECRETARY, OFFICE OF BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. Good afternoon. The subcommittee will come to order.

Today's hearing will focus on the Food and Drug Administration's (FDA's) fiscal year 2013 budget request. We welcome Commissioner Hamburg, Mr. McGarey, and Mr. Cochran. We appreciate your being here.

Before we begin, I'd like everyone to know that we have votes scheduled for 2:15 p.m. today. So right now we'll plan on just having opening statements by myself, Senator Blunt, as well as Commissioner Hamburg. Once the votes are called, we'll have to stand in recess until the votes are through, and we'll come back then and begin our questions. So we thank everybody for accommodating that.

The administration's budget request for fiscal year 2013 stands in stark contrast to the requests of recent years. Since 2008, the Congress has provided the FDA with budget increases totaling nearly 30 percent and the administration's requests have even been higher. This year, however, the FDA budget proposes an increase

of only \$15 million, bringing total funding to approximately \$2.51 billion.

Two main funding increases requested in this budget are \$10 million to enhance inspections of drugs and drug ingredients manufactured in China, and to work with Chinese manufacturers on ways to meet FDA standards; and \$18 million to complete the FDA's Life Sciences-Biodefense Laboratory complex. These increases are partially offset by decreases found elsewhere in FDA's budget.

As we are all aware, this subcommittee has worked over the past several years to provide FDA with increased funding for food safety activities. This year the only additional funds for food safety are requested in the form of a new user fee. My understanding is that negotiations on this user fee are in their earliest stages, and it is not likely to be passed this year. This means essentially that food safety activities are flat-funded in this budget, when we all know that the FDA's workload in this area has certainly not leveled off. That concerns us. I look forward to discussing this further.

I don't believe that this budget request reflects less support for FDA by the administration, but I do believe it reflects the budget realities that we continue to face. The FDA has been exempt from significant cuts found elsewhere throughout the Government. This will certainly prove to be the most difficult year in recent history. The importance of FDA's work has not diminished, and the agency's workload continues to increase. I have said in the past that I believe ensuring the safety of our food and drug supply is an important Federal function and should not and cannot be relegated to State and local governments as well as private industry.

As these functions continue to become more and more complex every day, we will do our best to provide FDA with the funding you need to do your job well, with the understanding that we are all being required to do more with less.

We look forward to your testimony, Dr. Hamburg. But first, Senator Blunt.

#### STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. Thank you, Mr. Chairman. Thank you for holding today's hearing on the FDA budget. I want to thank our witnesses for being here today. I look forward to working with the subcommittee, but particularly to working with the chairman, who has had such a good impact on FDA issues over his time on this subcommittee.

Commissioner Hamburg, thanks for your visit the other day. The agency you head regulates approximately 20 cents out of every \$1 spent in America and Americans expect the FDA-related products will be safe and effective. Similarly, the industry expects transparency and certainty from the FDA.

The agency has authority over 185,000 domestic establishments that range from food processing plants to facilities that manufacture life-saving medications. As companies struggle through the recession, FDA must be mindful that burdensome regulations can stifle innovation and lead to unnecessary expenses that limit small businesses' ability to create jobs.

For example, FDA's currently reviewing comments on a proposed rule that would require restaurants to list calorie content for standard menu items and of course very specifically defining standard menu items so you could know what that standard was. I believe the proposed rule that you've asked for comment on and haven't finalized is at this point still unnecessarily broad and too inflexible, but hopefully the final rule will benefit from the comments you're receiving.

When implementing the rule, you should adopt the least burdensome alternatives that meet your responsibility, and doesn't unnecessarily regulate stores that don't sell food as their primary business or other things that wouldn't be necessary under the act. In addition, the rule should be flexible enough to allow locations that don't serve their patrons on site the opportunity to provide nutrition information in a variety of formats.

I look forward to being able to discuss this issue a little further.

I'd also like to take a moment to mention that this very well may be the last hearing of the subcommittee this year. Chairman Kohl has announced that he'll leave the Senate soon, I suppose maybe to focus on basketball full-time or one of his other many activities that he's involved in. But this may be his final hearing as chairman. We're going to continue to work closely together to produce a bill.

I'd like to say that in leading this subcommittee he's really displayed keen knowledge of all the work of the subcommittee and—as you know, Commissioner—has shown particular interest and has been a real leader on FDA issues, particularly on food safety, and really, it's been an honor for me to get to work with him last year. I hope we produce a bill this year that we can get to the floor again, and we'll both be out there doing what we can to make this subcommittee work under the chairman's leadership.

Thank you, Mr. Chairman.

Senator KOHL. Thank you. Thank you, Senator Blunt.

Now, Dr. Hamburg.

#### STATEMENT OF DR. MARGARET HAMBURG

Dr. HAMBURG. Thank you, Chairman Kohl and Ranking Member Blunt. I do also want to take this opportunity to thank you, Chairman Kohl, for the extraordinary leadership that you've shown over so many years and the support you've given the FDA in our important mission.

I am joined, as you note, by Patrick McGarey, who is our Assistant Commissioner for Budget, and Norris Cochran, who's Deputy Assistant Secretary for Budget at the Department of Health and Human Services (HHS).

Let me begin by again thanking you and the subcommittee for your efforts in recent years to really try to shrink the gap between the agency's budget and its vast and evolving responsibilities. Your leadership has put us on a path towards more appropriate funding levels to support our unique and crucial mission. We are using these funds responsibly to reinforce our core functions and to obtain the most public health value for the Federal dollar during these challenging fiscal times. We're deploying smarter and more flexible regulatory approaches and better targeting of our

inspectional resources. We've consolidated our information technology (IT) infrastructure into modern data centers and expanded our efforts to leverage both financial and human capital through collaborations with public and private partners.

#### DRUG APPROVALS

With your support, we have produced concrete results that really matter. For example, we lead the world in the number and speed of drug approvals, while maintaining high standards for safety and efficacy. Last year we approved 35 innovative new drugs, many of them groundbreaking, the second highest number of approvals in more than a decade.

During this fiscal year, we've continued our strong performance and have already approved 15 innovative new drugs and biologics. Last year a total of 195 drug shortages were prevented through proactive collaboration with patients, healthcare providers, and manufacturers, and by exercising regulatory flexibility. This year we've already prevented another 30 drug shortages.

#### FOOD SAFETY MODERNIZATION ACT

Just 1 year after the enactment of the Food Safety Modernization Act, we've issued guidances and interim final rules and are on the way to meeting the 5-year inspection mandate for high-risk domestic facilities.

I think it is critical to note, though, that the volume and complexity of the products we regulate and the complexity of the supply chains by which they reach American consumers has increased dramatically. We receive thousands of medical product submissions each year and serve as the watchdog for the safety of tens of thousands of products that are already in the marketplace, and we oversee the safety of roughly 80 percent of the Nation's food supply. Imports of food products alone come from some 200 different countries and from more than 250,000 foreign facilities each year.

#### GLOBALIZATION

In addition, our core responsibilities are expanding to include additional product areas, such as tobacco, and evolving to accommodate scientific and technological advances and the challenges of globalization. Our budget request reflects these complexities and new demands, although, as you note, it is modest.

#### FISCAL YEAR 2013 BUDGET

The fiscal year 2013 budget recommends \$4.5 billion for FDA overall, a 17-percent increase from fiscal year 2012. User fees account for 98 percent of the increase, however. We're proposing cuts or savings in two areas, IT and related systems and building and facilities. FDA is also absorbing more than 80 percent of inflationary rent costs.

Our fiscal year 2013 budget authority increases will support import safety, medical countermeasures, White Oak facilities, the commissioned corps pay raise, and about 20 percent of our rent increase.

## BUDGET REQUEST

To strengthen the safety of foods and drugs from China, FDA is requesting \$10 million. Exports from China are experiencing unprecedented growth. In the last 5 years alone, shipments of FDA-regulated products from China increased by 62 percent. So that represents a fundamental shift of our economic and security landscape. These additional resources will strengthen our capacity to inspect Chinese facilities and our ability to work with our colleagues in China and our ability to perform risk analysis on Chinese exports.

## MEDICAL COUNTERMEASURES

Thanks to this subcommittee, FDA received a fiscal year 2012 appropriation of \$20 million for medical countermeasures. The fiscal year 2013 budget recommends an additional \$3.5 million to support development and review of new diagnostics, medical treatments, vaccines, and other technologies against a range of naturally occurring or deliberate chemical, biological, radiological, or nuclear threats, and new funding will help support initiatives focused on acute radiation syndrome, the needs of children and pregnant women, in vitro diagnostic tests, and building flexible medical countermeasure manufacturing capacity, and allow us to continue other ongoing efforts.

## LIFE SCIENCES-BIODEFENSE LABORATORY

The President's budget also proposes an increase of \$17.7 million to outfit the new Life Sciences-Biodefense Laboratory and ensure that all of the biosafety systems are operational before we occupy and can use the laboratory.

## USER FEES

User fees clearly represent a substantial part of our fiscal year 2013 budget and I want to address that briefly. The current user fee programs for drugs and medical devices expires, as you no doubt know, on September 30 of this year. The reauthorization process is now well under way and new user fee programs for generic drugs and biosimilars have also been put forward.

## FOOD SAFETY MODERNIZATION ACT

But to implement the Food Safety Modernization Act and reduce the burden of food-borne illness on consumers and American food producers, a new food facility registration fee that would generate \$220 million has been proposed. Additional proposals include new user fees to support the cosmetic and food contact substance programs, to compensate FDA for medical product reinspections, and support import operations at courier hubs.

## PREPARED STATEMENT

So, to conclude, let me emphasize that the resources in this budget are vital to our efforts to ensure timely access to innovative products, as well as our commitment to protecting the public from unsafe food and ensuring safe, effective medical products.

I appreciate your time and attention and will be happy to answer any questions you may have after you come back from your vote. [The statement follows:]

PREPARED STATEMENT OF DR. MARGARET HAMBURG

Chairman Kohl, Senator Blunt and members of the subcommittee, I am Dr. Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration. I am pleased to present the President's fiscal year 2013 budget request for the Food and Drug Administration (FDA).

I want to begin by thanking you for your efforts over the past few years to shrink the gap between the FDA's budget and its vast and evolving responsibilities. We have made every effort to spend those funds responsibly—to reinforce core functions and obtain the most public health value for the dollar.

As a science-based regulatory agency of global scope, FDA's mission is both exciting and daunting. Our core responsibilities are evolving and expanding to include additional product areas such as tobacco, to accommodate scientific and technological advances, and to step up to the global leadership role that FDA must play if we are to promote innovation and protect American consumers.

Our recent spending and new budget requests reflect this evolution. We are embracing these changes in several important ways—by deploying smarter and more flexible regulatory approaches, by identifying efficiencies and innovative approaches to deliver our core mission, improve outcomes, and better target our resources, and by using collaborations to leverage expertise, data, and experience. Through these approaches, we are already improving efficiency and achieving concrete results. While the challenges loom large, we are confident that we have identified investments and approaches that will allow us to continue this evolution and to protect and promote the public health.

FDA INVESTMENTS AND RESULTS

With the funding you have provided, FDA has delivered significant and quantifiable benefits for the American people, and we are very proud of these achievements.

In the area of drugs, FDA now has the highest first action approval rate for new drugs we have ever achieved, and we continue to look for ways to improve the predictability, consistency, and transparency of our drug review process. During fiscal year 2011, we approved 35 innovative drugs, many of them ground-breaking. This was the second-highest number of approvals in the past decade. These drugs represented real advances for patients, including breakthroughs in personalized medicine. They include two novel drugs that were developed and approved with diagnostic devices that will allow doctors to target the drug to those patients most likely to respond, as well as new drugs to treat important medical conditions.

To achieve these results and to speed access to the American people, we demonstrated regulatory flexibility, using, for example, accelerated approvals and innovative clinical trial designs. Of note, we lead the world in the number and speed of drug approvals. Of the 57 novel drugs approved by both FDA and the European Union between 2006 and 2010, 75 percent were approved first in the United States. Furthermore, between 2003 and 2010, all 23 cancer drugs approved by FDA and the European Union were approved first in the United States by FDA.

During fiscal year 2012, we continued our strong performance. Since October 1, FDA approved 15 innovative drugs and biologics. Of the 15, 11 (or 73 percent) were approved in the United States first. Fourteen of these products had Prescription Drug User Fee Act (PDUFA) deadlines, and we met the PDUFA deadline for 13 of the 14 products (that is, we met the PDUFA deadline 93 percent of the time). Just as important, of the 15 innovative drugs and biologics, 12 were approved on the first cycle, for an 80-percent first-cycle approval rate.

Some specific information on individual drug approvals will provide context for the importance of these actions. During January 2012, FDA approved a truly breakthrough product in the field of personalized medicine, a drug to treat a rare form of cystic fibrosis. Known as ivacaftor and sold under the trade name Kalydeco, this drug only works for patients with a certain genetic mutation. But, thanks to advances in personalized medicine, physicians can identify patients with this mutation. This allows doctors to use Kalydeco only for patients where the drug will be effective. For patients who respond to this drug, it can keep their lungs clear, help them breathe, and make an enormous difference in the quality of their lives.

The FDA drug review process normally takes about 10 months. But in the case of Kalydeco, a drug of great importance for patients in need, this drug was approved in less than 4 months.

FDA approved another drug in January 2012. Known as vismodegib and sold under the trade name Erivedge, it is the first FDA-approved drug for metastatic basal cell carcinoma, the most common type of skin cancer. This new drug interferes very little with the growth of healthy cells, but works by disrupting the molecular pathway in the body that causes cancer cells to grow. Given there were no available treatments at the time, FDA took measures to expedite its approval. As a result, Erivedge was approved in less than 5 months—or half the time of a typical FDA approval.

We have also been working aggressively to address and prevent drug shortages and to implement important Presidential directives. On October 31, 2011, the President issued an Executive order that directed FDA to take action to help further reduce and prevent drug shortages. In 2011, FDA successfully prevented at least 195 drug shortages. During the first 3 months of 2012, FDA prevented 22 shortages. FDA has sent letters to pharmaceutical manufacturers, reminding them of their legal obligations to report certain discontinuances to FDA, and urging them to voluntarily notify FDA of all potential disruptions of the prescription drug supply, even when not required by law. This has resulted in a significant increase in the number of potential shortages reported to FDA, and thus enhanced our ability to take action. In February of this year, we announced a series of steps to increase the supply of critically needed cancer drugs that were in short supply, including exercising enforcement discretion for the temporary importation of an alternative drug and approving a new manufacturer on an expedited basis.

We are also playing our part to address the rising costs of healthcare, by implementing a new approval pathway for biosimilar biological products and a user fee program to support review and evaluation of biosimilar products. We are also proposing a new generic drug user fee program that will support faster, more predictable reviews for generic drugs, effectively eliminate the current generic application backlog, and help assure quality by providing resources for regular surveillance inspections of manufacturers of generic drugs.

In the area of medical devices, in 2011, FDA released the Plan of Action for Implementation of 510(k) and Science Recommendations, which contained 25 specific actions that we would take in 2011 to improve the predictability, consistency, and transparency of our premarket programs. Seventy-five percent of those actions, plus eight additional actions, are already completed or well underway. We issued guidance on FDA's regulatory expectations for personalized medicine diagnostic devices that are developed along with a therapeutic product, to target that therapeutic product to the appropriate population. We launched the Innovation Initiative, which proposed actions that FDA could take to help accelerate and reduce the cost of developing and evaluating innovative medical devices, using science-based principles to maintain or improve patient safety.

In the area of food safety, the most sweeping reform of our food safety laws in more than 70 years was signed into law by President Obama on January 4, 2011—the FDA Food Safety Modernization Act (FSMA). We issued an interim final rule describing the criteria for administrative detention of food when there is reason to believe the food is adulterated or misbranded, and we have used this authority several times. We met the 1-year FSMA mandate for inspections of foreign facilities, and are well on the way to meeting the 5-year inspection frequency mandate for high-risk domestic food facilities. We also issued an updated guidance for the seafood industry on food safety hazards. We anticipate issuing several proposed rules called for in FSMA shortly. We post regular progress reports on implementation milestones on our Web site.

In the area of tobacco, we have been working to achieve a number of significant public health goals since enactment of the Tobacco Control Act of 2009. These include restricting youth access to cigarettes and smokeless tobacco, encouraging youth and adults who use tobacco products to quit, providing accurate information on the contents of tobacco products and the consequences of tobacco use to the public, and using regulatory tools to protect kids from initiating tobacco use and to begin to reduce the public health burden of tobacco in the United States.

We also have been aggressively and systematically addressing challenges that affect all products that FDA regulates. In June 2011, FDA issued our “Pathway to Global Product Safety and Quality” report, describing the challenges of regulating in the globalized world in which FDA now operates, calling for a paradigm shift in how we approach our duties in light of such challenges, and describing the concrete actions we will take in four areas:

- Assembling global coalitions of regulators dedicated to building and strengthening the product safety net around the world;

- Developing a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets;
- Expanding FDA’s capabilities in intelligence gathering and use, with an increased focus on risk analytics and thoroughly modernized IT capabilities; and
- Effectively allocating FDA resources based on risk, leveraging the combined efforts of Government and industry.

The essence of this strategy marries creative international coalitions with cutting-edge investigative tools to continue to provide the consistently high level of safety and quality assurance the public expects—and deserves.

#### MAXIMIZING THE IMPACT OF FDA FUNDS

At this time of fiscal restraint, FDA is focusing on its core responsibilities and working to identify opportunities to streamline activities and leverage human and financial resources.

I have instituted a series of reorganizations designed to ensure that FDA better reflects its evolving responsibilities, but that also recognizes our responsibility to make the most efficient use of our limited resources. Early in my tenure, I appointed a new Deputy Commissioner for Foods, to ensure coordination of our growing and rapidly evolving responsibilities for oversight of the domestic and global food supply chain.

Last year I created the new position of Deputy Commissioner for Global Regulatory Operations and Policy, to fully address the need to integrate domestic and foreign inspections, streamline procedures, and seek greater harmonization and opportunities for collaboration with our counterparts in other countries. I also appointed a new Deputy Commissioner for Medical Products and Tobacco, reflecting our recognition that the review of medical products increasingly cuts across center boundaries and that a new framework was necessary to address challenges like personalized medicine and combination products. Together, these changes build efficiencies into our organizational structure from the ground up and will make it easier to identify new opportunities for streamlining in the years to come.

We have made significant progress in consolidating our IT infrastructure into modern data centers. Simultaneously, we have modernized and standardized our hardware and software infrastructure, resulting in savings in power consumption and the ability to use FDA equipment and IT support resources more efficiently. You will see savings from this consolidation reflected in our proposed budget for fiscal year 2013, as well as additional proposed savings.

Another key area for improved efficiencies is improved targeting of inspection resources. We have been working hard to ensure that our import inspection programs are risk-based, targeting imports at port-of-entry more efficiently. We are redeploying current food inspection resources and pursuing efficiencies to support initial implementation of FSMA.

#### PREPARING FDA FOR THE CHALLENGES AHEAD

FDA’s mission is challenging, even in the best of times, with scientific advances occurring at breakneck speed and the pace of globalization accelerating. Our responsibilities are vast and growing, a trend that will only continue. We receive thousands of medical product submissions each year, and serve as the watchdog for tens of thousands of products on the market, ensuring that they continue to meet the highest standards.

We have evolved from a country that once consumed simple, primarily domestically produced goods to one that consumes complex products manufactured in every corner of the globe. We enjoy a greater variety of products from a greater range of places than ever before. The complexity of the products we regulate and the complexity of the supply chains by which they reach the eventual consumer has only increased. All of this means that FDA’s job has gotten more complex and the stakes have continued to increase.

As our fiscal year 2013 budget notes, FDA regulates more than \$450 billion of domestic and imported foods. Nearly 40 percent of the drugs Americans take are made overseas, and about 80 percent of active pharmaceutical ingredients are imported. Food imports have increased nine-fold since 1993. These food imports come from more than 250,000 foreign facilities in 200 countries. About 70 percent of seafood and about 35 percent of fresh produce consumed in the United States comes from foreign countries.

We are grateful that Congress has begun to help give FDA the tools needed to effectively regulate in a modern, complex, globalized environment. We are on the right path, but the road is long and challenging. The proposed fiscal year 2013

budget, described in more detail below, will continue the forward motion that you have supported.

#### FDA FISCAL YEAR 2013 BUDGET REQUEST

##### *Fiscal Year 2013 Summary*

The fiscal year 2013 budget recommends \$4.5 billion for FDA, a 17-percent increase from fiscal year 2012. The fiscal year 2013 increase for user fees, including increases for current law user fees and amounts for seven new user fee programs, accounts for 98 percent of the FDA budget increase.

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

For fiscal year 2013, FDA is proposing savings in two areas—information technology (IT) and the FDA Buildings and Facilities (B&F) account. In addition to these budget authority reductions, FDA is also absorbing more than 80 percent of the inflationary cost of rent activities.

After accounting for these savings, the net increase in budget authority is \$11.5 million for fiscal year 2013. Our increases support import safety, medical countermeasures, White Oak laboratory facilities, a portion of the increased cost of our rent activities, and the military pay raise that FDA Commissioned Corps officers will receive.

The Federal investment in FDA is small compared to the breadth of our mission and the \$2 trillion in products that we regulate. The investment in FDA is also an investment in the economic health of two of the largest sectors of America's economy: The U.S. food industry and the medical products industry.

##### *FDA Budget Authority*

###### *Fiscal Year 2013 Budget Reductions*

FDA made significant progress in recent years to consolidate our IT infrastructure into modern data center facilities. During the consolidation, FDA modernized and standardized its hardware and software infrastructure. This effort provides an FDA computing environment that reduces our costs and provides agility not previously possible. The result is savings in power consumption and more efficient use of FDA equipment and resources for IT support.

Under this fiscal year 2013 initiative, FDA will realize savings that flow from the consolidation effort. FDA will generate additional IT savings by streamlining other data management activities, reducing redundant IT devices, and reducing other IT costs, for a total savings of \$19.7 million. Finally, FDA will also save \$3.5 million by deferring repair and maintenance projects supported by our Building and Facilities account.

###### *Food and Drug Imports From China*

FDA is requesting a budget authority increase of \$10 million to strengthen the safety of foods, drug products, and ingredients exported from China to the United States. From fiscal year 2007 to 2011, the number of shipments of FDA-regulated products from China increased by 62 percent. This represents a fundamental change in our economic and security landscape, a change that requires FDA to alter its approach to protecting the health of the American public. To address this change, FDA must strengthen its capacity to inspect Chinese facilities that ship products to the United States and strengthen its ability to perform risk analysis on FDA-regulated products from China.

The addition of \$10 million will strengthen FDA's ability to protect American consumers and patients in important and fundamental ways.

- FDA will improve its food and drug inspection and analytical capabilities with 16 additional inspectors in China, and by adding three United States-based analysts.
- FDA will broaden the range of its inspections. In addition to inspecting Chinese facilities that manufacture food and medical products for export to the United States, FDA will inspect sites of clinical trials.
- FDA will strengthen the understanding of Chinese regulators and the exporting industry about U.S. safety standards through targeted workshops and seminars. This process will foster a constructive dialogue on improving the safety and quality of food and medical products.

With these resources, FDA will develop more robust knowledge about the complexities of regulatory pathways and supply chains within an increasingly globalized

environment. This understanding will allow FDA to make better evidence-based decisions and allocate FDA resources based upon risk.

#### *FDA Medical Countermeasures Initiative*

The FDA Medical Countermeasures Initiative (MCMi) is designed to help meet America's national security and public health requirements for medical countermeasure (MCM) readiness. MCMs include drugs, vaccines, diagnostics, and other medical products needed to respond to chemical, biological, radiological, nuclear (CBRN) threats and emerging infectious diseases.

Thanks to the efforts of this subcommittee, FDA received an appropriation of \$20 million in fiscal year 2012 to provide a base of funding for FDA's MCMi. For fiscal year 2013, the FDA budget includes an additional \$3.5 million for FDA medical countermeasures activities.

With the fiscal year 2012 base funding and the additional fiscal year 2013 resources, FDA will support partnerships with industry, academia, and Government partners to improve the development timelines and success rates for MCMs. FDA will also expand technical assistance to developers of the highest priority MCMs.

The top priorities for these MCM funds include FDA action teams to support the development of MCMs to address the following MCM needs:

- Warfighter care for American soldiers exposed to trauma or CBRN threats;
- Diagnosing and treating the multiple manifestations of acute radiation syndrome;
- Meeting the special needs of pediatric patients and pregnant women;
- Developing next generation in vitro diagnostic tests for CBRN threats; and
- Working closely with HHS to establish flexible manufacturing capacity in the United States.

Since the announcement of the FDA MCMi in August 2010, FDA and its drug, device and biologics programs have worked aggressively to ensure that the United States has access to high-priority MCMs during a public health emergency. Although less than 2 years old, FDA's MCMi has an impressive list of accomplishments, made possible by the resources that this subcommittee approved.

#### *FDA Regulatory Science Facilities*

On August 18, 2010, the General Services Administration (GSA) awarded the construction contract for the new laboratory complex at White Oak, and construction is well underway.

An fiscal year 2013 increase of \$17.7 million will allow FDA to outfit the new Center for Biologics Evaluation and Research (CBER)—Center for Drug Evaluation and Research (CDER) Life Sciences-Biodefense Laboratory complex that will support FDA's core regulatory science needs. FDA must make this investment now to ensure that all laboratory biosafety hazard systems are operational and the laboratory is ready for occupancy during fiscal year 2014.

#### *Pay and Rent*

The fiscal year 2013 budget also contains \$1.5 million to support the military pay increase for Commissioned Corps personnel serving at FDA and \$2.0 million to pay a portion of the inflationary rent costs for FDA for FDA programs. Funding these elements of the fiscal year 2013 budget will help ensure that FDA can retain the professional staff to perform our mission of protecting patients and consumers and improving public health.

#### *FDA User Fees*

##### *Prescription Drug User Fees*

In January 2012, the Administration submitted legislation to Congress to reauthorize the Prescription Drug User Fee Act (PDUFA). The proposed legislation recommends \$713 million in PDUFA fees for fiscal year 2013. The current law expires on September 30, 2012, and FDA is ready to work with Congress to ensure timely reauthorization of this vital program. To sustain and build on our record of accomplishments, reauthorization must occur seamlessly, without any gap between the expiration of the old law and the enactment of PDUFA V. The resources in PDUFA V will allow FDA to review and approve new and innovative therapies for patients, without compromising the FDA's high standards for demonstrating safety, efficacy, and quality of new drugs prior to approval.

##### *Medical Device User Fees*

For more than a year, FDA met with stakeholders and held discussions with the medical device industry in an effort to develop a package of recommendations to reauthorize the Medical Device User Fee Act (MDUFA). On February 17, 2012, FDA reached an agreement with representatives from the medical device industry, and

published draft recommendations to reauthorize MDUFA on March 15. The agreement would authorize FDA to collect \$595 million in user fees over 5 years, an amount that is subject to inflation increases. The agreement would also result in an fiscal year 2013 MDUFA fee amount is \$97.7 million.

The agreement strikes a careful balance between what industry agreed to pay and what FDA can accomplish with the proposed funding. We believe that it will result in greater predictability, consistency, and transparency through improvements to the review process.

Key features of the agreement include:

- Earlier, more transparent and more predictable interactions between FDA and applicants, both during the early product development stage as well as during the review process;
- More detailed and objective criteria for determining when a premarket submission is incomplete and should not be accepted for review;
- More streamlined FDA review goals that will provide better overall performance and greater predictability. This includes a commitment to provide feedback to an applicant if FDA's review extends beyond the goal date, so that the parties can discuss how to resolve any outstanding issues;
- Additional resources to support guidance development, reviewer training and professional development, and an independent assessment of the premarket review process to identify potential enhancements to efficiency and effectiveness;
- More detailed quarterly and annual reporting of program performance; and
- A commitment between FDA and industry to reduce the total average calendar time to a decision for premarket approvals (PMAs) and 510k applications.

#### *New User Fees for Generics and Biosimilars*

In addition to recommending the reauthorization of PDUFA and the Medical Device User Fee and Modernization Act (MDUFMA), the fiscal year 2013 budget recommends new user fee programs to support review and related activities for generic drugs and biosimilars. The proposed user fee programs for generic drugs and biosimilars are modeled on the successful PDUFA program, but are tailored to reflect the unique challenges and needs associated with regulating generic drugs and biosimilars.

*Generic Drug User Fees.*—As a result of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments, America's generic drug industry has been developing, manufacturing, and marketing—and FDA has been reviewing and approving—lower cost versions of brand-name drugs for more than 25 years. This legislation and the industry it fostered are a true public health success.

Last year, approximately 78 percent of the more than 3 billion new and refilled prescriptions dispensed in the United States were filled with generics, yet those drugs accounted for only 25 percent of prescription drug spending. In the last decade alone, generic drugs have provided more than \$931 billion in savings to the Nation's healthcare system.

The number of generic drug submissions sent annually to FDA has grown rapidly, reaching another record high during fiscal year 2011, including nearly 1,000 ANDAs. The current backlog of pending applications is estimated to be more than 2,500. The current median time to approval is approximately 31 months, although this includes time that the application is with the sponsor to address FDA questions about the application.

The Generic Drug User Fee Act (GDUFA) proposal submitted to Congress in January 2012 will put FDA's generic drugs program on a firm financial footing and provide \$299 million in additional resources to ensure timely access to safe, high-quality, affordable generic drugs.

*Biosimilars User Fees.*—A successful FDA biosimilars review program will spark the development of a new segment of the biotechnology industry in the United States. To advance this opportunity, the fiscal year 2013 budget includes a proposal for biosimilar user fees of \$20.2 million.

The proposed biosimilars user fee program will generate fee revenue in the near-term and enable sponsors to have meetings with FDA early in the process of developing candidates for biosimilar biological products. With these fees, FDA will develop the scientific, regulatory, and policy infrastructure necessary to review biosimilar biological product applications.

#### *Implementing FSMA—The Fiscal Year 2013 Food Establishment Registration Fee*

Food Safety remains a critical program area for FDA. FDA's fiscal year 2013 proposal for food safety aims to advance the vision of a strong, reliable food safety sys-

tem that Congress enacted in the landmark FDA Food Safety Modernization Act of 2011 (FSMA). The fiscal year 2013 budget proposal builds on the food safety increases that the subcommittee appropriated for fiscal year 2011 and fiscal year 2012 and calls for user fee revenue to allow FDA to establish a prevention-focused domestic and import food safety system, consistent with FSMA.

FSMA set out a vision for a modern food safety system that shifts the focus to preventing food safety problems, rather than relying primarily on reacting to problems after they occur. Implementing Congress' vision for a strengthened food safety system represents a dramatic expansion of FDA's workload. However, the simple truth is that FDA cannot meaningfully deliver on these mandates without the funding contained in the fiscal year 2013 budget.

The fee will support:

- Establishing new, effective, and comprehensive food safety standards;
- Establishing a new program for import safety;
- Increasing the number and efficiency of inspections;
- Launching an integrated national food safety system with States and localities;
- Expanding research activities, which will include improved data collection and risk analysis; and
- Improving FDA's capability to conduct risk-based decisionmaking.

These fees will allow FDA to reduce the risk of illness associated with food and feed and decrease the frequency and severity of food- and feed-borne illness outbreaks. With these fees, FDA can reduce instances of contamination and greatly diminish the burden on American businesses and the U.S. economy due to foodborne illness events. Without sufficient and reliable fee revenue, we can expect the unacceptably high human toll of foodborne illness to continue, with the resulting disruptions to the food system and the economic burdens to the food industry that result from foodborne illness outbreaks.

#### *Tobacco Product User Fees*

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) into law. Since 2009, the user fees authorized in the statute have allowed FDA's Center for Tobacco Products (CTP) to hire Center leadership and enable those leaders to initiate the scientific, educational, enforcement, and regulatory activities needed to accomplish the public health goals of the Tobacco Control Act. By the end of fiscal year 2011, the CTP had a staffing level of over 230 FTEs, and the Center anticipates meeting projected staffing goals in fiscal year 2013.

The fiscal year 2013 budget request for the Tobacco Program, including resources for CTP, is \$505 million, an increase of \$28 million above the fiscal year 2012 enacted budget. The amount requested is specifically authorized in the Tobacco Control Act and comprised entirely of tobacco user fees. Fiscal year 2013 priorities include protecting youth from tobacco, encouraging current users to quit, and making existing tobacco products less harmful.

#### *Other New User Fee Proposals*

*Cosmetics User Fee.*—The proposed cosmetic user fee of \$18.7 million will strengthen FDA efforts to protect public health by preventing harm to consumers, ensuring the safety of cosmetics and removing unsafe cosmetics from the market. With this fee revenue, FDA will develop necessary guidance and standards for industry. The fee revenue will also allow FDA to identify research gaps, such as gaps related to the safety of novel ingredients used in cosmetics.

*Medical Product Reinspection User Fee.*—The FDA Food Safety Modernization Act, which Congress enacted in December 2010, authorized fees for reinspections of food and feed establishments. FDA is proposing to expand this fee authority to medical product establishments. With this change, medical product establishments will pay the full cost of reinspections and associated follow-up work. FDA will impose the user fee when FDA reinspects facilities due to a failure to meet Good Manufacturing Practices (GMPs) or other important FDA requirements. The fiscal year 2013 estimate for medical product reinspection user fees is \$14.7 million.

*Food Contact Notification User Fee.*—FDA has statutory responsibility for the safety of all food contact substances in the United States. The Food Contact Notification (FCN) program supports applications for innovative food contact substances that help mitigate microbial food contamination and provide consumers with more healthful and safe food choices. The proposed user fees of \$4.9 million will support FDA efforts to increase the availability of safe food contact substances, to prevent unsafe food contact substances from reaching the market and to apply the most modern regulatory science to the review of food contact substances.

*International Courier Use Fee.*—For fiscal year 2013, FDA is proposing a new International Courier User Fee of \$5.6 million. The proposed fee will support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the increased cost of its international courier activities through user fees.

## CONCLUSION

The resources in this budget will allow FDA to perform its fundamental public health responsibilities in new and more efficient ways. Our budget also supports industry efforts to innovate and bring new products to market that will benefit American patients and consumers and strengthen our economy.

My goal with this proposed fiscal year 2013 budget is to position FDA to seize these opportunities. The resources in this budget will allow FDA to perform its core public health responsibilities in more efficient ways, to address these and the many other challenges at the heart of our mission. This budget also supports industry efforts to innovate and bring new products to market that will benefit American patients and consumers and strengthen our economy.

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

Senator KOHL. Thank you, Dr. Hamburg. The vote has been, at least for a while, postponed. So we'll just—

Dr. HAMBURG. Oh, okay.

Senator KOHL [continuing]. Start out with our questions.

Dr. HAMBURG. Excellent.

## FOOD SAFETY MODERNIZATION ACT

Senator KOHL. Dr. Hamburg, this budget request assumes \$220 million in additional funding that theoretically would be used to implement to the Food Safety Modernization Act. However, as you said, that funding increase would come in the form of a new user fee that has already been rejected by the Congress and that essentially has no chance of being authorized this year.

So what that really means is that this budget doesn't include any funding increase to implement the Food Safety Modernization Act, which is of great concern to many of us. How have you been working with both the Congress and the industry in order to get these user fees authorized?

Dr. HAMBURG. It is extremely important, as you note, to continue to implement the Food Safety Modernization Act, which gives us a chance to really reorient our whole food safety system towards preventing problems before they occur, rather than addressing them after the fact, which will have huge benefits both in terms of human health and reducing costs to the healthcare system, to the workplace, and to industry.

We are talking with industry about the importance of this work. They understand it. These are difficult, challenging economic times, however. We all recognize that. And we are, of course, working with other potential partners as we implement the Food Safety Modernization Act. We have made progress. We will continue to make progress, but we will have to prioritize in the context of reduced resources, and it will mean that we cannot accomplish all of the goals of the Food Safety Modernization Act, and I think it will mean that, unfortunately, we will not be able to put in place systems that would prevent disease and economic burdens as well.

But we hope that, though the process may take more time than we would like, we will continue to make progress in terms of the implementation of user fees. It's not inappropriate, I think, when

you look at the common good, the benefits to industry, as well as the benefits to the public, that support for this program be a shared responsibility. We've seen the benefits of user fees with our drug user fees and more recently the device user fees, and I do believe that when you look at the amount of resources available to support food safety in this country, we clearly need to do more.

Senator KOHL. But your budget assumes \$220 million necessary to discharge your responsibilities, but to be raised in the form of user fees which, let's be honest, isn't going to happen this year—\$220 million. How do you propose to even come close to discharging your responsibilities without that \$220 million?

Dr. HAMBURG. As I said, we are going to have to make very difficult choices. We are not going to be able to do all the things the Congress has asked us to do and that the American people expect us to do. We will place our emphasis and our resources on the highest priority issues. We do need to respond to the challenges of globalization and start to really ensure that import safety system—we will be taking more risk-based approaches so that we're targeting resources where the greatest need is, where the greatest risk is. We'll be working with States. We'd hoped to have resources to actually give to States as we build those partnerships for an integrated food safety system. That will be less possible, but we will have to find ways to work with State health and agriculture departments.

And we will have to work closely with industry and they will have to fully step up to the plate as partners. This is going to be a very, very challenging budget to implement and it will put very difficult choices in front of the Commissioner and her team.

#### GENERICIS

Senator KOHL. All right. One question on generics, then I'll turn to Senator Blunt. This budget request assumes the collection of \$299 million in new user fees for approval of new generic drugs. Assuming these fees are authorized—and we are more optimistic in this case that they will be, as you know—how long will it take to eliminate the backlog of generic drug applications that could immediately then be marketed?

Dr. HAMBURG. This is such an exciting and important opportunity to really move the generics program and its proven benefits to the next level. At the present time, we have unacceptable lags in the review of generic drugs, and we're also faced with the increasing challenge that so many of the manufacturers of generic drugs or components of generic drugs are overseas and we really have to level the playing field in terms of domestic and overseas inspections.

This user fee will enable us to do both. We've committed to reducing the review lag, which currently it takes an average of 30 months to review a generic application. We're going to bring that down to 10 months. We're committed to doing that in the 5-year span of this user fee program. And we also have committed to having equity between domestic and foreign inspections over that same time period.

Senator KOHL. Thank you very much.

Senator Blunt.

Senator BLUNT. Thank you, chairman.

Commissioner, on the \$220 million of additional fees, in that fee category what's produced now in the current fees, and the ones that expire at the end of this fiscal year? You have fees that expire at the end of this year. What do they produce?

Dr. HAMBURG. The fees that would expire in September of this year are the drug user fees.

Senator BLUNT. The drug fees.

Dr. HAMBURG. And the medical device user fees.

Senator BLUNT. So you have no fees in the food safety issue, right?

Dr. HAMBURG. We don't have an establishment fee, which is what is being recommended in this budget at the current time, no.

#### REINSPECTION FEE

Senator BLUNT. What kind of fees do you—

Dr. HAMBURG. There's one very small fee, which I have to turn to—reinspection. There's a reinspection fee in the food safety program.

Senator BLUNT. And the reinspection fee—

Dr. HAMBURG. But it's a very small amount of money and it's for after there have been problems in a facility and we go back in and reinspect to see if they've been corrected.

Senator BLUNT. So with that exception, there are no fees—

Dr. HAMBURG. Right.

Senator BLUNT [continuing]. Now, where you're proposing the \$220 million in fees?

Dr. HAMBURG. Yes.

Senator BLUNT. Would that be the same for the cosmetics? Are there fees there now?

Dr. HAMBURG. That's correct, there is not a cosmetics fee.

Senator BLUNT. And that's \$18 million?

Dr. HAMBURG. \$18.7 million, I think, yes.

Senator BLUNT. And what would the potential collection cost of that \$18 million be?

Dr. HAMBURG. I think that the—

Senator BLUNT. To put the fee in place and to collect it, however you would collect that fee?

Dr. HAMBURG. Having built a very robust infrastructure to deal with user fees in other components of FDA, I think we can move very quickly and efficiently to establish the user fee collection mechanism. It is important that it is done properly with the right safeguards and firewalls. But we do know how to do that now. We have 20 years of experience on the drug user fee side. So I think the greater challenge is sitting at the table and negotiating to achieve those user fee agreements.

#### COSMETICS

Senator BLUNT. Do you know what the average fee might be for the various categories of cosmetics producers, medium, small, or large? Do you have a sense of how this impacts the industry?

Dr. HAMBURG. I think we would have to sit down and really talk about the different strategies for approaching it and what would be the most appropriate way to structure the fee system so that there

would be the greatest benefit to the industry and it would align with the kinds of demands on our time and resources.

Senator BLUNT. So would that mean you haven't decided yet whether it would just apply to a finished product or have a fee during the entire production chain of cosmetics? I assume they get things—

Dr. HAMBURG. Yes, I think it would very likely be modeled on some of the other fees in terms of registration of establishments. But it is a different regulatory framework than for drugs. For example, where there's a pre-approval process with cosmetics, our legal regulatory responsibilities have to do with monitoring for safety issues and is really not focused on the pre-approval, so it wouldn't follow the exact kind of model of other user fees in existence today.

#### CHINA

Senator BLUNT. And the China inspection issue, would that be fee-based also, or would you propose some inspections in China?

Dr. HAMBURG. Yes, the China proposal is really to enable us to enhance our inspectional capacity and our presence on the ground in China, as well as to enhance our risk-based analytics and our strategies for our operations in China. But it would be building on existing activities. We'd be expanding our inspectional cadre in China by 16 people and correspondingly increasing the numbers of inspections in both food and drug. But it would not be part of our user fee program.

Senator BLUNT. So it's paid for out of regular taxpayer dollars?

Dr. HAMBURG. Yes.

Senator BLUNT. So these Chinese companies wouldn't pay for their inspection?

Dr. HAMBURG. No.

Senator BLUNT. Obviously, you'd have to agree that their products are going to have to go through this regimen for them to be allowed to come into the country?

Dr. HAMBURG. Right. If we are approving a new drug in this country, we need to inspect to make sure that, if it's being manufactured in another country, that the manufacturing meets our standards and requirements. If we are bringing a food product into this country, we need to inspect the facility to make sure that it's being made according to good manufacturing practice and meets our safety quality standards.

So it would be to enable us to expand work that is under way in China. But you can imagine, based on the huge increase in imports of the FDA-regulated products that I noted, that we are extremely hard-pressed to be able to even begin to do the range of inspections that really are important to assuring safety and quality to the American people.

Senator BLUNT. But under your proposal for food or cosmetics, as an example, either one, that would still be paid out of your taxpayer-funded budget. That's not in the fee proposal, the China inspection?

Dr. HAMBURG. The China inspections are going to be focused on food and drug inspections in China, building on a framework that already exists. We do have offices now in Shanghai, Beijing, and

Guangzhou and are doing inspections out of those offices, and also working with our counterpart regulatory authorities in China and industry that's based in China, either Chinese industries or United States companies, but that are manufacturing in China.

So that \$10 million will enable us to expand our capacity in ways that are very, very crucial.

Senator BLUNT. I guess the point that I'm trying to get established for myself is that we would still fund that effort on food, for instance, like we always have, but we would under your proposal have a fee for food inspection for U.S. companies in the United States, which I'd be reluctant to do. But we can visit about that later.

Dr. HAMBURG. What we're trying to do is really create an integrated program that is supported by both budget authority and user fees. In negotiating the user fees, we would be very explicit about how those user fee dollars would be used as part of this broader program. But they would not be siloed programs in terms of impact—

Senator BLUNT. But the user fees wouldn't be paid by the foreign companies. They'd be paid by U.S. companies, unless the foreign companies were producing in the United States?

Dr. HAMBURG. The user fees would be paid by the establishment that was manufacturing a product—

Senator BLUNT. In the United States?

Dr. HAMBURG. No. They could also be if you were manufacturing anything that would be FDA-regulated, foreign or domestic.

Senator BLUNT. So the Chinese company might pay the user fee if it was in China?

Dr. HAMBURG. Yes, yes.

Senator BLUNT. Okay, okay. That's the one point.

Dr. HAMBURG. No, I'm sorry I wasn't clear. But the \$10 million we're asking for now is to enhance our ability to inspect the facilities that are manufacturing goods that are FDA-regulated for export into the United States from China.

#### MENU LABELING

Senator BLUNT. Let me ask a couple of questions about probably the issue that we've gotten the most questions about of anything you're doing this year, which didn't maybe sound all that hard going in, but probably has turned out to be pretty complicated. And that's menu labeling. So if I understand the rule you've got out, on places where restaurant-type food is not the predominant part of the business, this would be certainly grocery stores that might have a food area, one of your options is that they wouldn't be subject to the rule. I think that's option two under your proposed rule. That's how I understand that, that that is one option you believe you have available.

Dr. HAMBURG. Yes. We put forward some draft proposed rule format for comments that included some of the different strategies that could be undertaken. As you note, it has proved very complicated, how you define a restaurant-like establishment and a standard menu. And we have gone out to get comment on the different approaches that could be used for defining the universe of restaurant-like establishments and what should be labeled and

how. And we are now in the process of responding to the comments that we've gotten. We got a lot of comments and they covered the waterfront in terms of perspectives on these issues, and we will be coming forward with a final rule in the near future.

Senator BLUNT. As I said in my opening comment, I would certainly be as flexible as you think the law allows you to be here, because there's lots of difficulty, it seems to me, in implementing this, particularly if it's not the principal thing you do, if it truly is arguably incidental to what you do. And the food options vary so much from one of the grocery stores you own to another grocery store you may own because of what's available that day or how the food counters are operated. I would encourage that.

#### MENU BOARDS

The other two questions that I had that I'd like you to comment on at least, one is the drive-through menu board; what do you think that might entail? And what about places where—I read somewhere in some information I had that Domino's Pizza, that 90 percent of the customers never, never come into a location. So for 90 percent of the customers, they're not going to see what's on the menu board anyway. Is there some understanding that that's a different environment? Do you want them to comply in a different way or do you want them to doubly comply, something on the Web site and something else on a wall that nobody sees? Or what are you thinking there?

Dr. HAMBURG. As I mentioned, we are finalizing the rule that will go forward, so I can't speak to specific details because it's still being discussed and worked through. But in terms of what was sort of put forward in the legislation was the recognition that there were different types of establishments, but how consumers access menus would be the place for communicating the information.

So if you have a storefront, but that isn't where consumers come in to order their pizza, it wouldn't make sense to require a menu board that no one would ever see. But if there's a menu that's on the Internet, that would certainly be an appropriate place, or a flyer that would be distributed, whatever, and the same with drive-through food establishments. Where there is a menu board that you look at to make your decisions, that would probably be the most appropriate place to have the communication as to calorie content of what's on the menu.

But with respect to all of the specifics, it is still in discussion, and we got across the range of different types of establishments a lot of suggestions about different ways to make information available so that it would be most consumer-friendly and-or least burdensome to the industries involved.

Senator BLUNT. My last question is, where I read "nutritional content" does that mean calories or does that mean a lot more than calories, as you comply with this?

Dr. HAMBURG. As I remember, calories was what was clearly indicated for posting with a requirement to indicate that additional nutritional information—

Senator BLUNT. Is available?

Dr. HAMBURG [continuing]. Would be made available on request from the consumer.

Senator BLUNT. Thank you.  
 Thank you, Mr. Chairman.  
 Senator KOHL. Senator Brown.  
 Senator BROWN. Thank you, Mr. Chairman.

## KV PHARMACEUTICAL

Thank you, first of all, for your decisive action a year ago on the Makena drug, the progesterone made by KV Pharmaceutical, when they took what was a compound, priced it \$10 to \$20 per injection, and a woman, a pregnant woman, needed about 20 injections, as you know, in the course of the treatment, and after getting FDA approval jacked the price up to \$1,500. Some would say they overreached. Others would say they were greedy.

Your action was important. However, some things have happened that I think demand more attention. As you instructed compounding pharmacies to keep compounding and not to respond to the cease and desist order, it was a real public health victory that you caused. So thank you for that.

Recently, KV Pharmaceutical—and it's pretty incredible behavior, a company that astounds me in its behavior and interaction with its patients—claimed that it collected contaminated samples of the compounded versions of the drug and asked the FDA to investigate. I am pretty amazed how they did it, what they did, but they did. This investigation and the length of it has caused some doctors to be reluctant in prescribing the compound, causing, I would be pretty certain, some women not to get the medication, which means a higher rate, I don't have evidence of that, but I assume—a higher rate of low-birth-weight babies or, second, great expense to insurance companies and taxpayers.

So my question is, what are you doing in this? Are you aware of this slowdown in prescriptions that we're told about, and what are you doing to speed up this investigation so we can put this behind us, so that women who are at high-risk of low-birth-weight babies get access to this drug for \$300 or \$400 instead, or this progesterone for \$300 or \$400, instead of—well, they dropped the price from \$1,500 to \$690. That was really kind of them, so it's only \$20,000 instead of \$30,000.

What are you doing to fix this public health hazard?

Dr. HAMBURG. When we do get a report, wherever it comes from, of a potential public health concern regarding an activity that we regulate, we take it very seriously and we do follow up. So we are in the process of an inspection, an investigation of the concerns that were raised. Obviously, we need to do this based on more than just reports, especially if the reports come from—

Senator BROWN. The manufacturer.

Dr. HAMBURG [continuing]. The manufacturer.

However, it is an ongoing investigation and I can't really report on details of findings or timing. I have not been made aware of concerns that during this process that there has been a decline in access to the therapeutic intervention overall. And I will go back and look at that.

Senator BROWN. We'll compile what information we can.

Dr. HAMBURG. Okay.

Senator BROWN. Some in the medical community have told us that the number of prescriptions has slowed as a result of the fear that doctors have because this company has made accusations that certainly serve its financial interest. Maybe they're true. I understand you have that responsibility. But you have a responsibility to move as quickly as you can in this case because it's clearly a huge public health threat. Okay, thank you.

#### IMPORTED DRUGS

Second group of questions. Tainted heparin from China—and I want to follow up on some things that Senator Blunt asked about—in 2008 it killed 100 people in this country, including, I believe—around the world; I'm not sure—including 3 people from Toledo, Ohio. In 2007–2008, melamine was found in pet food and in infant formula in China. I've heard recently, in the last year, from a number of dog owners who lost their animals as a result, their beloved animals, as a result of tainted chicken treats from China.

More recently, the identity and safety of imported fish has become a growing concern, a recurring concern also. You know the importance of this. You've asked for \$10 million in your budget, as you pointed out to Senator Blunt and he pointed out, 16 new full-time employees, 7 food safety inspectors, including 7 new safety inspectors and 9 drug safety—7 food, 9 drug safety.

This is a huge problem. There is no way, when you look at—my understanding is it would take the FDA 9 years to perform one inspection at the high-priority pharmaceutical facilities in China and 13 years to inspect all of the foreign-based pharmaceutical manufacturing plants.

Understand \$10 million is important. The inspectors are important. But isn't the goal to make the companies that import these drugs—I don't care if they're American companies or if they're French companies or Chinese companies that are selling into the American market. Shouldn't your goal be to make them personally responsible?

I mean, if a chief executive officer (CEO) is not certain where all the ingredients come from, and those ingredients coming from wherever end up killing a patient in Toledo, shouldn't that CEO go to jail? Shouldn't that CEO, that company, be fined huge amounts of money?

We'll never be able to inspect every place in China. What do we do about this? Come up with something more creative than begging the Congress for \$10 million so we can sprinkle a few food inspectors and safety and pharmaceutical inspectors in a country of 1.3 billion. Come up with something—

Dr. HAMBURG. I want to reassure you that, number one, this is a huge priority for us and we have a multifaceted program. The \$10 million is a small drop in the bucket of what our overall needs are. We do believe that we have to have a strategy that rally increases standards and accountability in the countries of manufacture, that increases the ability for us to work with other regulatory authorities to share information, because many countries are facing the same challenge. We need to really carve up the landscape.

We need to also target our inspectional resources more efficiently so that they can be extended further. And of course, we have to

continue our border import safety activities as well, but do it in a more risk-based way.

Senator BROWN. I'm going to interrupt. I'm sorry, Commissioner. Is there any way to do these inspections, short of threatening legal action—and I don't care about, I really don't care about a CEO going to jail or I don't care about a huge fine against the companies. I want these companies to be responsible for their ingredients. Is there any way to do that short of some legal process?

#### FOREIGN IMPORTER

Dr. HAMBURG. Yes. And in fact, the Congress has helped us in that domain. The Food Safety Modernization Act included a component for foreign importer verification and really puts a requirement on people that are bringing products into this country to verify that they were manufactured in compliance with our standards.

Senator BROWN. And if the ingredients have shown to be contaminated and cost lives, what is the legal resource for a consumer or a family or a country?

#### ENFORCEMENT

Dr. HAMBURG. I think on the drugs side there's legislation that's currently being considered to give us additional authorities to be able to act and enforce. On the food side, we have been able to achieve more of the tools and authorities that we need. It still is a real problem to take enforcement action proactively in another country, and I think it does speak to the fact that we need to continue to work, as we are, making this a very important area of focus within the FDA, to really—

Senator BROWN. I understand that. But for 100 years in this country, from the creation of the FDA after Upton Sinclair's book, we have worked hard to protect public health and protect food safety and pharmaceutical and drug safety. And just because the company—you don't have jurisdiction in another country doesn't mean that they should have access to our markets unless those companies, the importer or the company, whoever it is that's bringing it in, that they should have ultimate liability for that.

Mr. Chairman, if I could go one other short set of questions. Thank you.

Dr. HAMBURG. I just want to tell you that this is a huge priority, and it's one that we talk about every day in terms of we as a Nation have to really address this. FDA is at the cutting edge of much of this in terms of responding to the challenges of globalization. At the present time, we don't have the tools and authorities that we fully need to achieve that, nor do we have the resources.

Senator BROWN. I respect you. I've watched your career. I'm not convinced yet that you are aggressive enough.

On the question of drug shortages, thank you for your work on that. Thank you for the comments from the chairman.

#### REPACKAGING

On the issues of repackaging, we sent you a letter about repackaging within a specific hospital. They get 15 vials of drug X, they break it into 5 packages of 3 each to treat a patient, that they're

able to repackage and use those, helping to perhaps preclude a drug shortage. I sent you a letter suggesting we do that. We will follow up with some legislative language.

The letter that you sent back to us yesterday was to us inconclusive. I mean, Erin in my office, it wasn't clear to her in reading it that that was a very specific answer. I'd just like to ask you to work with us on the whole repackaging issue, because that can preclude some of these drug shortages.

Dr. HAMBURG. I'd be happy to work with you. I think that actually some of the restrictions have to do with other components of HHS activity, and we need to work—

Senator BROWN. We'll work with you.

Thank you.

Senator KOHL. Thank you, Senator Brown.

Senator Moran.

Senator MORAN. Mr. Chairman, thank you. Thank you to you and to the ranking member.

#### ANTIBIOTICS—LIVESTOCK

Commissioner, I'm pleased by your presence here today. Recently the FDA-issued guidance concerning antibiotic use by farmers and ranchers in regard to their livestock. Was that guidance based upon peer-reviewed science? The second question is: Would you provide this subcommittee with the science on which that guidance was based?

Dr. HAMBURG. Certainly. We did review an enormous amount of literature over quite a long period of looking at these questions. We also worked very closely with all of the critical stakeholders as we move toward putting forward that guidance, which is to restrict the use of antibiotics for growth promotion and feed enhancement purposes. We actually got a lot of support in both the analytic work for that and in the determination to go forward from our colleagues in animal and veterinary health, and the pharmaceutical manufacturers involved also, I think, believe that the world has changed considerably and we now know a great deal about the impact of injudicious use of antibiotics and the development of antibiotic resistance, that we as a Nation and as a global community are facing a very, very serious public health challenge with respect to antibiotic resistance and that this can make a real difference in order to really reduce this public health threat to both humans and animals with respect to ensuring that we have antibiotics that work.

Senator MORAN. I think you were suggesting that there is broad consensus to back up, in the industry, both the users and the scientific community, to support the guidance that you have issued.

Dr. HAMBURG. Nothing we do ever has consensus, but we did work hard to listen to the concerns of all of the stakeholders and address them.

Senator MORAN. Is it related to the use? When you talk about use for growth, I assume that's as compared to treating disease and infection?

Dr. HAMBURG. Correct.

Senator MORAN. Did the guidance have any implications on that use of antibiotics?

Dr. HAMBURG. Not for treating disease. We do believe that these antibiotics, just as in human populations, antibiotics are used under prescription and guidance of medical professionals, that veterinary professionals should be overseeing the appropriate use for treatment of disease.

Senator MORAN. Commissioner, would you work with my staff to give us—

Dr. HAMBURG. Certainly.

Senator MORAN [continuing]. A summary of the scientific basis for that guidance?

Dr. HAMBURG. Certainly.

[The information follows:]

Questions regarding the use of antimicrobial drugs in food-producing animals have been raised and debated for many years. A variety of recognized international, governmental, and professional organizations have studied the issue. Within the FDA Guidance for Industry No. 209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” we have briefly summarized the findings and recommendations from some of the notable reports that have addressed this issue over the past 40 years. These reports provide context to FDA’s current thinking on this issue and highlight the longstanding concerns that have been the subject of discussion in the scientific community as a whole.

We acknowledge that a significant body of scientific information exists, including some information that may present equivocal findings or contrary views. However, below is a list of some of the scientific literature that FDA considered in developing this guidance, including some key reports and peer-reviewed literature. This list is not intended to represent an exhaustive summary of the scientific literature but rather to highlight some of the more recent scientific research related to the use of antimicrobial drugs in animal agriculture and the impact of such use on antimicrobial resistance.

- 1. 1969 Report of the Joint Committee on the Use of Antibiotics in Animal Husbandry and Veterinary Medicine.
- 2. 1970 FDA Task Force Report, “The Use of Antibiotics in Animal Feed.”
- 3. 1980 National Academy of Sciences Report, “The Effects on Human Health of Subtherapeutic Use of Antimicrobial Drugs in Animal Feeds.”
- 4. 1984 Seattle-King County Study: “Surveillance of the Flow of Salmonella and Campylobacter in a Community.”
- 5. 1988 Institute of Medicine (IOM) Report: “Human Health Risks with the Subtherapeutic Use of Penicillin or Tetracyclines in Animal Feed.”
- 6. 1997 World Health Organization (WHO) Report, “The Medical Impact of Antimicrobial Use in Food Animals.” <http://whqlibdoc.who.int/hq/1997/WHO EMC ZOO 97.4.pdf>
- 7. 1999 National Research Council (NRC) Report: “The Use of Drugs in Food Animals—Benefits and Risks.”
- 8. 1999 United States Government Accountability Office (GAO) Report—“Food Safety: The Agricultural Use of Antibiotics and Its Implications for Human Health.” <http://www.gao.gov/archive/1999/rc99074.pdf>
- 9. 1999 European Commission Report, “Opinion of the Scientific Steering Committee on Antimicrobial Resistance.” [http://ec.europa.eu/food/fs/sc/ssc/out50\\_en.pdf](http://ec.europa.eu/food/fs/sc/ssc/out50_en.pdf)
- 10. 2000 World Health Organization (WHO) Expert Consultation: “WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food.” [http://whqlibdoc.who.int/hq/2000/WHO\\_CDS\\_CSRAPH\\_2000.4.pdf](http://whqlibdoc.who.int/hq/2000/WHO_CDS_CSRAPH_2000.4.pdf)
- 11. 2003 Report, “Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment.” <http://www.who.int/foodsafety/publications/micro/en/amr.pdf>
- 12. 2003 Institute of Medicine (IOM) Report, “Microbial Threats to Health: Emergence, Detection and Response.”
- 13. 2004 Report, “Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options.” [http://www.oie.int/fileadmin/Home/eng/Conferences\\_Events/docs/pdf/WHO-CDS-CPE-ZFK-2004.8.pdf](http://www.oie.int/fileadmin/Home/eng/Conferences_Events/docs/pdf/WHO-CDS-CPE-ZFK-2004.8.pdf)
- 14. 2004 United States Government Accountability Office (GAO) Report—“Antibiotic Resistance: Federal Agencies Need to Better Focus Efforts to Address

- Risks to Humans from Antibiotic Use in Animals.” <http://www.gao.gov/new.items/d04490.pdf>
- 15. 2005 Codex Alimentarius Commission (Codex), “Code of Practice to Minimize and Contain Antimicrobial Resistance.” [http://www.codexalimentarius.net/download/standards/10213/CXP\\_061e.pdf](http://www.codexalimentarius.net/download/standards/10213/CXP_061e.pdf)
  - 16. 2006 Antimicrobial Resistance: Implications for the Food System, Comprehensive Reviews in Food Science and Food Safety, Vol. 5, 2006.
  - 17. 2009. American Academy of Microbiology. Antibiotic Resistance: An Ecological Perspective on an Old Problem. 1752 N Street, NW, Washington, DC 20036, (<http://www.asm.org>).
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Senator MORAN. Thank you very much.

#### NUTRITION LABELING

Let me express my concern—and Senator Blunt raised this topic, but the nutrition labeling of standard menu items at chain restaurant provisions was authorized by the Patient Protection Affordable Care Act. It's my view that that law was intended to provide a uniform standard for chain restaurants with 20 or more locations to comply with various State and local menu labeling laws.

The concern I want to express is that the expansion of that—those regulations, to grocery stores is in my view a serious problem. In fact, the Office of Management and Budget (OMB) determined that this was the third most burdensome regulatory implementation of any law. Of any law that's currently being implemented, OMB says this is the third-largest regulatory burden. They estimated an increase of over 14.5 million hours of work and almost \$70 million for increased recordkeeping costs alone.

I would just encourage you strongly and insist to the degree that I can that you not take this opportunity to regulate further than is required by the law. In part, I would express my concern, certainly about the cost that is occurring or will occur to the grocery store businesses. For many members of Congress, I assume that's a large chain. We have a bit of that in Kansas, but many of our grocery stores are very small. They are marginal. We struggle—in fact, I remember numerous times in my time as a House member, now as a Senator, telling people that where I come from economic development can be whether or not there's a grocery store in town. It's a very basic need.

In fact, I'm a co-chair of the Senate Hunger Caucus. We're working with colleagues here in the Senate, but with the U.S. Depart-

ment of Agriculture (USDA), in regard to so-called food deserts, where grocery stores are not available. It's often the core center of cities, often rural communities. The ability for a grocery store to survive is very difficult now, and the burdens that you may place upon grocery stores will exacerbate the problem of access to high-quality foods, including fruits and vegetables.

I didn't see in what I read about FDA's cost analysis that there were very many benefits as far as calorie intake or health of the consumer related to the additional regulation of grocery stores in regard to so-called menu labeling. I want to point out the significant increase in cost, but I also want to point out these regulations may significantly damage the ability of everyday Americans who live in places that are already difficult to access quality food—it may reduce the access to that quality food even further.

Dr. HAMBURG. I appreciate your comments, but I just want to make clear that the law did indicate restaurants and restaurant-like establishments. That was not intended, obviously, to address every single grocery store. But the challenge has been trying to determine—there are big grocery stores that have restaurant-like cafés with a menu and prepared food. So that's a very different thing than looking at menu labeling of everything that would be sold in a grocery store, whatever.

So I just want to make clear that I think that the universe that would apply to a grocery store is much smaller than perhaps you have understood. We have put out for comment various potential strategies for how you would define a restaurant-like establishment, and of course the issue of how to deal with grocery store cafés and these kinds of prepared foods for immediate consumption. That's been one of the huge areas of complexity and where we're still trying to sort out what does make sense in terms of benefits to consumers, but not being overly burdensome, and having it really be implementable.

So I take very seriously what you say.

Senator MORAN. Commissioner, thank you. Even if it is a larger grocery store, I assume the kinds of things that may get picked up are salad bars and fruit stands. Fruits and vegetables are a significant component of increasing the healthiness of the American consumer. Let's make certain that in the quest to further regulate we don't actually diminish the opportunities for—I can see the circumstance in which a grocery store, if you pursue these regulations, simply decides: We're no longer going to provide the salad bar or the opportunity for fresh fruit; it's just not worth trying to comply with these regulations that FDA is pursuing.

Finally, Mr. Chairman, I would just express concern about the fees that you're talking about. Mr. Blunt—my time has expired, but the ranking member raised this topic. Those are significant increases in cost of doing business, that in this economic time can be very damaging to the ability of a business to stay in business.

Thank you, Mr. Chairman.

Senator KOHL. Senator Pryor.

Senator PRYOR. Thank you, Mr. Chairman.

Thank you for being here today, Commissioner. It's always good to see you. I want to start with a quick observation, that's going to take some follow-up because I don't have all my facts today. I

was in Arkansas over this most recent recess, and I talked to a pharmacist. She told me that one of the games that the pharmaceutical companies are playing right now allow a company to take an old drug that's been around forever and somehow gain exclusively to sell the drug.

But nonetheless, the cost has gone up considerably and it's the same old drug. So I'd love to sit down with you or your team and talk about that.

#### FACILITIES

Let me ask you about your budget, and specifically about buildings and facilities. I know that we're on a spending decline for most agencies. In fiscal year 2011, as I understand it, for your building and facilities fund you had \$12.75 million; fiscal year 2012, \$8.7 million; fiscal year 2013, \$5.3 million. So you're really shaving down the building and facilities account.

That concerns me because you do very valuable, very important work. I know this isn't the budget, if you had a magic wand that you would choose. But we are where we are.

Do you share that concern that I have, that you may not have enough money for facilities?

Dr. HAMBURG. I do. As you know, this is a budget of very hard choices. And it's discouraging in such critical areas as building and facilities, as well as other arenas, to see limitations on dollars that are needed to make a difference. It will mean that we'll have to defer some maintenance activities, some upgrade activities. It means we're going to have to really prioritize to address those buildings and facilities issues that are most critical to supporting our mission in terms of being able to review and approve products and do the research necessary to support those efforts and to make sure that we have the safety systems in our laboratories, for example, that are necessary for our employees.

#### NATIONAL CENTER FOR TOXICOLOGY RESEARCH

It is a huge concern, I'm sure you recognize, that the National Center for Toxicology Research (NCTR) in Arkansas is a place that we have a very important and unique lab resource, and this is a reduction that will come very hard on them. But we will work carefully with them to make appropriate decisions.

I should note that 2011 was really a high water mark in our buildings and facilities budget. It's not as though we have been at a steady state. We have always been stretched very thin, and I think it is reflected, unfortunately, in our inability to maintain all of our facilities at the levels that we would like.

#### NANO

Senator PRYOR. You mentioned NCTR and I know that you're very familiar with the work they do down there. One type of work is this new and emerging nano research. I would hate to see that slowed down or stopped based on the facilities, because they're obviously going to need space and infrastructure to have the ability to do this work.

They have plenty of room out there to do it. It's just a question if they have appropriate space within their existing facilities or if they need to reconfigure the space. But I hope, as you're going through this year and managing the agency, you will always remember them and try to continue on with that mission.

Let me move on to the next topic, which is again back on NCTR. I know you came down there. Was that last year, I guess?

Dr. HAMBURG. I've been there a couple times, but I was most recently there in August of last year.

Senator PRYOR. August of last year.

Dr. HAMBURG. It was hot.

Senator PRYOR. Yes, it was. I remember that. Thank you for coming down again.

We're trying to establish this virtual center of excellence in regulatory science. I'm curious about an update on that. As you know, that's a multi-partner thing that they're trying to pull together.

Dr. HAMBURG. Yes.

Senator PRYOR. So where are we on that?

#### NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH COLLABORATION

Dr. HAMBURG. It's an exciting collaboration. It involves the State of Arkansas, the five research universities in Arkansas, and the FDA through the National Center for Toxicological Research. There are a number of things that are under way or about to happen. One is that there will be a regulatory science credentialed program, training program, at the University of Arkansas in their school of public health. The first class will begin in the fall, and that will be very, very important in terms of helping to ensure that we have the cadre of trained professionals that we need going forward, whether they work in academia, industry, or government. We need those people for the future.

The State of Arkansas will be helping to support stipends for students in that program and we'll be helping with teaching and developing the curriculum.

We also have a research agenda focused in the nanotechnology area, and that is producing some exciting projects and collaborations really looking at issues at the present time of characterization and toxicology with respect to nano materials and nanotechnology processes.

Senator PRYOR. That's great. I think that is truly a partnership, a collaboration of lots of different entities. You guys are obviously very critical to that. But Arkansas's pitching in a lot, too. Thank you for your leadership on that.

Now, I have another question, since we've been talking about nanotechnology here, in 2007 there was a nanotechnology task force report. Here we are 5 years later. I'm wondering if that needs to be updated. Also, do you have a state of nano regulation, so to speak? How's the process going of trying to get your hands around nanotechnology?

Dr. HAMBURG. The work of that task force is ongoing and there is measurable progress in some critical areas, some of it reflected in what we were just discussing in terms of ongoing research and training activities. Also, FDA has been working with industry in

the areas that we regulate where nanotechnology or nano materials are now being used.

We're actually about to issue a couple of new guidances, I believe any day now, that will be I think very helpful to the food industry and cosmetics with respect to their use of nano materials and nanotechnology.

We are dealing with nanotechnology as we deal with other emerging technologies where we have an important responsibility to help to advance the opportunities that are part of these new technologies, but also to really study and ensure safety short-term and long-term in terms of the use. We are seeing the application of nano-related techniques and materials across many domains of FDA activity—drugs, devices, food, cosmetics. So it's an area that is very, very active at the present time.

Senator PRYOR. And you think that the FDA has its arms around the direction nano is taking here and the resources to take care of that?

Dr. HAMBURG. I think that we do. I think that the opportunity to engage in public-private collaborations is very, very critical so that we can assure access to the best and the brightest minds, wherever they are, in terms of the research that needs to be done, and then working closely with industry to address both the potential uses and the opportunity to really understand and identify any potential concerns in relation to that, so that we can look at both the ability to deliver innovative new products and strategies, but also assure safety.

Senator PRYOR. Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Pryor.

Senator Collins.

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

#### DRUG SHORTAGES

Dr. Hamburg, physicians, pharmacists, and patients throughout this country are continuing to struggle with alarming shortages of certain vital drugs. I've heard about this from virtually every hospital in my State. Many of the drugs in short supply are truly vital. They're used for chemotherapy, for example, or for anesthesia or for the treatment of infections.

There are also shortages of drugs used in emergency rooms and intensive care units. Eighty percent of hospitals are reporting that they've had to delay treatment due to shortages. That is so troubling to me, and it's why I've joined with Senator Amy Klobuchar of Minnesota in introducing a bill to require pharmaceutical manufacturers to report to the FDA whenever they see evidence that they're going to have a shortage of a drug, whether it's because of raw material shortages or contamination, whatever the reason.

Now, this builds on the model of a drug shortage program that already exists in FDA, but it is a voluntary program for manufacturers. Nevertheless, it's my understanding that FDA, acting on these voluntary reports, has been able to avert almost 200 shortages in the last year.

There's been a tripling of the funding for the drug shortage program and yet we still see these shortages of critical drugs. So could you first give me some insight as to why these shortages are per-

sisting, what FDA thinks should be done, and whether or not you have the resources and authority that you need?

Dr. HAMBURG. Thank you and we appreciate your leadership and work on the drug shortage issue. It's a huge concern, of course, to our country. As you identify, it cuts across many important areas of medical care.

In recent years we have seen the numbers of drug shortages going up, although there was a report—I saw it in the Washington Post—that the University of Utah, which tracks drug shortages, is actually reporting that the numbers so far this year are one-half what we saw in the same timeframe last year. So that is encouraging.

But drug shortages are occurring for a number of different reasons, complex reasons, that have to do with the nature of the drugs in short supply. The majority of the drugs that are in shortage are sterile injectables that present very specific manufacturing issues and also often are older drugs and generic drugs with a limited number of manufacturers.

There also are economic forces at play, and I think we need to continue to work to fully understand the factors that are causing the drug shortages, so as a Nation we can best address those.

With respect to the FDA role, we can't stop the shortages from happening. We can't compel manufacturers to make drugs if they choose to discontinue. We cannot assure that all of the precursor materials will be available or that the manufacturing will meet the quality standards that the American public expect and demand.

But what we can do, and as the proposed legislation really addresses, is respond quickly and with a lot of flexibility when we have early warning that a shortage may occur and a disruption in the supply chain. That's how we were able to prevent, as you noted, almost 200 drug shortages last year and about 30 so far this calendar year.

We did put out a request at the end of October to drug manufacturers to voluntarily report to us if they saw a potential shortage situation looming. Since that time we've gotten a sixfold increase in reports and that has been very, very helpful. But we think that there is real value in making it more explicit through legislation and really enabling us to systematize the information that we get, and I think that will help us to also establish the kind of databases that we need to be able to track more effectively and learn from the shortages.

But we have, using our ability to work with manufacturers to address quality issues, our ability to work with manufacturers who aren't facing quality issues or distribution issues but make the same drug, to increase their manufacture to address the shortage problem, to bring a new manufacturer on board in some instances, and sometimes to look overseas if there's a drug that can address the shortage need and make sure that that drug meets our standards of safety and efficacy, but for targeted use bring it over.

So we do have tools when we know about a shortage situation or a looming shortage, and we look forward to working with you.

Senator COLLINS. And of course, if you're able to notify healthcare providers that a shortage is upcoming, they may be able

to substitute a drug without interrupting treatment halfway through.

Dr. HAMBURG. Right, and we can work with them on that, and we do.

#### ARTIFICIAL PANCREAS

Senator COLLINS. There is, very quickly, another issue I want to raise. I'm the co-chair and the founder of the Senate Diabetes Caucus, and I'm very excited about the potential for an artificial pancreas. I know that it would have the impact of dramatically improving the health and quality of life for individuals living with diabetes, particularly type 1 diabetes.

The FDA has moved forward, has issued draft guidance—I was encouraged that that happened last December—to move to clinical trials from an inpatient to an outpatient basis. It's my understanding that the first outpatient trial using an artificial pancreas will be held at the University of Virginia. So I commend you for that.

I know there's been a lot of comments on the draft guidance by the Juvenile Diabetes Research Foundation (JDRF) and other stakeholders, and I hope you'll look at those comments.

What I want from you today is a timetable. Could you tell us when you plan to finalize the draft guidance on the artificial pancreas, and also the draft guidance on the low glucose suspend system, which is available in other countries, and thus it's been a source of frustration to a lot of people living with diabetes that it's not available here?

Dr. HAMBURG. Both of these guidances represent very important advances, as you know. If we could get an artificial pancreas on the market, it would make a huge difference in the lives of so many patients living with diabetes and their families. It is something that we're very excited about the opportunity that advances in science and technology now offer. We want to do our part in making sure that we can advance this as quickly as possible, but mindful that this is a very sensitive kind of a medical device and you want it to work properly or else it doesn't benefit anyone.

I can't give you an exact timeframe. We are actively looking at comments and we have been working very intensively and closely with organizations like JDRF and healthcare providers in this area. We very much want to move it forward swiftly and we think that there's a lot of alignment in terms of the strategies, and we've gotten a lot of input in terms of the strategies for moving, as you point out, quickly to the clinical assessment and moving from a more controlled hospital environment to the more real world outpatient. But we want to do it right, but we want to do it in a way that's mindful of the fact that time matters to people who are living with diabetes type 1.

Senator COLLINS. I do hope that you'll be able to finalize the guidance this summer. I know that's the hope of many of the advocacy organizations and physicians and other experts in this field.

I thank you, Mr. Chairman, ranking member, for your patience.  
Senator KOHL. Thank you, Senator Collins.

## PREMARKET APPROVAL

Dr. Hamburg, in your statement, you spoke about improving the premarket approval process for medical devices, which is important to get the best medical care to patients. I and others have been concerned about the postmarket surveillance of medical devices and introduced bipartisan legislation to improve the surveillance. As you know, recent news reports have highlighted postmarket problems with medical devices, such as hip implants and most recently heart wires.

Given these reports of serious medical device failures, don't you agree that your current tools and strategies for postmarket safety, nearly all of which are voluntary, are in need of improvement?

It's my understanding that FDA is working on a new comprehensive postmarket surveillance strategy and is planning to unveil it shortly.

Dr. HAMBURG. This is correct.

Senator KOHL. Could you give us some indication and some elaboration on what you're planning to do?

Dr. HAMBURG. There are a number of different ways that we have to address the issues of ongoing monitoring of safety and efficacy once a product is in the marketplace. We are putting forward a strategy to strengthen postmarket surveillance and to really build on data that is available in terms of electronic health records and information that is already being collected, but that we can tap into to strengthen our ongoing monitoring.

We also have, as you probably know, introduced in some of these higher risk areas requirements, working with the manufacturer, for ongoing targeted data collection as to safety in the experience with these products once they are in use and once we have the opportunity to really understand more about how they're really working in the medical care context and in the context of daily lives.

We also are eager to—in some key areas this has already been begun—create some registries that will enable us to have a deeper knowledge and understanding about the experience with these products, and we also believe that fairly soon we'll be able to implement the unique device identifier, which will again create an infrastructure for better monitoring of devices in the postmarket setting.

So there's a lot of different strategies under way that get to the heart of your question, which is the concern for oversight of the lifecycle of these products and the ability to respond quickly to emerging public safety issues.

## INFORMATION TECHNOLOGY

Senator KOHL. All right. Secretary Hamburg, the budget request offsets some of your proposed increases through a decrease of \$8 million in IT and administrative savings. As we know, budgets are not increasing, so we all have to work smarter. An obvious way to do that is to eliminate redundant or wasteful programs. Which are some of the programs you've found to be in that category and does your budget request deal with some of those programs? If so, tell us about those programs?

Dr. HAMBURG. Yes. In the area of IT we are going to be able to find some meaningful cost savings through activities to both con-

solidate our systems into a data center and have savings in terms of efficiencies and reductions in contract costs. As well, we're moving towards a system that will enable us to avoid duplication in terms of laptops and other IT equipment, and that actually is going to produce a surprisingly large amount of savings.

Then through other IT initiatives, retiring old legacy systems and really looking at our business processes and a number of other actions being taken, we will be able, I think, to meet our targeted reduction of, I think it's \$19.7 million, in the fiscal year 2013 budget.

I have to say, and embarrass him because he's here, we have a wonderful new chief information officer (CIO), Eric Perakslis, who is really bringing a whole new way of thinking and doing business to FDA, strengthening both our IT systems and also enabling us, I think, to really deepen and strengthen our scientific computing, which will make such a difference in our ability to really address critical issues of safety, efficacy, and quality of the products that we regulate.

Senator KOHL. Okay, Dr. Hamburg.

Senator BLUNT.

Senator BLUNT. Thank you, Mr. Chairman. I just have a couple more questions.

Actually, since we're talking about IT, let's just go ahead and go there. That was one of the areas I wanted to visit with a little bit. The Government Accountability Office (GAO) report wasn't very good and do you want to talk a little more about how the new CIO is responding to that and how you feel about it? Information technology is about 10 percent of the money you're spending and GAO just frankly said they didn't think you were spending it very well.

Dr. HAMBURG. I think that they will have a different message soon. That certainly is my hope and my commitment. They looked at a period that was time-limited and doesn't, I think, reflect many of the advances that have been made and that are continuing to be made. They address a number of issues about our application list, which in fact we are in a very different place now. And while that will always be a dynamic listing because we want people to be introducing new applications and trying new things, we feel that we now have the kind of list that GAO is looking for and we'll be able to sit down and talk with them about it.

They talked about—the bulk of our money is really being spent on a limited number of really major systems, and it is very, very important that we examine those systems to make sure that they are working, that we really need them. We're transiting to other ways of doing business that will in fact be both more effective and more efficient.

They talked about that we didn't have a strategy. We have a strategy that again is in its final stages. He's been working hard since he's been with us. He came on board at the end of October.

#### INFORMATION TECHNOLOGY PROGRESS

But we have made enormous progress and, while I think it was a little discouraging to see their report because we know it doesn't reflect all the progress that has been made, the good news is that that progress has in fact been made. It is very much in correspond-

ence with the kinds of recommendations that GAO put forward in their report, and it is my strong belief that they will be pleased to see the progress made, and I hope that you will be pleased to see the progress made.

Senator BLUNT. Have you been in a position to replace some of your old systems? Is that one of the things you're evaluating, whether there is a much cheaper alternative to the old systems you had?

Dr. HAMBURG. Yes, definitely. Consolidation of systems and using new strategies. I'm not an IT person, I will admit, but moving to cloud computing and other things changes the landscape dramatically.

#### LIFE SCIENCES-BIODEFENSE LABORATORY

Senator BLUNT. The other thing I wanted to talk about, you had a request here to move into the new building. Where will this request get you if we're able to get to most of that?

Dr. HAMBURG. This request will enable us to actually go in and use this laboratory space to do absolutely critical work in the drug and medical countermeasures arena in particular. We have a building that has been basically built out by the General Services Administration (GSA), but in order to occupy it with laboratories that meet safety codes and other things we do need those additional dollars. It would be a tragedy, I think, to have invested so much in building this new, critically needed and unique facility, and then not be able to actually utilize it.

Senator BLUNT. And that amount for outfitting that building, does somebody have a number there?

Dr. HAMBURG. \$17.7 million.

Senator BLUNT. A little over \$17 million.

#### MEDICAL COUNTERMEASURES

You mentioned medical countermeasures and that was the last thing I was going to ask about. Talk to me a little about that, and talk to me about what you are doing or you believe you could do, or we could help you do, with like the Department of Defense (DOD), that clearly has done a whole lot of work in this area. A lot of what they've done could serve a bigger population, and maybe is. I'm asking for information here.

Dr. HAMBURG. The medical countermeasures is obviously a critical area in terms of health, safety, and security of our Nation. It involves our ability to have the medical tools, the diagnostics, the drugs, the devices, and other technologies to enable us to respond to a set of naturally and deliberately caused threats, whether it's pandemic flu or a nuclear, radiological, chemical, or biological attack, but the kinds of threats that could really be catastrophic in their implications for health and stability in our country.

We do work closely with DOD and other components of government in terms of our activities. But we are a critical link in the chain. Whether it's a product for DOD or a product for civilian use, FDA standards review and approval is necessary for use. Through this program, which has sort of three main pillars—one is to make sure that we have the best possible review systems for dealing with these often complex products, that we have the underlying science

to enable us to deal with these products, and that we have really the updated legal and regulatory framework for dealing with medical countermeasures.

In all these areas there are complexities that may not exist in other domains, because sometimes you're talking about a disease that actually doesn't occur naturally in nature and where you can't possibly expose people to see if your drug or your diagnostic works and there may not be an animal model. So we have to be very flexible in our regulatory pathways. We have to develop new science, whether it's the appropriate models or innovative clinical trial strategies, to really ask and answer important questions about safety and efficacy, and then of course working with the companies that might be developing some of these new products. Because of an increased level of scientific and regulatory uncertainty, our ability to work closely with them really matters.

So this program is very, very important. I think that's recognized by all of our partners in government and outside. We have really been trying to work closely with the DHS and DOD to really identify what are the critical threats, what are the gaps in terms of available products, and what's needed to address those.

In this budget request for fiscal year 2013, one of the areas of critical focus is in fact on the warfighter and the need for additional products in some key areas that have to do with trauma sustained in the battlefield, and also the potential threat of chemical, biological, radiologic, and nuclear exposures.

Senator BLUNT. Very good.

Mr. Chairman, I think that's all I have for today.

Senator KOHL. Thank you very much, Senator Blunt.

We'd like to thank you, Dr. Hamburg, for being with us today.

#### ADDITIONAL COMMITTEE QUESTIONS

Members of the subcommittee can submit questions in a week's time, by Thursday, April 26, and we'd appreciate your response within 1 month of our submitting those questions to you.

Dr. HAMBURG. We certainly will.

Senator KOHL. Thank you so much.

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

#### QUESTIONS SUBMITTED TO DR. MARGARET HAMBURG

##### QUESTIONS SUBMITTED BY SENATOR HERB KOHL

###### FOOD SAFETY

*Question.* Dr. Hamburg, this budget request assumes \$220 million in additional funding that theoretically would be used to implement the Food Safety and Modernization Act. However, that funding increase would come in the form of a new user fee that has already been rejected by the Congress and that essentially has no chance of being authorized this year. So what that really means is that this budget doesn't include any funding increase to implement the Food Safety and Modernization Act, which is of great concern to me.

If this new user fee isn't authorized, and at this point it appears it won't be, what does that mean for FDA's ability to implement the food safety law? What won't happen?

*Answer.* The FDA Food Safety Modernization Act (FSMA) envisions a modern new food safety system that is prevention-oriented, science- and risk-based, and efficient.

However, it cannot be fully realized without the proposed fiscal year 2013 resources. If FDA does not receive the additional resources recommended in the fiscal year 2013 budget, then implementing FSMA will be significantly delayed or limited in several priority areas. Specifically, in the absence of the funding proposed for fiscal year 2013, FDA must delay its implementation of preventive controls because it will have limited capacity to develop guidance, conduct outreach and provide science-based technical assistance to industry, and retrain FDA and State inspection forces. FDA will also experience delays in its ability to create the new import oversight system required by FSMA and fulfill the FSMA vision of an effective, credible food safety system that uses the best modern tools to prevent food safety problems.

*Question.* Assuming we are working under the same budget restraints as you are, please send us information shortly on what the highest priority activities are that would have been funded with the user fees.

*Answer.* Priority FDA activities for implementing the FDA Food Safety Modernization Act would include continuing to focus on rulemaking to implement FSMA. FDA would also prioritize funding for the national integrated food safety system in the form of State grants, contracts, or cooperative agreements with regulatory and public health partners to improve, strengthen, and standardize regulatory activities among all partners as mandated by FSMA. As FDA enhances its risk-based decisionmaking efforts, another priority area for FDA is improving knowledge management tools for risk analysis, such as iRisk and iPrioritize, and investing in innovative information technology that will provide a systematic and transparent approach to identify, characterize, and evaluate food safety risks throughout the food supply system and to evaluate the potential impact of control measures or intervention strategies. Finally, FDA will further expand planning and response tools and systems to collect information for surveillance and outbreak detection, from traceback, and for post-response activities. This effort will allow FDA to identify trends and improve the effectiveness of future response and prevention activities.

#### MEDICAL COUNTERMEASURES

*Question.* The budget request includes a small increase of \$3.5 million for your Medical Countermeasures Initiative, which helps FDA work to develop drugs, vaccines, diagnostics, and other medical products needed to respond to chemical, biological, and other threats and emerging infectious diseases. Congress provided \$20 million last year for this initiative.

Can you talk about what you have accomplished so far, and what you plan to do this year?

*Answer.* We have made significant progress in implementing FDA's Medical Countermeasures Initiative (MCMi). Key accomplishments include establishing action teams to identify and help resolve challenges to developing multiplex diagnostic tests and medical countermeasures (MCMs) for acute radiation syndrome, warfighter-trauma care, and at-risk populations such as children and pregnant women. We have also established an action team to develop strategies to assess MCM safety and performance during public health emergencies.

FDA held workshops on developing and evaluating next-generation smallpox vaccines, regulating multiplex diagnostic tests, and ethical and regulatory challenges for MCMs in pediatric populations. FDA also held advisory committee meetings on smallpox drugs, MCMs for pneumonic plague, and antimicrobial medkits. These efforts have assisted us in establishing clear regulatory pathways for a next-generation smallpox vaccine, smallpox drugs, and multiplex diagnostic tests.

Additionally, FDA finalized a pre-emergency use authorization package for an acute radiation syndrome MCM that is in strategic national stockpile, which will help enable rapid distribution in a radiological or nuclear event. FDA also launched a rigorous MCM regulatory science program, a program to qualify animal models, and a multifaceted MCMi professional development program.

Our fiscal year 2012 MCMi priorities include sustaining FDA action teams and the MCM regulatory science program, with a focus on critical regulatory gaps and emerging technologies. We plan to strengthen our MCM regulatory science partnerships with academia and U.S. Government partners. And we plan to identify and communicate best review practices for MCMs across FDA and to re-issue draft guidance on addressing efficacy under the Animal Rule.

FDA will also be holding workshops on developing animal models of pregnancy for MCM development and on radiation biodosimetry. FDA also plans to enhance pre-event planning and our process for rapid deployment of MCMs. Finally, FDA will continue our professional development program and expand our outreach activities.

*Question.* With resources becoming more limited every year, but the need for this work continuing as threats evolve and change, how do you prioritize to ensure that you're using the money in the most effective way?

*Answer.* FDA is working very closely with our U.S. Government partners through the Department of Health and Human Services' interagency Public Health Emergency Medical Countermeasures Enterprise (Enterprise) to build and sustain the civilian MCM programs necessary to respond to public health emergencies. FDA is fully engaged with our enterprise partners at all levels to help develop and stay abreast of near-, mid-, and long-term MCM priorities and requirements and to ensure that our activities and investments are aligned with Enterprise goals and priorities, which are driven by threat and risk assessments. For example, FDA subject matter experts and senior leadership participate in the various Enterprise partner committees and working groups that develop MCM requirements, plans, priorities, and policies and that conduct program oversight and integration.

FDA has also engaged Enterprise partners in implementing our Medical Countermeasures Initiative (MCMi) to ensure appropriate alignment with Enterprise priorities. For example, we have established a steering committee comprised of Enterprise partners to peer review research proposals for our MCM regulatory science program. This steering committee ensures that the regulatory science research that we fund is in alignment with Enterprise MCM priorities and focused on critical gaps or important emerging technologies.

We also regularly meet with senior leadership at the Department of Defense to coordinate MCM activities and to ensure that our investments are appropriately aligned to Department of Defense MCM priorities and goals.

#### CHINA IMPORT INITIATIVE

*Question.* The budget request includes \$10 million to increase FDA's inspection capabilities in China, as well as work with the Chinese regulators and industry on maintaining U.S. quality and safety standards. You noted previously that the number of shipments of FDA-regulated products from China increased by 62 percent from 2007 to 2011, so the emphasis there is understandable.

Is the FDA working alone on this, or is this part of a larger Government initiative?

*Answer.* With reference to increased FDA staffing in China, FDA is working with Chinese regulators and the U.S. Department of State. On the broader topic of imported commodities originating from China, FDA continues to work with other U.S. Federal agencies, including the U.S. Departments of Agriculture, Homeland Security, and Commerce, the Office of the U.S. Trade Representative, other agencies within the U.S. Department of Health and Human Services, as well as other Federal counterparts, with U.S. State regulatory agencies and with other foreign regulatory counterparts. As part of a comprehensive strategy to strengthen trade enforcement and enhance trade related inspections, the fiscal year 2013 budget includes an additional \$10 million to expand FDA's presence in China and ensure the safety of imports before they enter the United States. As growth in imports of FDA-regulated products continues to increase, and such products travel through increasingly complex supply chains, FDA continues to leverage relationships with relevant stakeholders to fulfill our mission to protect the health of American consumers.

*Question.* The proposal would add 16 additional inspectors based in China, and three analysts based in the United States. That averages out to over half a million dollars for each additional person—that is a lot of money, so you must have additional plans for these funds.

How else will this \$10 million be used? Specifically, how do you plan to enhance Chinese understanding of U.S. standards besides hiring additional inspectors?

*Answer.* While the vast majority of work done by new proposed staff will be in the area of inspections, FDA will use some funding for workshops, conferences, and strategic seminars that will further our efforts to ensure that Chinese manufacturers comply with relevant FDA requirements for safety and quality. The new staff will work to expand FDA's capacity-building efforts to strengthen China's regulatory capacity and will provide the information, tools, and training that will enhance the safety of FDA-regulated products exported from China to the United States.

FDA's primary goal of increasing staff in China is to enhance compliance with relevant FDA regulations and requirements for FDA-regulated goods exported from China. Inspections can drive increased compliance, as can strategically targeted training and capacity building. Often, these activities complement one another. In China, we have used information from investigations performed by in-country inspectors to undergird and inform our strategy for capacity-building. The overarching

goal of these training activities is to encourage Chinese manufacturers to implement measures to ensure that their products meet FDA requirements.

*Question.* Is this a scalable initiative?

*Answer.* The fiscal year 2013 China Initiative contains additional positions to meet FDA's expanding workload in China. We hope that the following background will highlight how FDA has already been scaling up activities in China.

Each year since opening our China Office, FDA has set year-on-year records for numbers of FDA inspections in China. In fiscal year 2008, FDA performed 87 inspections in China. By fiscal year 2011, that number had grown to 245. Since 2009, two food investigators and two medical products investigators have served within FDA's China Office. These staff has helped FDA achieve these significant increases in inspection numbers. Our inspections abroad will continue to increase under the requirements of the Food Safety Modernization Act and the Food and Drug Administration Reform Act.

*Question.* What work, if any, have you done with the Chinese Government in preparation for this initiative?

*Answer.* FDA has initiated discussions with the Chinese Government and the U.S. Department of State to seek approval for this increase in FDA staffing in China. The FDA Commissioner has also informed her regulatory counterparts in China through written correspondence of FDA's interest in expanding its inspection presence in China. The staff that established the FDA China Office in 2008 included four investigators. This cadre's work has provided Chinese regulators with ample evidence of both the seriousness with which FDA regards its mission to protect U.S. public health and of the mutual benefit that the presence of FDA inspectors in China can bring.

#### DRUG SHORTAGES

*Question.* Dr. Hamburg, we have all been reading in the news recently about the large number of drug shortages, often for critical diseases such as cancer and heart disease. In your statement you note that in 2011, FDA prevented at least 195 drug shortages. This is impressive, but still the number of shortages continues to grow. In fact, they tripled from 2005 to 2010, and reached record levels in 2011. Recently, legislation has been introduced that would require drug companies to notify FDA of impending shortages so your agency can begin to take action sooner.

Understanding this is a complicated issue, can you speak to what you believe are some of the underlying causes of this increase in shortages?

*Answer.* In 2010, there were 178 drug shortages reported to FDA, 132 of which involved sterile injectable drugs. In 2011, FDA continued to see an increasing number of shortages, especially those involving older sterile injectable drugs. Two hundred and fifty-one shortages were recorded for 2011, and 183 of these involved sterile injectable drugs. These shortages include cancer drugs, anesthetics used for patients undergoing surgery, drugs needed for emergency medicine, and electrolytes needed for patients on IV feeding.

A number of different factors contribute to the shortage of sterile injectables and other drugs, including manufacturing issues and economic factors. Some companies have decided to discontinue making their products for business reasons, others have had problems with their raw material suppliers, and some have shown manufacturing deficiencies that compromise the safety and efficacy of their products. Even when there is more than one firm making a drug, there is limited manufacturing capacity for sterile injectables at each manufacturer. When one firm has a delay or other problem, it is difficult for the remaining firms making the drug to increase production quickly to avoid or address a shortage.

FDA works to find ways to mitigate drugs shortages. However, there are a number of factors that can cause or contribute to drugs shortages that are outside of FDA's control. Also, FDA has no legal authority to compel drug manufacturers to manufacture or continue to manufacture a drug.

*Question.* In what ways could we be of assistance to you as you try to deal with this issue? Are there additional tools that you could use?

*Answer.* Early notification from manufacturers to FDA can help prevent drug shortages in certain circumstances. With earlier notification, FDA may be able, for example, to work with the company on the issues causing the shortage before the supply is depleted and may be able to contact other manufacturers of the drug to encourage them to increase production.

FDA is doing everything it can, within the agency's authority, to mitigate and manage shortages as they occur. However, many drug shortages arise from quality or other issues experienced during the manufacturing process. Manufacturers therefore play a large role in preventing or mitigating potential shortages by having rig-

orous quality assurance and risk management processes in place and contingency plans to respond to a drug shortage—for example, redundancy built into manufacturing capabilities to allow continued production even if the main manufacturing site experiences problems, or identification of alternative active pharmaceutical ingredient and component suppliers in the event the original supplier becomes unavailable.

FDA supports provisions encouraging manufacturers to institute such policies, consistent with our recommendations in the draft guidance for industry, Notification to FDA of Issues that May Result in a Prescription Drug or Biological Product Shortage.

#### LAB FUNDING

*Question.* The largest requested budget increase is \$17.7 million to outfit a new biodefense and life sciences laboratory complex currently being constructed at FDA's White Oak facility. This new lab will support essential research by FDA scientists to protect patients and consumers. I understand that construction is nearly complete, and this funding will fully equip the lab and make the complex operational so research can begin there in 2014.

If this funding is provided, will there be any additional costs beyond this, or will this particular project be complete?

*Answer.* The increase of \$17.7 million for fiscal year 2013 is required for special facility-related costs for outfitting, commissioning, and providing the essential equipment and infrastructure for the laboratories to be certified and operational. In subsequent years, FDA must determine how to replace aging laboratory equipment that cannot be moved from the existing laboratories and other equipment issues.

*Question.* What will the effect be if this funding is not provided, or is only partially provided? Is this a scalable project?

*Answer.* These costs have a direct relationship to the highly specialized construction of state-of-the-art laboratories. There are unique, one-of-a-kind installations and commissioning requirements needed to ensure acceptable operation of these facilities. The BSL-3 labs need to be in place and operational in 2013 to ensure they are certified for occupancy. Delay in certification will lead to the reduced ability to make advances in regulatory science, including efforts by scientists to do applied research and support regulatory decisionmaking in the areas of medical countermeasures and complex and novel product applications involving stem cells, tissues, blood and blood products, and vaccines. This building was designed in support of the consolidated Center for Biologics Evaluation and Research (CBER) Life Sciences-Biodefense Lab requirement to meet FDA's mission. If funding is not provided and commissioning is not completed as scheduled, notifications will have to be provided to landlords of the existing facilities and leases will have to be extended. This will lead to rental payments on both facilities causing the programs to absorb these added costs. This project is not a scalable project. If the full \$17.7 million is not received, certification will not be achieved and the facility will not be operational.

*Question.* Is this the FDA's top priority for this fiscal year?

*Answer.* This is FDA's top facilities priority in the fiscal year 2013 budget.

#### USER FEES

*Question.* Dr. Hamburg, in your statement, you point out that of FDA's total budget request, 98 percent of the requested increase will come from user fees, including current user fees and seven new proposed fees.

Can you speak briefly about the status of each of the new user fees?

*Answer.* The following is a summary of the status of FDA's new user fees:

#### PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2012

The proposed Prescription Drug User Fee Amendments of 2012 (PDUFA), Generic Drug User Fee Amendments of 2012 (GDUFA), and Biosimilar User Fee Act of 2012 (BsUFA) were submitted to the appropriate authorizing committees of the Congress on January 13, 2012, and are currently being considered by Congress. The draft legislative package for the Medical Device User Fee Amendments of 2012 (MDUFA) was submitted to Congress on April 20, 2012; this is also currently being considered by Congress.

#### MEDICAL PRODUCT REINSPECTION

Regarding the Medical Products Reinspection User Fee, the Administration has not submitted a proposal for medical product reinspection user fees at this time.

However, FDA is ready to work with Congress and stakeholders to advance this user fee program. A fee structure and related proposals would be developed through negotiations with industry and other stakeholders.

#### COURIER

Regarding the International Courier User Fee, the Administration has not submitted a proposal for authorizing this user fee at this time. However, FDA is ready to work with Congress and stakeholders to advance this user fee program. A fee structure and related proposals would be developed through negotiations with industry and other stakeholders.

#### COSMETICS

FDA has met with industry representatives to discuss their ideas for possible new authorities, such as mandatory facility registration and ingredient listing. FDA is ready to work with Congress and stakeholders to advance this user fee program. A fee structure and related proposals would be developed through negotiations with industry and other stakeholders.

#### FOOD CONTACT NOTIFICATION USER FEE

The Administration has not submitted a proposal for authorizing this user fee at this time. The Administration has not submitted a proposal for authorizing this user fee at this time. FDA is ready to work with Congress and stakeholders to advance this user fee program. Industry has previously expressed support for user fees to ensure continuation of the Food Contact Notification (FCN) program. A fee structure and related proposals would be developed through negotiations with industry and other stakeholders.

#### FOODS AND VETERINARY MEDICINE PROGRAM

Regarding the Food Establishment Registration Fee, the Administration has not submitted a proposal for authorizing this user fee at this time. However, FDA is ready to work with Congress and stakeholders to advance this user fee program. A fee structure and related proposals would be developed through negotiations with industry and other stakeholders.

FDA recommends that the proposal authorize the agency to establish a system of food establishment registration user fees to support food safety activities. The programs and activities that the fee will support are: Establishing new, effective, and comprehensive food safety standards, establishing a new program for import safety, increasing the number and efficiency of inspections, launching an integrated national food safety system with States and localities, expanding research activities, including improved data collection and risk analysis, and maintaining a current facilities registration database and supporting other information technologies to improve FDA's risk-based decisionmaking capabilities.

*Question.* I do understand that user fees allow FDA to raise additional funds without additional budget authority, but it is striking that so much of your proposed budget growth is slated to come from new fees, which obviously must be negotiated with the affected industries.

Does this concern you? Do you believe FDA could be hampered in its ability to function when so much of its budget is dependent upon fees that must be paid by, and therefore agreed to, by the industries FDA regulates?

*Answer.* The job of protecting patients and consumers requires stable and adequate sources of funding. FDA has benefited from user fees since the introduction of PDUFA in 1993. It is only appropriate that the industries who directly benefit from the actions taken at FDA pay a moderate fee to increase capacity at the agency. At a time when the availability of budget authority to support FDA programs is constrained, user fees provide an essential source of funding to conduct product reviews and ensure product quality and safety.

#### DRUG LABELING DURING PREGNANCY

*Question.* I have been working with you and the FDA to improve drug labels for women during their pregnancies. As you know, an estimated 75 percent of pregnant women use about five prescriptions or over-the-counter drugs during their pregnancies. The FDA proposed rules to make drug labeling easier to understand and easier to use for women during pregnancy. This process began 15 years ago with the FDA's Pregnancy Labeling Task Force and led to a proposed rule in 2008. As of today, 4 years later, these rules have not yet been finalized.

In previous inquiries, you told me that pregnancy drug labeling is a priority for FDA. If this rule is a priority, can you commit to me that FDA will finalize these labeling requirements by the end of this year?

Answer. FDA is committed to finalizing a rule that will improve drug labeling for women who are pregnant, and we are diligently working to issue this important rule. Because of the complexity of this rule and the time required to review and finalize this rule, it is not possible to say whether the final rule will publish during 2012.

However, we want to emphasize that, in addition to finalizing the pregnancy and lactation rule, FDA has other important and ongoing projects related to the health of pregnant and lactating women. For example, on April 30–May 1, 2012, as part of the FDA Medical Countermeasures Initiative (MCMi), FDA held a “Public Workshop on Developing Animal Models of Pregnancy to Address Medical Countermeasures for Influenza.”

In addition, FDA has issued five scientific guidance documents relating to pregnancy and lactation that support women’s health:

- Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities (final guidance);
- Establishing Pregnancy Exposure Registries (final guidance);
- Pharmacokinetics During Pregnancy and Lactation (draft guidance);
- Evaluating the Risks of Drug Exposure in Human Pregnancies (final guidance); and
- Clinical Lactation Studies-Study Design, Data Analysis, and Recommendations for Labeling (draft guidance).

#### SEAFOOD CONSUMPTION DURING PREGNANCY

*Question.* In 2004, your agency published an advisory to pregnant women on seafood nutrition, which, unfortunately, had a negative consequence and was interpreted as a warning for all Americans to limit or stop consuming seafood altogether based on concerns over mercury. According to FDA’s own data, pregnant women have reduced their seafood consumption to less than 2 ounces per week since that advisory was issued. The updated U.S. Dietary Guidelines for Americans, released over a year ago, recommend that pregnant women eat at least 8 ounces of seafood per week—a quadrupling of current levels.

Given the stark scientific evidence that women of childbearing years, pregnant women, and mothers with young children are eating too little seafood for their health and their babies’ health, when will FDA finalize and publish an updated advisory for seafood consumption for pregnant women?

Answer. FDA agrees that the fish consumption advice issued in 2004 jointly by FDA and the Environmental Protection Agency (EPA) is in need of an update. We have been working together to issue draft new advice for public comment this year.

*Question.* One of the problems with the current FDA advice to pregnant women is it takes a “risk only” approach that has been misinterpreted by consumers and the media as Federal advice to reduce or stop seafood consumption.

What is the FDA doing to ensure that the updated advice is drafted in a way that includes both benefits and risks and is understandable to the average consumer?

Answer. The Administration currently has several conflicting opinions on seafood advice to pregnant women. NOAA recently released a video called “Fish, Mercury, and Nutrition: The Net Effects” which includes a virtual “who’s who” of leading Government and academic scientists that lay out the science of why eating fish is important for all Americans, especially pregnant and breastfeeding moms. The scientists in the video question the 12 ounce consumption limit created by the FDA stating that it limits the benefits accrued from seafood consumption. The Washington Post ran an article on the front page of the Health section earlier this month that highlighted how the current conflict in seafood advice is confusing consumers.

*Question.* How is the Administration working together to ensure that there is consistent advice across all Federal departments and agencies to pregnant women on the consumption of seafood during pregnancy?

Answer. FDA agrees that the fish consumption advice issued in 2004 jointly by FDA and the Environmental Protection Agency (EPA) needs an update. FDA and EPA have been working together to issue draft new advice for public comment this year.

As you point out, the 2004 advice was risk oriented, in that its primary objective was to limit exposure to methylmercury during pregnancy. Methylmercury is a neurotoxin and the developing fetus can be particularly sensitive to it. Since that advice issued, a number of research studies have consistently indicated that fish consumption during pregnancy can benefit fetal neurodevelopment even though the

fish contain at least some methylmercury. The research further indicates that for most fish, greater consumption can be more beneficial than less consumption, at least up to some point. Evidence shows, however, that the methylmercury in the fish can affect the size of the benefit, or, if exposure is high enough, whether there is a benefit at all. Too much methylmercury could still lead to neurodevelopmental deficits.

Taking these findings into account, the Departments of Agriculture and Health and Human Services updated the Dietary Guidelines for Americans that the two agencies publish every 5 years to recommend that pregnant women eat more fish. As you noted, the Dietary Guidelines for Americans 2010 essentially modified the 2004 FDA–EPA advice by adding a consumption target of 8–12 ounces per week of a variety of fish lower in methylmercury to promote cognitive development. The 2004 advice does not contain a consumption target and, in that respect, is now inconsistent with the advice in the Dietary Guidelines for Americans 2010.

In another development, FDA has performed a quantitative assessment of the net effects of fish consumption during pregnancy on fetal neurodevelopment that has produced results supportive of a consumption target in the range recommended in the Dietary Guidelines for Americans 2010. The FDA assessment was published in draft in 2009 and is now being prepared for publication in final form.

Updated advice should be consistent with the 8–12 oz. per week consumption target for pregnant women for commercial fish as is now recommended in the Dietary Guidelines for Americans 2010. That objective has been fully recognized by FDA and EPA in their joint effort to update their advice. Although updated advice could retain a short list of fish that women should probably avoid during pregnancy—as the Dietary Guidelines for Americans 2010 now does—the advice should also be crafted in a way that does not scare women away from a consumption target well beyond what most women are now eating. Median fish consumption by pregnant women in an FDA survey was 1.8 ounces per week, as you have noted.

It is also imperative that the advice have a solid scientific and analytical basis that is in the public domain. We expect that basis to consist of the research published since 2004, the FDA assessment as described above, and another assessment of the net effects of fish consumption published recently by the Food and Agriculture Organization of the United Nations and the World Health Organization. That assessment produced results consistent with the FDA assessment.

#### SEAFOOD SAFETY

*Question.* Dr. Hamburg, the safety of imported seafood is a significant concern. FDA does not currently have the resources to inspect seafood at the point of origin, and is inspecting less than 2 percent of imported seafood. However, we understand that many seafood buyers already require testing of product in the country of origin, and use third-party organizations, including qualified laboratories, to do this testing. This does have the advantage of detecting unsafe product before it enters the United States. Last year, in both the Senate Report and Conference Statement of Managers, we directed FDA to develop a comprehensive program for imported seafood.

What are you doing to implement this directive? In particular, does FDA currently have the authority to recognize third-party inspection and testing in seafood, and, if so, are you giving this concept any consideration?

*Answer.* FDA regulates imported seafood by, among other things, reviewing U.S. Customs entries, conducting field exams, collecting samples for laboratory analysis, and placing products and processors with a history of problems on detention without physical examination—requiring the importer to demonstrate compliance, usually through third-party analysis, for future shipments. These procedures address the control of pathogens, filth, parasites, decomposition, animal drugs, bio-toxins, and illegal food and color additives in imported fish and fishery products, among other hazards.

The implementation of the Seafood Hazard Analysis Critical Control Program (HACCP) regulation in 1997 initiated a landmark program designed to increase the safety that U.S. consumers already enjoyed and to reduce seafood related illnesses to the lowest possible levels.

Under the HACCP system of controls, the importer and the foreign processor share the responsibility for seafood safety. Foreign processors that ship fish or fishery products to the United States must operate in conformance with the seafood HACCP regulation. In addition, importers are required to take steps to verify that their imported products are obtained from foreign processors that comply with the seafood HACCP regulation. Compliance is verified through inspections.

The FDA Food Safety Modernization Act (FSMA) directs FDA to establish a program for accreditation of third-party auditors to conduct food safety audits to assess foreign food firms for compliance with FDA requirements. Based on audit results, accredited third-party auditors may issue certifications to foreign food firms. In addition, FSMA authorizes FDA to set up a program for accredited laboratories to perform food testing. Neither program is specific to seafood or to any other particular commodity. However, the FSMA requirement is consistent with the report language asking FDA to develop a comprehensive program for imported seafood.

#### BLOOD PLATELETS

*Question.* A recent study in Transfusion showed that the vast majority of bacterially contaminated platelet units are being missed by culture testing performed by the blood collectors and that testing on the day of transfusion detected more than twice as many contaminated units in an inventory where the culture positives had already been removed. While patients can be assured that there is virtually no risk of viral contamination in transfused blood products in the United States, the same cannot be said for bacterial contamination. It is estimated that 1 of every 3000 units of platelets being transfused is contaminated with bacteria at clinically significant levels. What is the FDA doing to make the medical community aware of the safety risks to transfusion patients from bacterially contaminated blood platelets?

*Answer.* FDA has the vital role of ensuring the safety of the approximately 17 million donations of Whole Blood and Red Blood cells collected from approximately 11 million donors each year. These Whole Blood donations are processed into approximately 23 million components, including platelets, which are transfused to approximately 4.5 million recipients.

Bacteria may contaminate platelet products if bacteria are introduced during collection or through the presence of transient bacteremia in blood donors. Because platelets are stored at room temperature, if the product is contaminated, the bacteria can proliferate throughout the storage period. To improve the safety of platelet products, collection centers have implemented a number of measures over the past several years.

FDA has been diligent in its research and regulatory efforts to address and improve the safety of platelet transfusion. FDA has sponsored numerous workshops and advisory committee meetings and taken regulatory actions to address issues related to the bacterial contamination of platelets. Dating back to 1986, FDA reduced the shelf life of platelets from 7 days to 5 days based on reports of septic reactions. In 2003, FDA approved blood bags that facilitate diversion of the first 15 ml of blood collected into a diversion pouch in order to reduce the possibility of bacterial contamination.

FDA has also cleared several bacterial detection devices for the quality control of platelet products. For example, in 2009 FDA cleared the Verax Platelet PGD® Test System for use as a quality control test for the detection of bacteria after platelets derived from whole blood have been pooled, just prior to a patient platelet transfusion. However, because of the complexity involved with the implementation of this test and its variable sensitivity in the detection of bacteria, further consideration is warranted prior to recommending its routine use. Given the continued risk of bacterial contamination of platelets, FDA will continue to collaborate with the transfusion community and will consider implementing additional measures that may further improve the safety of platelet transfusions as technology develops.

#### RARE AND NEGLECTED DISEASES

*Question.* The Food and Drug Administration plays an essential role in capacity-building abroad to help build strong regulatory authorities in other nations. In addition, FDA's funding for new global health tools and its leadership in reviewing and licensing global health technologies is key to sustaining and supporting American investment in this area.

In the 2010 Appropriations legislation for FDA, Congress directed FDA to establish review groups on rare diseases and on neglected diseases of the developing world and to report to Congress on the agency's development of guidance for development of new technologies in these areas.

Would you please provide the Committee an update on the monitoring, evaluation and progress of the "Pathway to Global Product Safety and Quality"? In the update, please provide the following information in discussing the review of drugs and other products for neglected diseases:

—The frequency and barriers to the use of priority review;

- Ways to work with sponsors to facilitate expanded access to investigational products;
- Ways FDA can increase coordination and interaction with the World Health Organization, European Medicines Agency, and other international regulatory agencies on these drugs and products;
- Ways FDA can implement mechanisms to enhance collaboration between the Food and Drug Administration and National Regulatory Authorities in developing countries;
- Ways FDA can increase coordination among individual drug, biological product, and device review divisions across Food and Drug Administration centers to support the development and monitoring of safe and effective medical products for rare and neglected diseases.

Answer. The Pathway to Global product Safety and Quality is a major shift in the regulatory posture of intercepting harmful or contaminated medical products, to anticipating and preventing the arrival of violative and unapproved goods in the United States. As part of its global transformation, FDA is building an international operating model that relies on enhanced intelligence, information-sharing, data-driven risk analytics and the smart allocation of resources through partnerships. The following information addresses the separate issue of review of products for rare and neglected tropical diseases and the collaboration with stakeholders to develop and monitor drug development in this area.

#### *The Frequency and Barriers to the Use of Priority Review*

FDA has an existing priority review policy that is described in our Manual of Policy and Procedures. Products that qualify for priority review based on demonstrating an advantage will receive priority review based on the merits of the drug. FDA also prioritizes review of applications for antiretroviral drug products associated with the President's Emergency Plan for AIDS Relief (PEPFAR Program) drugs, as discussed below, and applications for drugs that are in short supply. There are no barriers to the application of the priority review policy.

#### *The Tropical Disease Priority Review Voucher Program*

Regarding the Tropical Disease Priority Review Voucher program, to date, that program, implemented in 2007, appears to have provided limited, if any stimulus to development of drugs for neglected tropical diseases. One voucher has been issued and redeemed to date. This voucher was received for the approval of artemether-lumefantrine tablets—Coartem®—for treatment of malaria, and the voucher was redeemed for the review of canakinumab for treatment of gouty arthritis.

#### *Ways To Work With Sponsors To Facilitate Expanded Access to Investigational Products*

FDA has specific provisions in its regulations, which were updated just a few years ago, to facilitate access to investigational drugs when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The details in FDA regulations appear at 21 CFR 312 Subpart I—Expanded Access to Investigational Drugs for Treatment Use. This revision of the investigational new drug (IND) regulations, promulgated in 2009, was intended to clarify the procedures for obtaining investigational drugs for treatment use, by describing in detail three categories of expanded access to investigational drugs: Provides clarity for sponsors in characterizing expanded access of investigational products for individual patient use, for use in intermediate-sized patient populations, and for use in a treatment IND or treatment protocol. FDA also issued a companion rule at that time on charging for investigational products, to clarify and expand the number of scenarios where charging would be permitted.

#### *Ways FDA Can Increase Coordination and Interaction With the World Health Organization (WHO), European Medicines Agency (EMA), and Other International Regulatory Agencies on These Drugs and Products*

The Center for Drug Evaluation and Research (CDER) interacts with WHO, EMA, and other international regulatory agencies on an increasingly frequent basis on a variety of review issues. These interactions have promoted a familiarity with one another's programs and processes and lead to increased collaboration on numerous review-based activities.

An example is our collaboration with WHO on the review of antiretroviral drug products associated with the President's Emergency Plan for AIDS Relief (PEPFAR) program. FDA actively worked with companies to facilitate the development and review of applications for fixed dose combination products, in order to help ensure consistent availability of these products under PEPFAR for use in treatment programs.

FDA and the European Medicines Agency collaborate on a regular basis on orphan product designation and development. There is a common application form for submission to both agencies for orphan designation. Sponsors may file a common Annual Report to both agencies. Sponsors are encouraged to seek parallel scientific advice on orphan product development from both agencies. FDA most recently met with the European Union and Japanese regulatory agencies on the common application last February in Japan while at the International Conference for Rare Diseases and Orphan Drugs.

EMA has a program involving WHO which may assist in the development of neglected diseases outside our respective territories, and FDA participates in this program when sponsors seek parallel scientific advice.

With regard to the "Pathway to Global Product Safety and Quality" Report, FDA, EMA, European National Competent Authorities, the European Directorate for the Quality of Medicine, WHO, and Australia's Therapeutic Goods Administration collaborate on information-sharing and joint inspections of the manufacturers of active pharmaceutical ingredients. The program focuses on best use of international inspectional resources and information to help secure the global supply chain.

*Ways FDA Can Implement Mechanisms To Enhance Collaboration Between the Food and Drug Administration and National Regulatory Authorities in Developing Countries*

Since September 2005, CDER has offered the CDER Forum for International Drug Regulatory Authorities every spring and fall. The first nine programs focused on an overview of the CDER review process and major offices. Starting with the 10th program, the focus shifted to the review process and specifically the information posted at DRUGS@FDA to promote a more detailed understanding of the CDER's Review process and the scientific disciplines involved. The CDER Forums are very interactive and promote the possibility of drug regulatory authorities to learn from one another in a collegial way.

To date, regulators from more than 70 countries have participated. Worthy of note is that many countries have now included this activity in their budgets to allow staff to participate in the program on a regular basis.

Interactive modules have been created from CDER Forum lectures and they may be found on the CDER Web site under CDER World. Details on the CDER forum and other activities may be found in FDA's recently published report Global Engagement.

*Ways FDA Can Increase Coordination Among Individual Drug, Biological Product, and Device Review Divisions Across Food and Drug Administration Centers To Support the Development and Monitoring of Safe and Effective Medical Products for Rare and Neglected Diseases*

In 2010, the Center for Drug Evaluation and Research (CDER) established a rare diseases program to increase coordination among the individual offices and review divisions within the Office of New Drugs on the review and regulation of rare diseases and orphan products. This program is due to expand in fiscal year 2013 under the Prescription Drug User Fee Act (PDUFA) V, with increased staff, staff training, guidance, policy and advice generation, and increased coordination and outreach among rare disease stakeholders both within and outside of FDA. PDUFA V will also establish a rare disease liaison within the Center for Biologics Evaluation and Research (CBER) with similar responsibilities. The proposed PDUFA V legislation should contribute to and continue to enhance existing efforts at CDER to facilitate, support, and accelerate rare disease drug development.

To help facilitate medical device applications for rare diseases, the Center for Devices and Radiological Health (CDRH) released final guidance on the Humanitarian Device Exemption (HDE) process in July 2010 as well as draft guidance on the Humanitarian Use Devices (HUD) designation process (with CBER and the Office of Orphan Product Development) in December 2011. The proposed User Fee Amendment legislation should promote increased use of the HDE pathway for devices to treat rare pediatric and adult conditions and further the goal of the availability of medical devices for pediatric populations through continued funding of the consortia grants for medical device development.

*Question.* It is my understanding that Chagas disease is not on the list of neglected diseases as currently defined by the FDA.

Please explain why this is not the case and how the agency could include Chagas disease in its list of neglected diseases in line with the WHO list of Neglected Tropical Diseases.

*Answer.* In addition to the list of tropical diseases provided in section 524(a)(3), other infectious diseases for which there is no significant market in developed na-

tions and that disproportionately affects poor and marginalized populations could be designated as tropical diseases by regulation (section 524(a)(3)(Q)). We have heard from other stakeholders in public comments to us that Chagas disease should be added to the list of neglected tropical diseases. FDA is considering this suggestion as we work through the rulemaking procedures for designating other diseases as tropical diseases. FDA has reviewed a list of tropical infectious diseases that are not specifically listed in section 524(a)(3) and will provide a discussion of why or why not we are to proposing to designate them as tropical diseases in the Notice of Proposed Rulemaking.

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QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

ANTIBIOTICS

*Question.* In 2010, nearly 12.5 million kilograms of antibiotics were used in animal agriculture. It is widely believed that the vast majority of these drugs were given in low doses to healthy animals for the sole purpose helping them gain weight. The overuse of antibiotics in animals has contributed to bacteria resistance and new, more deadly forms of bacteria that were once easily treatable.

Commissioner Hamburg, the Food and Drug Administration's (FDA's) announcement calling on drug companies to help limit the use of antibiotics given to farm animals is a step in the right direction. However, it is important to note that the new guidance is voluntary, and I have real doubts that this industry will make these changes willingly.

What steps are you taking to ensure that companies that do not voluntarily revise their antibiotic use, cause no additional harm to human health?

Answer. FDA is confident that the cooperative framework outlined in the draft Guidance for Industry (GFI) No. 213, Revising Approved Conditions of Use for New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals, will help limit the use of antibiotic given to farm animals, which is why we are initially pursuing this voluntary approach. FDA anticipates that sponsors of affected products should be able to complete implementation of the changes discussed in this draft guidance within 3 years from the date of publication of the final version of this guidance.

FDA will continue to monitor the progress of the voluntary adoption strategy, including the progress of measures intended to facilitate an orderly and minimally disruptive transition. Three years after issuing the final version of GFI No. 213, FDA intends to evaluate the rate of adoption of the proposed changes across affected products. FDA will consider further action, as warranted or required, in accordance with existing provisions of the Food, Drug, and Cosmetic Act (FD&C Act) for those products that have not been updated with the recommended changes through the voluntary process.

*Question.* How much do you expect this policy to reduce the total volume of antibiotic use, in terms of kilograms? What metrics are you using to judge the success of this initiative?

Answer. At this time, FDA does not have detailed drug use data that would enable us to estimate quantitatively the reduction in the total volume of use that would be expected with phasing out the production or growth promotion uses of medically important drugs. However, FDA does believe that eliminating production uses and limiting remaining use to address animal disease under the direction of a veterinarian represents a significant change to how these drugs have been used for decades in animal agriculture.

As discussed in FDA's Guidance for Industry (GFI) No. 209, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," a key objective is to limit the use of medically important antimicrobial drugs in food-producing animals to those uses that are necessary for addressing animal health needs. Animal health needs are to treat, control, or prevent a specifically identified disease. Such uses typically involve drug administration at higher, therapeutic doses, for shorter durations to targeted animals that have a disease or are at risk of disease. In contrast, production or growth promotion uses are not necessary for maintaining animal health. Such uses are not intended to manage any disease and typically involve administering drugs at lower drug doses for prolonged durations to entire herds or flocks of animals.

FDA acknowledges the importance of assessing the effectiveness of measures intended to curb antimicrobial resistance. However, identifying appropriate metrics is challenging. In conjunction with finalizing its plans for implementing the recommendations outlined in GFI No. 209, FDA is considering approaches for assessing

the impact of such measures over time. This includes exploring mechanisms for enhancing the drug sales and distribution data that it already receives and other metrics such as data provided by the National Antimicrobial Resistance Monitoring System (NARMS), to track trends in antimicrobial resistance over time.

*Question.* How does this announcement interact with the recent court ruling that will require FDA modify its approved uses of penicillin and tetracycline?

*Answer.* FDA is continuing its work with the animal pharmaceutical industry, veterinarians, and producer and consumer groups to ensure the judicious use of antimicrobials of human health importance. FDA is studying the opinion and determining how this will affect the voluntary approach outlined in GFI No. 209.

However, to the extent that the court's decision, dated March 22, 2012, is not ultimately reversed on appeal, and if sponsors have not already voluntarily withdrawn the growth promotion indications for their penicillin and tetracycline drug products used in animal feed, the application of the court's opinion would appear to require FDA to initiate mandatory withdrawal proceedings pursuant to section 512(e) of the FD&C Act. The Court's opinion does not address any other medically important antibiotics. Thus FDA does not believe that the March 22 decision precludes FDA from continuing to pursue the voluntary approach to phasing out growth promotion uses for those other drugs. In addition, the court's decision does not affect FDA's implementation of the second principle in GFI No. 209, which uses a voluntary approach to phase in veterinary oversight for approved therapeutic uses of medically important antimicrobial drugs in the feed or water of food-producing animals.

#### ARSENIC IN CHICKEN STUDIES

*Question.* Commissioner Hamburg, I was recently made aware of the John's Hopkins Center for a Livable Future study which suggests that poultry are fed banned antibiotics, low levels of arsenic, caffeine, and over-the-counter drugs—all illegal—in an effort to fatten them up and keep the meat tender.

This concerns me, because consumers have no way of knowing if the chicken they are consuming have been fed these dangerous chemicals.

How is the FDA responding to the industry's use of illegal chemicals in poultry?

*Answer.* FDA is aware of the recent studies published in *Science of the Total Environment* and in *Environmental Science and Technology* that analyzed chicken feather meal for bioaccumulated levels of arsenic and certain pharmaceuticals and personal care products. Scientists at FDA Center for Veterinary Medicine (CVM) are currently working to evaluate the methods used in and conclusions drawn by these studies. FDA takes this kind of information very seriously and, based on the outcome of our evaluation, will act accordingly.

FDA has conducted its own scientific investigation to determine whether the use of the arsenic-based animal drug, roxarsone, causes carcinogenic residues in edible tissues of chickens. As part of this work, FDA scientists developed an analytical method capable of detecting inorganic arsenic in edible tissues. FDA scientists found that the levels of inorganic arsenic in the livers of chickens treated with 3-Nitro, also known as roxarsone—were increased relative to levels in the livers of the untreated control chickens. Based on this information, FDA met with the drug sponsor, Alpharma LLC, a subsidiary of Pfizer Inc., and developed a plan to address the concerns raised by the study. As a result, the drug sponsor voluntarily suspended the sale of the product in the United States.

In addition, FDA and the United States Department of Agriculture's Food Safety Inspection Service (FSIS) and the Environmental Protection Agency (EPA) continue to work collaboratively to control and monitor veterinary drug, pesticide, and environmental contaminant residues in FSIS-regulated foods. FSIS, through the National Residue Program, tests meat, poultry and egg products to verify that tolerances or action levels are not violated. When FSIS identifies violations, FDA uses its enforcement tools to address the violation. This includes issuing warning letters and seizures and injunctions. Throughout the years, the two agencies have pursued a number of cases which have resulted in consent decrees.

*Question.* What research do you have that suggests that drugs like Prozac and Benadryl are safe food additives or food animal drugs?

*Answer.* As mentioned above, scientists at FDA's Center for Veterinary Medicine (CVM) are currently working to evaluate the study that reported finding residues of these drugs and other compounds in feather meal. At this time, FDA has no evidence that U.S. poultry producers are adding these chemicals to animal feed and it remains unclear whether other factors are involved, including exposure to environmental sources of these compounds. As this is the first study to examine feather meal for these types of compounds, additional research is needed to verify the results and to investigate exposure sources.

## FOOD SAFETY

*Question.* In May 2011, the U.S. Department of Agriculture (USDA) received a petition to declare antibiotic-resistant salmonella as an “adulterant” in poultry. This would mean that products containing these bacteria could not be sold. I would support any decision that protects consumers from dangerous pathogens, particularly if that decision allowed USDA to recall contaminated poultry before consumers get sick.

Is FDA collaborating with USDA on this issue of antibiotic-resistant organisms in meat?

*Answer.* Yes, FDA and USDA have worked together on this issue since 1997 when USDA joined FDA’s NARMS program. USDA Hazard Analysis and Critical Control Point (HACCP) samples, which are tested for antibiotic resistance, include retail meat products in the sampling design. The results of this work are published in the NARMS annual reports on FDA’s Web site. In conjunction with HACCP sampling, FDA continues to collaborate with USDA on the collection of additional isolates that are more representative of food animal production. Additionally, with respect to monitoring the use of antibiotics in other nations, FDA works in conjunction with USDA’s Food Safety Inspection Service when residues are identified in imported meat and meat products.

*Question.* The most recent data produced by the FDA’s National Antimicrobial Resistance Monitoring System (NARMS) shows that nearly 30 percent of poultry tested contain antibiotic resistant strains of salmonella. But the monitoring system doesn’t even test for highly dangerous and resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA).

Are there any plans to expand the scope of this important monitoring tool?

*Answer.* Yes, needed improvements are being made to the sampling design for the food animal component of NARMS that will result in more reliable data on antibiotic resistance trends. NARMS is an important monitoring tool and it is critical to have a flexible program that is able to address current and emerging challenges. Regarding MRSA specifically, FDA is well aware of the recent research on this issue. FDA, the Centers for Disease Control (CDC), and USDA are in agreement that the epidemiology of community-associated MRSA does not point to the food supply as an important mechanism for spreading this infection.

## FOOD SAFETY MODERNIZATION ACT

*Question.* Commissioner Hamburg, on January 4, 2011, the President signed the Food Safety Modernization Act into law. This law ensures that we are working to prevent foodborne pathogens from entering the food supply rather than just responding to outbreaks. However, it is now more than a year since enactment and we still have not seen many of the regulations required by this law.

Will you please provide an update on the timeline for the full implementation of the Food Safety Modernization Act?

*Answer.* The numerous provisions of the FDA Food Safety Modernization Act (FSMA) present FDA with a unique opportunity to improve food safety. This also represents an enormous challenge to develop and issue more than 50 regulations, guidance documents, and reports under very tight timeframes. FDA is committed to issuing all of the rules and regulations in FSMA and is prioritizing its work by concentrating first on the rulemakings that will form the foundation of the preventive controls framework envisioned in FSMA. FDA currently has four FSMA proposed rules—Preventive Controls for Human Food, Preventive Controls for Animal Food, Produce Safety Standards, and the Foreign Supplier Verification Program—currently under review with the goal to issue these documents as soon as possible.

*Question.* How does FDA plan to differentiate between high-risk and low-risk products?

*Answer.* The provisions of the FDA Food Safety Modernization Act (FSMA) contain many references to high-risk and low-risk products, facilities, activities, or situations. FSMA frequently mandates that FDA consider risk and be risk-based in its actions. In some sections, FSMA provides criteria for evaluating risk and in other sections it does not. For example, section 204—Enhancing Tracking and Tracing of Food and Recordkeeping—states that each designation of a high-risk food shall be based on:

“(i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;

“(ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic

microorganisms due to the nature of the food or the processes used to produce such food;

“(iii) the point in the manufacturing process of the food where contamination is most likely to occur;

“(iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;

“(v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and

“(vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.”

In implementing the various provisions of FSMA, FDA will consider the specific text related to risk in the relevant section and then, to the extent the text allows, strive to be consistent in our implementation across the provisions.

#### REGISTRY OF LEGITIMATE ONLINE PHARMACIES

*Question.* The Internet has made it shockingly easy for patients to obtain—and become addicted to—prescription drugs. In a report published in January, the National Association of Boards of Pharmacy found that 96 percent of the nearly 9,000 Internet drug outlets it reviewed were not in compliance with pharmacy laws or established industry standards.

These Web sites are increasingly sophisticated, making it difficult for consumers to distinguish between legitimate online retailers and those that unlawfully sell prescription drugs. Oftentimes, illegal online pharmacies impersonate the layout of legitimate pharmacies; claim to be endorsed by Government agencies; or display licenses, phone numbers, and addresses, all to deceive consumers.

I have introduced bipartisan legislation with Senators Sessions, Cornyn, and Schumer to protect consumers from these rogue Internet pharmacies. Because it is so difficult for consumers to distinguish the legitimate online pharmacies from the illegitimate ones, the bill as introduced proposes that FDA create a registry of legitimate pharmacy Web sites. This would make sure consumers are protected by providing accurate information about the legitimacy of pharmacy Web sites. I understand that FDA staff has some concerns with this approach. But the Internet is not going anywhere, and neither is the problem posed by rogue pharmacy Web sites.

Will you work with me to devise solutions to better educate consumers so that they can make informed decisions when they seek to purchase prescription drugs online?

*Answer.* One of our concerns with establishing a list or registry of “legitimate” online pharmacies as a resource for consumers is that the unregulated nature and volume of Web sites on the Internet would make it nearly impossible to monitor and maintain such a list with any form of real-time accuracy of the legitimacy of the online pharmacies. FDA does not have the ability to assure that every site listed in such a registry would always remain safe at the time of purchase. Despite being listed as “legitimate,” an online pharmacy may later decide to sell or dispense illegal products that may cause consumers harm. Additionally, criminals could also use the list to target online pharmacies and masquerade as a listed Web site to sell unapproved, adulterated, or counterfeit medicines. Therefore, consumers could be misled into thinking that the Web sites listed were completely safe sites from which to buy medicines.

FDA looks forward to working with you and other stakeholders on solutions for empowering consumers to make informed decisions when they are considering purchasing prescription drugs online. FDA is committed to educating the public on how to safely buy prescription medicines online and about the risks associated with purchasing prescription drugs on the Internet from illegal Web sites. We currently have educational materials available on FDA’s Web site, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/default.htm>, and continue to research consumer and healthcare professional perceptions about buying prescription drugs online in order to improve these educational materials.

#### DEFINITION OF VALID PRESCRIPTION

*Question.* An estimated 1-in-6 Americans—36 million people—have purchased prescription medication online without obtaining a valid prescription. This has contributed to a growing prescription drug abuse in our Nation.

For example, a man in Wichita, Kansas took eight or nine pills of the muscle relaxant Soma each night to help him sleep, even though the recommended dosage is only one pill every 6 to 8 hours. One morning, his wife found him dead in bed from an accidental overdose of this drug. She had assumed that the pills were being

prescribed by a doctor, but she was wrong. Her husband had obtained the drugs from an illegal Internet pharmacy without ever visiting a doctor.

In another example from my home town, a doctor in San Francisco wrote thousands of prescriptions for painkillers for customers of a rogue Internet pharmacy. The prescriptions were based on brief telephone conversations. The doctor never examined or even met the patients. One patient, who also lived in San Francisco, became addicted to narcotics and developed liver damage after receiving multiple orders of the pain killer Darvocet.

These tragedies occurred because there is a loophole in current law that allows prescriptions for noncontrolled substances to be issued without a patient ever visiting a doctor. In 2008, Congress enacted legislation that I had introduced—the Ryan Haight Online Pharmacy Consumer Protection Act—that requires that a patient receive at least one in-person medical evaluation before prescriptions could be issued for a drug that is a controlled substance. It is time that we extend this provision to cover all prescription drugs, not just controlled substances, and I have introduced bipartisan legislation with Senators Sessions, Cornyn, and Schumer that would achieve this result.

I know that the President's U.S. Intellectual Property Enforcement Coordinator has issued reports that call for "valid prescription" to be defined in the law for prescription drugs that are not controlled substances.

Could you describe why the Administration has taken this position?

Answer. The Administration is correct in being concerned about the lack of a clear Federal definition of a "valid" prescription for the purposes of online drug sales of non-controlled substances. Although it will not solve all problems associated with Internet sales of prescription drugs, creating a national definition of a valid prescription would be helpful to broadly address some of the challenges associated with Internet pharmacies. A uniformly applicable definition of what constitutes a "valid" prescription would be beneficial for all prescription drugs as an enforcement tool, regardless of whether they are controlled or non-controlled substances.

Prescription drugs may only be dispensed upon a prescription ordered by a State-licensed healthcare practitioner for specific patients based on a medical need determined by that healthcare practitioner. To ensure the safe use of a prescription drug, the drugs should be used under the supervision of a licensed healthcare practitioner by law to administer such drug (section 503(b) of the Food Drug & Cosmetic Act).

Illegal online drug sellers (including many located outside the United States) pretend to be legitimate Internet pharmacies and offer prescription drugs for sale without requiring that the purchaser have a valid prescription for such drugs.

FDA is concerned about the public health risks associated with consumers buying prescription drugs from online drug sellers on the Internet, because some of these products, particularly those sold without requiring a valid prescription, may be ineffective and unsafe. Specifically, illegal Internet pharmacies are more likely to offer products that are counterfeit, contaminated, contain the wrong active ingredient(s), have too much or too little active ingredient, are not stored or handled under proper conditions, or are produced under filthy conditions. As a result, consumers may experience adverse health effects.

FDA has several examples demonstrating our concern for the public's safety when using illegal Internet pharmacies to buy prescription drugs:

—A dangerous counterfeit product that was purchased using the Internet, that contained the wrong active ingredient: <http://www.abbott.com/vicodin-consumer-alert.htm>

—A past advisory about foreign products with confusing names or the same name, but that may have different active ingredients than the FDA-approved drug: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/PublicHealthAdvisories/ucm173134.htm>

—FDA found that products purchased from "Canadian pharmacies" actually came from 27 different countries: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108534.htm>

To help U.S. consumers who buy prescription drugs on the Internet protect themselves from receiving unapproved, unsafe, and ineffective drugs, FDA recommends that they buy only from online pharmacies that:

- Are located in the United States;
- Are licensed by the State board of pharmacy where the Web site is operating;
- Have a licensed pharmacist available to answer questions;
- Require a prescription from a doctor or other healthcare professional licensed to prescribe in order to buy a prescription medicine; and

—Provide contact information that allows the consumer to talk to a person if he or she has problems or questions.

Additional advice to consumers about how to buy medicines online safely can be found on FDA's Web site at: <http://www.fda.gov/Drugs/ResourcesForYou/ucm080588.htm>

#### NUTRITION LABELING STANDARDS

*Question.* I have heard from constituents in my State who own restaurant chains like Carl's Junior and Domino's. They are concerned about the implementation of the final rule of section 4205 of the Patient Protection and Affordable Care Act, Nutrition Labeling of Standard Menu Items at Chain Restaurants.

These restaurant chains, which employ thousands of people in my State, are concerned that the implementation of this final rule could be overly burdensome, particularly in these challenging economic times.

I appreciate your request for comments on many parts of the proposed rule, including on the use of stanchions, the declaration of variable menu items, and a discussion of different options for the final rule.

The FDA estimates the initial mean cost of complying with the requirements of the rule will be \$315 million, with an estimated ongoing cost of over \$44 million. I believe this regulation should be implemented in a way that is the least burdensome. In what ways is the FDA working with industry to ensure the final regulations are the least burdensome and least costly?

*Answer.* FDA conducted multiple listening sessions with the industry and other stakeholders when developing the proposed rule. The industry supplied numerous comments in response to the proposed rule and FDA is giving these comments careful consideration in development of the final rule.

FDA examined the impacts of the proposed rule as required under Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits (both quantitative and qualitative) of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

In addition, FDA evaluated the impacts of the proposed rule pursuant to the Regulatory Flexibility Act, which requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA's analysis of the regulatory impact of the proposed rule was made available for public comment and FDA is considering the comments received in developing the final rule.

*Question.* Will you allow any flexibility in deadlines for small businesses to comply with the regulations?

*Answer.* FDA proposed that the final rule become effective 6 months from the date of its publication. FDA also requested comments on whether the effective date should be extended for a greater period of time after the publication of the final rule (76 FR 19192 at 19219). FDA also sought comment on whether we should provide for staggered implementation based on the size of a chain or of a specific franchisee (76 FR 19192 at 19220). FDA is reviewing and considering the comments and will include its decisions on the effective date and on staggered implementation in the final rule.

*Question.* What is the status of the final rule?

*Answer.* FDA is currently reviewing and considering the comments, and developing the final rule.

*Question.* Does the FDA have a target date for implementing the final rule?

*Answer.* FDA will specify the effective date in the final rule when it is published.

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#### QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

##### BIOSIMILARS USER FEE PROGRAM

*Question.* When Congress adopted the Biologics Price Competition and Innovation Act (BPCIA), it did so to ensure a consistent standard during the review process, as well as the same level of expertise with the reviewers as the Prescription Drug User Fee program. As a result of BPCIA, FDA has recently submitted a fee proposal for the review of biosimilar products to Congress.

As a part of this legislative package, why is FDA proposing an additional \$20 million in appropriated funds, commonly referred to as a trigger, for each of the program's 5 years?

Answer. Under the "Biosimilars User Fee Act of 2012" (BsUFA), FDA will allocate at least \$20 million, adjusted for inflation, in non-user fee money for biosimilar review activities to ensure that user fees represent supplemental funding to the biosimilar program and to avoid redirection of resources from PDUFA to BsUFA activities.

*Question.* Does BPCIA include a specific requirement to develop this separate funding trigger?

Answer. BPCIA does not include a specific requirement for funding, but directs FDA to develop a biosimilar user fee program for fiscal years 2013 through 2017. Similar to FDA's other medical product user fee programs, under BsUFA, user fee funding supplements dedicated non-user fee funding to ensure sufficient resources for the biosimilar review program.

#### BIOSIMILARS

*Question.* How did FDA arrive at the \$20 million figure, and what data or information did you use to support at that number? Is FDA currently spending appropriated funds on activities related to biosimilars?

Answer. FDA considers the review of biosimilar biological products, which offer the potential for a safe and effective, and more affordable alternative to innovator biologics to be a high priority. FDA has devoted an increasing amount of resources to the biosimilar program since BPCIA enactment in March 2010. FDA is developing regulatory policies and guidance on the new biosimilar approval pathway, and building the review capacity to facilitate biosimilar biological product development. On February 9, 2012, FDA released three draft guidance documents on biosimilar product development. The draft guidances are "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product", "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product", and "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009." FDA is currently seeking comments on the guidance documents and will consider information received from the public in finalizing the documents. FDA is spending appropriated funds on activities related to biosimilars. During fiscal year 2011, FDA spent \$7.9 million on biosimilar activities.

Characterizing biological products for the purpose of determining biosimilarity or interchangeability is challenging because the molecules of biological products tend to be much larger and have a far more complex spatial structure than small-molecule drugs. Therefore, FDA generally expects the level of effort and expertise required to review biosimilar applications to be comparable to that required to review innovator biologic applications. As a result, the proposed fee levels under BsUFA are similar to the fee levels under PDUFA. Industry agreed to these fee levels only if FDA committed to review performance goals that would quickly become comparable to the goals of the more mature, established PDUFA program. As a result, the proposed performance goals for BsUFA include goals related to meetings with sponsors, application review, and other biosimilar review activities. For certain goals, the target performance levels start at 70 percent and increase to 90 percent by the fifth year of the program, while others begin at 90 percent and remain at this level for the 5 years of the program.

Although FDA has been meeting with, and providing advice to, sponsors of biosimilar product candidates since May 2010, FDA has not received a biosimilar biological product application, and there are no currently marketed biosimilar biological products. The biosimilar program is relatively new, leading to uncertainty regarding future program size and user fee collections. To ensure resources for biosimilar review activities, while avoiding redirection of resources from PDUFA, FDA estimated at least \$20 million in non-user fee money plus biosimilar user fee collections would be required to have sufficient minimum program staffing capacity to be able to achieve these aggressive performance goals in the first 5 years of the BsUFA program.

*Question.* Does this new trigger require Congress to appropriate an additional \$20 million specifically for the biosimilar program each year?

Answer. BsUFA does not require Congress to appropriate funds for the biosimilar program, but requires FDA to spend at least \$20 million each year, adjusted for inflation, in non-user fee money for biosimilar review activities.

*Question.* If the FDA intends to reallocate or reprogram the \$20 million from other FDA existing programs and accounts, from precisely what programs and in what amounts would the funding be derived?

Answer. FDA considers the review of biosimilar products to be a high priority. In fiscal year 2011, FDA received an increase of \$1.8 million in non-user fee money for the biosimilar review program. For fiscal year 2013, if FDA does not receive approximately \$20 million in new budget authority for the biosimilar review program, then FDA must reassess other priorities, and redirect budget authority funding from other programs.

#### DEVICES AND DIAGNOSTICS

*Question.* Guidance documents can be a useful tool to provide flexible, rapid direction to industry and agency personnel on FDA policy or issues. However, the proliferation of guidance documents issued by FDA, particularly the Center for Devices and Radiological Health, has created some confusion in the industry. Issuing numerous guidance documents on related topics over a short timeframe creates a patchwork of industry responsibilities that may be difficult to navigate. The agency claims this “mosaic” will fit together smoothly once all the pieces are issued; however, it is difficult to see the agency’s vision.

Dr. Hamburg, can you help me understand FDA’s end strategy regarding these guidance documents?

Answer. In recent years concerns have been raised both within and outside of FDA about our regulatory review processes. In August 2010, the Center for Devices and Radiological Health (CDRH) released two reports that identified issues regarding our premarket programs and proposed potential actions for us to take to address the underlying root causes. After considering extensive and varied public input on our recommendations, in January 2011, CDRH announced a Plan of Action that included 25 specific actions that we would take to improve the predictability, consistency, and transparency of our premarket programs.

The Plan of Action outlines which recommendations CDRH intends to implement including the identification of eight specific guidance documents that will help CDRH to better meet its mission of protecting and promoting the public health. To date six of the eight originally identified guidance documents have been issued in draft.

FDA believes the actions identified in the Plan for Action, including the associated guidance documents, will strengthen our premarket review programs. By increasing the predictability, reliability, and efficiency of our regulatory pathways, FDA can help ensure that better treatments and diagnostics are provided to patients more quickly, stimulate investment in and development of promising new technologies to meet critical public health needs, and increase the global market position of U.S. medical devices.

A detailed report informing constituents of the many actions CDRH is undertaking to improve its premarket programs is available on FDA’s Web site: (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm276272.htm>).

*Question.* Until recently, FDA has exercised enforcement discretion when diagnostic products labeled Research Use Only (RUO) are used in clinical settings. Some are concerned that ending this practice will result in manufacturers discontinuing many RUO products, thus limiting patient access to innovative diagnostics, particularly in the personalized medicine arena.

Can you comment on whether you believe FDA is striking the right balance between protecting the public health and ensuring patient access to new therapies?

Answer. FDA believes that products intended for use in patient diagnosis should not be marketed or distributed with the label, “For research use only. Not for use in diagnostic procedures.” FDA has not had a policy of enforcement discretion for Research Use Only—or RUO—labeled products that are marketed for clinical diagnostic use. Our regulations, promulgated in 1976, require manufacturers to label products consistent with their intended use. Because RUO products are not intended to affect patient care, they are exempt from the safety-oriented regulatory controls applied to medical devices that are intended for diagnostic use. This exemption facilitates the marketing and shipping of devices that are intended for research use only by not requiring the same level of regulatory controls that are required for devices which are used to make patient management decisions.

The RUO draft guidance was issued June 11, 2011. The policies outlined in the draft guidance are supported by longstanding statutory and regulatory requirements; the RUO labeling regulation was originally promulgated on March 15, 1973, and the definition of intended use for devices was promulgated on February 13, 1976. The purpose of the draft guidance is to leverage our enforcement resources by reminding companies that these regulatory requirements exist, that FDA does enforce them, and that by ignoring these regulations, companies may be causing

their devices to be adulterated and/or misbranded under the Federal Food, Drug, and Cosmetic Act.

In finalizing the guidance, we will carefully consider how the guidance might affect access and availability of certain products, and will take steps to assure that the public health is not put at risk.

*Question.* It has been brought to my attention that FDA's recent guidance on Research Use Only products could restrict patient access to important diagnostics by restricting sales of these products. Does the agency have any evidence of patients being harmed by Research Use Only products? What is the agency's sense of the scope of this perceived problem?

*Answer.* Because RUO products are exempt from the usual regulatory controls applied to medical devices, including exemption from registration of the manufacturer and listing of the devices sold, and the requirement to report adverse events to FDA, we do not typically receive reports of RUO device failures and malfunctions, or any adverse events related to such failures and malfunctions. However, we have encountered examples of advertisements, package inserts, and other marketing materials in which a device labeled for research use and not in compliance with FDA device regulations is promoted for clinical diagnostic use. We are also aware of anecdotal evidence that use of such products may have contributed to incorrect diagnoses, and errors in public health actions.

We believe that clinical diagnostic use of products that are not labeled for diagnostic use and do not comply with FDA regulations presents safety concerns, in part because there is no assurance that such products are manufactured in any controlled way. There is also no assurance that such products perform as stated, that manufacturers will address problems with these products, that there will be uniformity between products of the same type, or that potential users will be notified if the products are defective or could cause harm.

In finalizing the guidance, FDA will carefully consider how the guidance might affect access and availability of certain products, and will take steps to assure that the public health is not put at risk.

*Question.* FDA's current regulatory principles hold manufacturers responsible only for their own actions and clearly state that "intended use" is determined by objective actions taken by the manufacturer, such as product claims. Under the draft RUO guidance, FDA's position on this matter has changed significantly. The draft guidance states that a product is subject to regulation based on how a customer uses the product, even if the manufacturer has labeled and promoted it properly.

What is the basis for FDA's position that a manufacturer's knowledge of its customer's use of the product—rather than the manufacturer's conduct—makes the product subject to device regulations?

*Answer.* We do not believe the draft RUO guidance represents a significant change, as the regulations governing RUO labeling and the definition of intended use that underlie the policies announced in the draft guidance have been in place since 1973 and 1976 respectively. Under these regulations, a manufacturer has the responsibility to label devices consistent with their intended use, and intended use may be shown by the circumstances surrounding the distribution of the device, including knowledge of actual use. We have observed a striking increase in marketing of products that clearly have a diagnostic purpose under the RUO label, and wish to remind manufacturers that putting an RUO label on a product and then marketing it for diagnostic use is violative.

We consider a number of factors when determining whether a manufacturer is in violation of the labeling requirements and believe a "totality of the evidence" approach is appropriate to determining whether a manufacturer has acted in accordance with the regulations.

#### MENU LABELING

*Question.* FDA is currently working on the final rule in regards to menu labeling. This is a tremendous undertaking for restaurants. Specifically, the law recognizes that the making of restaurant meals is different than manufacturing packaged foods and thus was explicit about the use of "reasonable basis" to enforce the law.

Do you intend to follow the intent of the law in regards to uniform enforcement with "reasonable basis"? What is your current thinking on how to approach this issue?

*Answer.* Section 4205 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) states that "a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of title 21, Code of Federal Regulations (or any successor regula-

tion) or in a related guidance of the Food and Drug Administration” (21 U.S.C. 343(q)(5)(H)(iv)). FDA specifically requested comment on the appropriateness of its compliance approach in the proposed rule (76 FR 19192 at 19218). The comment period for the proposed rule closed on July 5, 2011, and FDA received comments, including comments from other members of Congress, on the issue of reasonable basis. We assure you that FDA will consider alternative solutions to address this complex issue. We evaluate all comments before issuing a final rule.

#### ANTIMICROBIAL RESISTANCE

*Question.* What are the metrics FDA will use to measure “success” of the recently released Guidance No. 209?

*Answer.* FDA acknowledges the importance of assessing the effectiveness of measures intended to curb antimicrobial resistance, but recognizes that identifying appropriate metrics as indicators of “success” is challenging. In conjunction with finalizing its plans for implementing the recommendations outlined in Guidance for Industry (GFI) No. 209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” FDA is considering approaches for assessing the impact of such measures over time. This includes looking at other metrics such as, exploring mechanisms for enhancing the drug sales/distribution data that we already receive and National Antimicrobial Resistance Monitoring System (NARMS) data to track trends in antimicrobial resistance over time.

*Question.* The National Antimicrobial Resistance Monitoring System (NARMS) has been a collaboration between FDA, the Centers for Disease Control (CDC), and USDA. I have been informed that FDA is planning on discontinuing funding to USDA while continuing to fund CDC. If NARMS data is one potential metric to be used to measure the impact of Guidance No. 209 does FDA feel that program can be viewed as impartial and unbiased if the FDA does not have input from outside HHS in survey design and data collection?

*Answer.* FDA has been working collaboratively with its USDA and CDC partners in developing a strategy for instituting enhancements to the NARMS program. We do not expect this strategy to reduce total funding to USDA, but rather it provides for a redeployment of funding within USDA to provide for significant improvements in sampling design for the food animal component of NARMS. The NARMS program has and will continue to be a collaborative effort between FDA, CDC, and USDA. The changes that are currently under development will serve to enhance the NARMS program and strengthen the utility of its data for supporting efforts to address antimicrobial resistance.

*Question.* If metrics such as antibiotic resistance do not decrease, what does FDA see as next steps?

*Answer.* As noted above, identifying appropriate metrics for assessing the effectiveness of measures implemented to curb antimicrobial resistance is challenging. In addition, FDA expects that such metrics will need to be observed over a number of years in order to identify any trends in the data. The strategy outlined in Guidance No. 209 and draft Guidance No. 213 represents an appropriate path forward for addressing this important public health issue in a manner that also ensures that animal health needs continue to be met. If following implementation of the recommended changes, assessments do not indicate positive effect. FDA will evaluate what additional measures, if any, may be needed.

#### QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

##### ADDRESSING DRUG SHORTAGES

*Question.* Has the Food and Drug Administration (FDA) evaluated whether policies and regulations of the Drug Enforcement Administration (DEA) have contributed in any manner to the drug shortage problems we are currently seeing in our country?

*Answer.* FDA and DEA are continuing to work together to address evolving and potential drug shortages of critical care medications and prescription drugs. FDA applies the full range of regulatory and administrative tools available and engages in extensive cooperative efforts with DEA to manage issues associated with this public health crisis. These efforts are designed to avoid the concern raised by your question.

*Question.* Does the FDA study or plan to study whether DEA policies and regulations contribute to drug shortage problems?

*Answer.* FDA is not studying whether DEA policies and regulations contribute to drug shortage problems. However, we understand that the Government Account-

ability Office (GAO) intends to conduct a study of the extent to which the Drug Enforcement Administration policies and regulations contribute to the growing drug shortage crisis with regard to controlled substances prescribed by physicians. FDA will support this GAO study as needed.

*Question.* What collaborative efforts does FDA engage in with the DEA to address drug shortages that may be caused by some degree by current DEA quotas?

*Answer.* FDA is very concerned about drug shortages and is working diligently with firms, stakeholders, and other Federal agencies as appropriate. The amount of raw material that a firm can make of a controlled substance is under the purview of DEA. However, when firms have notified FDA that additional raw material is needed to avoid shortages of controlled substances, FDA has worked closely with DEA to notify DEA of the potential for shortage. FDA and DEA are continuing to work together to address evolving and potential drug shortages of critical care medications and other prescription drugs. At this time, FDA is working closely with DEA to respond to shortage reports being shared with both organizations.

#### MENU LABELING

*Question.* As you stated, and was stated in the proposed rule, one of the alternatives that FDA is considering is option 2, which would narrow the scope of menu labeling regulations to only restaurants and retail establishments whose primary business is the selling of restaurant or restaurant-type food. Since I'm assuming that the proposed rule was cleared by FDA's General Counsel's office, then FDA can implement the restaurant menu labeling regulations under the option 2 alternative and remain in compliance with the law, correct?

*Answer.* Section 4205 of the Affordable Care Act requires that certain chain restaurants and similar retail food establishments disclose nutrition information for standard menu items. As we discussed in the proposed rule, the statutory term "restaurants and similar retail food establishments" is ambiguous, and it is possible to imagine a range of interpretations.

FDA proposed an interpretation alongside alternatives for public comment (76 FR 19192 at 19195–19196). Accordingly, in the proposed rule, FDA presented the approach of option 2 as an alternative to the proposed definition of "restaurant or similar retail food establishment" (76 FR 19192 at 19198), and considered the costs and benefits of option 2 as a regulatory alternative under Executive Orders 12866 and 13563 (76 FR 19192 at 19223). Option 2 includes requirements similar to the proposed rule, but defines "restaurant or similar retail food establishment" as retail establishments where the sale of restaurant food or restaurant-type food—as opposed to food in general—is the primary business activity. Option 2 covers all establishments included in the proposed rule, with the exception that grocery and convenience stores would not be subject to the proposed requirements. FDA specifically requested comment on the proposed definition of "restaurant or similar retail food establishment" and on the alternatives, and is reviewing and considering the comments received as we are developing the final rule.

*Question.* Can you explain how President Obama's Executive Order 12866 and Executive Order 13563 have impacted your proposed implementation? Would the option 2 alternative fulfill Executive Order 12866 and Executive Order 13563 by minimizing burdens while achieving the statutory directives? Can you demonstrate that you are taking the least burdensome path in implementing these regulations?

*Answer.* Under Executive Orders 12866 and 13563, FDA examined the regulatory impacts of the proposed rule and assessed the costs and benefits of a number of regulatory alternatives. The proposed rule reflects FDA's tentative conclusion that the benefits of the proposed rule justify the costs as required by Executive Order 12866, and that the proposed rule is "the least burdensome tool for achieving [the] regulatory ends" of the statute as required by Executive Order 13563. In the proposed rule, FDA identified option 2 as a regulatory alternative to the proposed rule, and assessed its benefits and costs. We will review and consider comments on our preliminary regulatory impact analysis of the proposed rule and the regulatory alternatives in selecting the regulatory approach in the final rule that minimizes costs and maximizes net benefits.

*Question.* Can you explain why, under "option 1" or the proposed rule itself, you use foods that already have nutritional information labeled or displayed under the Nutrition Labeling and Education Act (NLEA) as a trigger for establishments to be captured under this regulation?

*Answer.* FDA considered comments received prior to the publication of the proposed rule as well as the language and purpose of section 4205 when considering the scope of establishments covered by section 4205 and deliberating on how to define "restaurants and similar retail food establishments" in the proposed rule. FDA

proposed that that the term “restaurant or similar retail food establishment” means a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of that establishment (76 FR 19192 at 19197). FDA refers to this definition in the Preliminary Regulatory Impact Analysis (PRIA) as “option 1.”

In the proposed rule, FDA also offered an alternative to this proposed definition. Under this alternative, a restaurant or similar retail food establishment means a retail establishment where the sale of restaurant or restaurant-type food—as opposed to food in general is the primary business activity of that establishment (76 FR 19192 at 19198). Therefore, neither the proposed definition of “restaurant or similar retail food establishment” nor the alternative definition uses the sale of packaged food that is required to bear nutrition information on its label under the Nutrition Labeling and Education Act (NLEA) as the trigger for establishments to be covered by section 4205. FDA asked for comment on the proposed and alternative definitions as well as any other option for defining the term “restaurants and similar retail food establishments.”

We further note that in the proposed rule, FDA tentatively concluded that some packaged food offered for sale in covered establishments is “food served in restaurants or other establishments in which food is served for immediate consumption or that is sold for sale or use in such establishments,” and would therefore meet the definition of “restaurant food.” To the extent that packaged food is “restaurant food” and otherwise satisfies the requirements of section 4205, such packaged food would be covered by the menu labeling requirements. FDA recognizes that such packaged food includes on its label the nutrition information required by the NLEA and in the proposed rule, has provided some flexibility to industry for satisfying the requirements of section 4205 (76 FR 19192 at 19217).

*Question.* In the proposed rule, FDA uses the term “restaurant-type” food even though that term is nowhere in the statute. Can you explain how you came up with that term and then why you created a new food category (restaurant-type food) to cover another category beyond “restaurant food”?

*Answer.* The 1990 NLEA amendments included exemptions for nutrition labeling for two categories of food:

- Food “which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or used in such establishments,” and
- Food “which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is the type described in [(1)] and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment” (21 U.S.C. 343(q)(5)(A)(i) and (ii)).

The terms “restaurant food” and “restaurant-type food,” as used in the proposed rule, reflect these two categories of food. As explained in the proposed rule, we looked to this statutory context as a starting point for developing a regulatory definition of the term “restaurants and similar retail food establishments,” as used in section 4205 of the Affordable Care Act (76 FR 19192 at 19196). We are reviewing and considering comments that address the scope of establishments covered by section 4205 as we develop the final rule.

*Question.* Have you accounted for how much the proposed rule’s definition of “restaurant-type” food, as “food not sold for immediate consumption, but ready for human consumption and processed or prepared in a retail establishment”, which is sold at practically every grocery store, expands the scope of the regulations?

*Answer.* In the proposed rule, FDA proposed that a restaurant or similar retail food establishment be defined as a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of that establishment (61 FR 19192 at 19233). The proposed rule—option 1—therefore encompasses grocery stores that are chain retail food establishments as defined in the proposed rule. In the proposed rule, FDA also estimated the cost of an alternative to this proposed definition—option 2—that limits the definition of “restaurant or similar retail food establishment” to retail establishments where the sale of restaurant food or restaurant-type food is the primary business activity, and therefore excludes grocery stores from the coverage of section 4205 (76 FR 19192 at 19223). Comparing option 1 to option 2 shows that covering grocery stores and convenience stores adds about \$10.9 million to the cost of the proposed rule. FDA has received comments on the scope of establishments covered by section 4205 and will address this issue in its response to comments in the final rule.

*Question.* Have you accounted how the term “restaurant-type” food also expands the number of items that would be regulated, particularly for grocery stores?

Answer. The Preliminary Regulatory Impact Analysis (PRIA) did not estimate the extent to which the definition of restaurant-type food expands the number of items that would be regulated. FDA has received comments on this issue and will address this issue in its response to comments in the final rule.

*Question.* Please provide a revised estimate of the costs of option 1 to grocery stores based on your use of “restaurant-type food” and compare it with the costs estimated in your PRIA and by the Office of Management and Budget (OMB) in its September 2010 paperwork burdens report.

Answer. FDA has received comments on this issue and FDA is giving those comments careful consideration in the development of the final rule.

*Question.* In FDA’s cost-analysis, there appears to be very few—if any—studies showing a change in diets, obesity rates, health costs, and clearly no economic benefit that can be attributed to menu labeling. Can you compare the economic benefits of expanding these regulations to grocery stores versus the added costs to retailers?

Answer. The Preliminary Regulatory Impact Analysis references the following studies showing a change in diets attributed to menu labeling:

- Bollinger, B., P. Leslie, and A. Sorensen. “Calorie Posting in Chain Restaurants.” *American Economic Journal: Economic Policy*, 2011, 3(1): 91–128, 2011.
- Bassett, M. T., T. Dumanovsky, C. Huang, L. D. Silver, C. Young, C. Nonas, T. D. Matte, S. Chideya, and T. R. Frieden. “Purchasing Behavior and Calorie Information at Fast-Food Chains in New York City, 2007.” *American Journal of Public Health*, 98(8):1457–59, 2008.
- Downs, J.S., G. Lowenstein, and J. Wisdom, J. “The Psychology of Food Consumption: Strategies for Promoting Healthier Food Choices”. *American Economic Review: Papers & Proceedings*, 99(2): 159–164, 2009.
- Elbel, B., J. Gyamfi, and R. Kersh. “Child and Adolescent Fast-Food Choice and the Influence of Calorie Labeling: A Natural Experiment,” *International Journal of Obesity*, Advance online publication, February 15, 2011.
- Elbel, B., R. Kersh, V. L. Brescoll, and L. B. Dixon. “Calorie Labeling And Food Choices: A First Look At The Effects On Low-Income People In New York City.” *Health Affairs*, 28(6):W1110–W1121, 2009.
- Finkelstein, E.A., L. Kiersten, N.L. Strombotne, L. Chan and J. Krieger. “Mandatory Menu Labeling in One Fast-Food Chain in King County, Washington,” *American Journal of Preventive Medicine*, 40(2):122–127, 2011.
- Tandon, P. S., J. Wright, C. Zhou, C. B. Rogers, and D. A. Christakis. “Nutrition Menu Labeling May Lead to Lower-Calorie Restaurant Meal Choices for Children.” *Pediatrics*, 125(2):244–48, 2010.
- Yamamoto, J.A., J.B. Yamamoto, B.E. Yamamoto, and L.G. Yamamoto. “Adolescent Fast Food and Restaurant Ordering Behavior with and without Calorie and Fat Content Menu Information.” *Journal of Adolescent Health*, 37: 397–402, 2005.

Comparing option 1 to option 2, FDA estimates that covering grocery stores and convenience stores adds about \$10.9 million to the cost of the proposed rule. FDA spent a significant amount of time considering the regulatory impact of the scope of establishments covered by section 4205. FDA will continue to consider the costs and benefits of covering grocery stores as we develop the final rule, and will address this issue in its response to comments in the final rule.

*Question.* Have you factored in the cumulative effect of regulatory burdens that grocery stores already face as compared to restaurants?

Answer. Executive Order 13563, which states that to the extent permitted by law, each agency must take into account “among other things, and to the extent practicable, the costs of cumulative regulations,” was issued on January 18, 2011. FDA published the proposed rule on April 6, 2011. The Office of Management and Budget (OMB) issued guidance on how to consider the cumulative effects of regulations, as directed by Executive Order 13563, on March 20, 2012, nearly 1 year after FDA published the proposed rule. FDA did not have sufficient time to estimate the cumulative effect of regulations for the proposed rule. However, FDA will carefully consider OMB’s guidance, and to the extent permitted by law and practicable, FDA will take active steps to take account of the cumulative costs of new and existing rules in the final rule.

*Question.* The House Appropriations Committee included the following Report Language in support of FDA’s option 2 alternative for restaurant menu labeling with the fiscal year 2012 Agriculture Appropriations bill that was later accepted by the Senate-House Conference Committee when it reached final agreement and approved FDA:

- Nutrition Labeling.*—The Committee is concerned with the proposed rule that FDA issued on April 6, 2011, on nutrition labeling of standard menu items in

restaurants and similar retail food establishments. The proposed rule would include establishments that are not primarily in the business of selling food for immediate consumption or selling food that is prepared or processed on the premises. These establishments are not similar to restaurants and the Committee believes that FDA should define the term “restaurant” to mean only restaurants doing business marketed under the same name or retail establishments where the primary business is the selling of food for immediate consumption. The Committee urges FDA to use the proposed alternative definition in the rule that would encompass only establishments where the primary business is the selling of food for immediate consumption or selling food that is prepared and processed on the premises.

Please explain how your agency has considered this report language.

Answer. In addition to the report language that you cite, FDA received comments in response to the proposed rule that also support option 2, the proposed alternative definition of “restaurant or similar retail food establishment.” FDA will fully consider the comments received in response to the proposed rule as we develop our final rule. We want to clarify that under option 2, the term “restaurant or similar retail food establishment” means a retail establishment where the sale of restaurant or restaurant-type food—as opposed to food in general—is the primary business activity of that establishment. Restaurant-type food means food of the type described in the definition of restaurant food that is ready for human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside the establishment. Therefore, option 2 would not define “restaurant or similar retail food establishment” to exclusively mean establishments where the primary business activity is the sale of food for immediate consumption.

#### INTERNAL EFFICIENCIES

*Question.* USDA Secretary Vilsack has procured significant savings from increased operational efficiencies within USDA. He has reduced travel, utilized early retirement programs, and consolidated cell phone contracts from over 700 to 10. Secretary Vilsack saved approximately \$90 million with these actions. In addition, the Farm Service Agency (FSA) office consolidation initiative will save approximately \$60 million a year. Has FDA considered any actions like these, as opposed to raising taxes on food makers? Perhaps you could look at eliminating duplication with State inspections, or maybe some internal budget reductions?

Answer. FDA has proposed savings as part of our fiscal year 2013 budget related to information technology expenditures. The estimate of IT savings for fiscal year 2013 is \$19.7 million, and the savings will occur in three areas.

First, FDA has been working to consolidate its IT infrastructure into more modern data center facilities. During fiscal year 2013, we will realize \$6.0 million in savings as due to our consolidation efforts. Second, we are launching an initiative to reduce the number of redundant laptops and other IT devices. This effort will produce \$5.1 million in savings. Finally, other initiatives across all FDA programs will yield an additional \$8.6 million in IT savings. The other initiatives include retiring legacy IT systems, modifying IT business processes, and other forms of IT database savings.

#### MEDICAL RESEARCH

*Question.* Since the FDA Accelerated Approval process began, of the 80 products approved under Accelerated Approval, 32 have targeted AIDS, 29 cancer, and 20 all other disorders. (Source: Janet Woodcock, “FDA User Fees 2012: How Innovation Helps Patients and Jobs,” Statement before the Committee on Energy and Commerce Subcommittee on Health, U.S. House of Representatives, April 18, 2012, p. 7.) Similarly, a recent study by Friends of Cancer Research highlighted the agency’s performance for oncology drugs, noting that most novel oncology products have been approved in the United States ahead of Europe. (Source: Samantha A. Roberts, Jeff D. Allen, Ellen V. Sigal, “Despite Criticism of the FDA Review Process, New Cancer Drugs Reach Patients Sooner in the United States,” Health Affairs, June 2011.) Clearly, cancer is an area where agency processes seem relatively consistent and predictable. However, there is growing concern that in other important public health and unmet medical needs areas—diabetes, cardiovascular disease, obesity, and central nervous system (CNS) conditions for example—FDA review processes are viewed as increasingly unpredictable and inconsistent. Understanding that the science across these various areas are very different, what is the agency doing to improve these variances?

Answer. The Accelerated Approval program has been a great success in bringing innovative new drugs to patients with serious or life-threatening diseases in a timely manner. While it is true that the program has been used most often in approval of drugs to treat cancer and HIV/AIDS, Accelerated Approval applies across all therapeutic areas where the science supports approval and the conditions established in the statute and regulations are met. FDA is actively working to improve awareness of this pathway for interested stakeholders and FDA staff. There are other initiatives in place to accelerate development and approval of important new drugs, including the Fast Track Program, Rolling Review, and Priority Review. These programs apply across the spectrum of therapeutics and have been used frequently to facilitate rapid development and approval of innovative medicines. Moreover, FDA recognizes the need for these new drugs and actively works with sponsors to facilitate the development of their safety, effectiveness, and high quality. FDA conducts over 2000 formal meetings with drug sponsors each year to discuss drug development programs. Also, the FDA publishes guidance documents outlining its current thinking on topics such as development of a drug for a specific disease and broader topics such as use of adaptive trial designs.

*Question.* What metrics and data does the agency use, similar to that reported in the aggregate in its annual user fee performance reports, to monitor and address performance variances across its internal review divisions?

Answer. In the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), senior management conduct ongoing oversight of the advice given and decisions made by the therapeutic review divisions and we carefully track the performance of divisions in meeting PDUFA review goals. As part of the proposals for PDUFA V there will be programs to further strengthen FDA's capacity to respond to the rapidly changing science in areas such as pharmacogenomics, patient reported outcomes, meta-analyses, and rare disease drug development. These programs are expected to enhance our interactions with sponsors across the various therapeutic review divisions, which should streamline the development and approval of innovative new drugs to meet unmet medical needs.

#### ANIMAL ANTIBIOTICS

*Question.* Farmer's and rancher's number one priority is taking care of their livestock and producing a safe and healthy food supply. Recently FDA issued concerning guidance about antibiotic use that suggests farmers and ranchers are not caring for livestock in the most appropriate way possible.

Why did FDA issue this guidance?

Answer. Current science supports the finding that widespread use of antimicrobials for growth promotion in animals can contribute to the emergence of drug resistance which may be transferred to humans, thereby reducing the effectiveness of these drugs for treating human disease. To address this concern, FDA's Guidance for Industry No. 209 is intended to ensure that medically important antibiotics are used judiciously in food-producing animals by recommending a pathway to limit their use, in consultation with a veterinarian, to only address the health needs of animals, namely to treat, control, or prevent disease.

*Question.* Was this guidance based on peer reviewed science?

Answer. A variety of recognized international, governmental, and professional organizations have studied the judicious use of medically important antimicrobial drugs. Within the Guidance for Industry No. 209, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," we have briefly summarized the findings and recommendations from some of the notable reports and peer-reviewed scientific literature that have addressed this issue over the past 40 years. These reports provide context to FDA's current thinking on this issue, and highlight the longstanding concerns that have been the subject of discussion in the scientific community as a whole.

*Question.* Can you provide me with the scientific evidence that supports the guidance that you issued?

Answer. Below is a list of some of the scientific literature that FDA considered in developing the Guidance for Industry No. 209, including some key reports and peer-reviewed scientific literature. This list is not an exhaustive summary of the scientific literature, but only highlights some of the more recent scientific research related to the use of antimicrobial drugs in animal agriculture and the impact of such use on antimicrobial resistance. We acknowledge that a significant body of scientific information exists, including some information that may present equivocal findings or contrary views.

—1. 1969 Report of the Joint Committee on the Use of Antibiotics in Animal Husbandry and Veterinary Medicine.

- 2. 1970 FDA Task Force Report, “The Use of Antibiotics in Animal Feed.”
- 3. 1980 National Academy of Sciences Report, “The Effects on Human Health of Subtherapeutic Use of Antimicrobial Drugs in Animal Feeds.”
- 4. 1984 Seattle-King County Study: “Surveillance of the Flow of Salmonella and Campylobacter in a Community.”
- 5. 1988 Institute of Medicine (IOM) Report: “Human Health Risks with the Subtherapeutic Use of Penicillin or Tetracyclines in Animal Feed.”
- 6. 1997 World Health Organization (WHO) Report, “The Medical Impact of Antimicrobial Use in Food Animals.” <http://whqlibdoc.who.int/hq/1997/WHO EMC ZOO 97.4.pdf>
- 7. 1999 National Research Council (NRC) Report: “The Use of Drugs in Food Animals—Benefits and Risks.”
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## QUESTIONS SUBMITTED BY SENATOR JOHN HOEVEN

*Question.* I would like to ask you about the Food and Drug Administration's (FDA's) lack of enforcement action against companies that market products as being eyelash growth promoters, without FDA approval, when those products contain prostaglandin analogues (PGAs) or derivatives of PGAs. North Dakota has ophthalmologists who prescribe Latisse, the FDA-approved drug counterpart to these cosmetic products and I am concerned these alternative cosmetic products may pose a public health threat to those that purchase them, such that additional enforcement action may be beneficial.

I understand that this issue was raised before the House Appropriations Subcommittee on Agriculture on February 29, 2012, and you stated that you planned to further investigate the issue.

What have you and the agency done since that hearing in February to address this issue and, if necessary, to protect consumers?

*Answer.* Consistent with FDA priorities, resources, and legal authorities, FDA's objective is to identify, investigate, and take corrective action against violative products. If violations are identified, FDA uses a variety of enforcement tools to address these violations and to facilitate compliance and protect the public health. These tools include but are not limited to warning letters, seizures, injunctions, and criminal prosecution. We appreciate and share your concerns about the potential risks posed by eyelash products that contain PGAs or their derivatives and are marketed as cosmetics. FDA will communicate information regarding any action taken related to these products when that information is available for disclosure.

*Question.* Would the agency be willing to release a public health advisory about the health risks associated with the products so that the State Attorneys General can police the sale of these products, if necessary?

*Answer.* FDA shares your concern about these PGA-containing products marketed as cosmetics. FDA is considering your suggestion and is committed to protecting the public from potential harm. We encourage the ophthalmologists in your State to submit any adverse events related to these PGA-containing eyelash products to FDA's Medwatch Adverse Event Reporting program.

## QUESTIONS SUBMITTED BY SENATOR FRANK R. LAUTENBERG

*Question.* The Family Smoking Prevention and Tobacco Control Act of 2009 specifically banned candy flavorings in cigarettes. Now, tobacco companies are using flavored cigars to encourage kids to smoke. Cigars with candy-like flavorings such as strawberry, watermelon, vanilla, and chocolate attract kids to smoking and help hook them on this addictive habit. An estimated 1.8 million high school students and 475,000 middle school students smoke cigars. The Centers for Disease Control (CDC) estimates that, in 13 States, more high school males smoke cigars than smoke cigarettes. Does the Food and Drug Administration (FDA) believe youth cigar smoking is a problem? What is the agency doing to stop this epidemic and appropriately regulate flavored cigars?

*Answer.* The restriction on cigarettes with characterizing flavors is in effect and is actively being enforced. With respect to products other than cigarettes, FDA is pursuing a proposed rule to deem all products meeting the statutory definition of "tobacco product" to be subject to the Food, Drug, and Cosmetic Act (FD&C Act). This would enable FDA to take further action with respect to flavorings in other tobacco products if FDA concludes that it is appropriate to do so in order to protect the public health.

FDA is currently engaged in research that is exploring the role that flavorings play in prompting the initiation and use of various tobacco products, particularly among youth. FDA is also continuing to evaluate the impact of menthol on youth initiation, and will determine what action, if any, is appropriate based on the scientific evidence.

*Question.* The myth of the healthier cigarette continues to threaten the well-being of Americans. For decades, tobacco companies claimed that some cigarettes were "light," "mild," or "low," misleading Americans about the safety of the products. The Family Smoking Prevention and Tobacco Control Act helped put an end to this deceptive marketing, specifically prohibiting companies from using terms like "light," "mild," "low," or "similar descriptors." However, the agency has failed to offer any regulations or guidance restricting the use of "similar descriptors," and cigarette companies continue to use words like "natural," "organic" and "smooth" to mislead consumers about the health of their products. When does the agency plan to issue guidance or regulations on the use of "similar descriptors"? What is the FDA doing to prevent this deceptive marketing?

Answer. FDA has been actively enforcing the modified risk tobacco product provisions of the FD&C Act, particularly the provisions that pertain to reduced risk of disease, reduced level or lack of a substance, and the use of the descriptors “light,” “low,” and “mild” on regulated tobacco product label, labeling, and advertising. FDA has not, at this time, issued a regulation or guidance that specifically defines the term “similar descriptors” and has been gathering information regarding descriptors that may be considered similar to “light,” “low,” or “mild” and could impact consumer perceptions of risk. This will help inform FDA’s implementation and enforcement of the modified risk tobacco product provision, which could include, for example, providing additional guidance.

FDA is in the process of conducting consumer perception studies on terms that could be considered “similar descriptors.” FDA will continue to pursue violations for label, labeling, or advertising where FDA has sufficient evidence of claims that the product presents a lower risk of tobacco related disease, a reduced level of or exposure to a substance, or is free of or does not contain a substance.

*Question.* Roll-your-own cigarette shops allow customers to make their own cigarettes. These stores exist in at least 15 States, including New Jersey, and I am concerned that these shops may be violating Federal cigarette laws and regulations by marketing their cigarettes as “healthier” and not appropriately restricting access to only those 18 and older. FDA has yet to assert its authority over the cigarettes produced in these shops. Is FDA aware of the proliferation of roll-your-own shops? Does the agency believe these shops are currently in violation of Federal law?

Answer. FDA is aware of retail establishments with roll-your-own cigarette machines that permit customers to make their own cigarettes and is gathering more information about this practice to determine the appropriate regulatory response.

*Question.* Under the Tobacco Control Act, the FDA has the authority to regulate tobacco products, but, without an important “deeming” regulation, the agency’s jurisdiction extends to only a small set of products. Products like cigars, hookah tobacco, dissolvable tobacco, and electronic cigarettes remain unregulated by FDA, putting Americans’ health at risk. Last year, FDA committed to issuing a “deeming” regulation by October 2011 that would extend its rightful regulatory authority over these of tobacco products. What is the status of this important regulation? Why is this regulation now 6 months overdue?

Answer. The Tobacco Control Act provided FDA with immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The act also authorizes FDA to deem, by regulation, other tobacco products to be subject to chapter IX of the Food, Drug, and Cosmetic Act or FD&C Act. FDA has publicly announced its intention to deem all products that meet the statutory definition of tobacco product to be subject to the FD&C Act. Deeming would ensure that all tobacco products are subject to FDA’s tobacco control authority, which will help to address existing regulatory gaps.

In the February 2012 edition of the Unified Agenda, FDA included an entry for a proposed rule that would deem products meeting the statutory definition of “tobacco product” to be subject to chapter 9 of the FD&C Act.

While FDA cannot comment on the details of pending rulemaking, FDA continues to work diligently to issue the proposed rule in the near future. It is important to note that the process for issuing any proposed rule on this issue will provides the opportunity for public comment as part of the rulemaking process. FDA routinely allows a minimum of 60 days for public comment and carefully considers these comments when it develops the final rule.

#### CONCLUSION OF HEARINGS

Senator KOHL. This hearing is recessed.

[Whereupon, at 3:24 p.m., Thursday, April 19, 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 2013**

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

**MATERIAL SUBMITTED BY AGENCIES NOT APPEARING FOR  
FORMAL HEARINGS**

[CLERK'S NOTE.—The following agency and related agency of the Department of Agriculture did not appear before the subcommittee this year. The following submitted testimonies are in support of their fiscal year 2013 budget requests.]

DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

PREPARED STATEMENT OF HON. PHYLLIS K. FONG, INSPECTOR GENERAL

I am pleased to submit testimony to Chairman Kohl, Ranking Member Blunt, and members of the subcommittee concerning the Office of Inspector General's (OIG) fiscal year 2013 budget request. My statement will also provide the subcommittee with the highlights of OIG's recent and planned audit and investigative work.

OIG's oversight work continues to achieve substantial and far-reaching results. In fiscal year 2011, our audit and investigative work obtained potential monetary results totaling over \$4.3 billion. We issued 45 audit reports intended to strengthen Department of Agriculture (USDA) programs and operations, which produced about \$4.2 billion in potential results. OIG investigations led to 449 convictions with potential results totaling almost \$113.6 million. These large monetary results far surpass our annual budget, which was \$88.5 million in fiscal year 2011.

The first part of my statement describes our ongoing work to assess and improve the Department's programs and operations under the American Recovery and Reinvestment Act of 2009 (Recovery Act). I will then summarize our most significant recent audit and investigative activities under our major strategic goals. My statement concludes with a description of the cost-saving actions OIG is taking in fiscal year 2012 to live within its budget constraints, as well as a summary of the President's fiscal year 2013 budget request for OIG.

OIG'S OVERSIGHT OF RECOVERY ACT PROGRAMS

With the additional funds this subcommittee appropriated for Recovery Act oversight, we have been able to perform a comprehensive review of USDA programs intended to ensure that the \$28 billion in Recovery Act funds provided to USDA served their intended purpose. Notably, the funds OIG received allowed us to perform more audits with statistical samples. Sampling enables us to obtain a "bird's eye view" of how a program is operating and draw more detailed and accurate conclusions concerning whether a program is functioning effectively or not.

*Recovery Act Single Family Housing Direct Loan Program*

OIG is at the end of a review of the \$1 billion the Recovery Act allotted to single family housing direct loans. These loans are intended to help very-low- and low-income households buy homes when they cannot qualify for other credit. Based on a statistical sample of 100 loans, we identified 18 loans where we questioned the borrower's eligibility because field personnel had not ensured that borrowers were likely to repay their loans. Based on our overall sample results, we estimate that 1,450 loans (18 percent of the single family housing direct loans), with a projected total value of \$173 million, may have similar issues that will result in increased risk of default. We recommended that Rural Development (RD) strengthen its controls to ensure that it lends only to qualified applicants, and agency officials generally agreed.

*Recovery Act Business and Industry (B&I) Guaranteed Loan Program*

The Recovery Act provided an additional \$130 million in budget authority for RD's B&I guaranteed loan program, which seeks to finance business and industry in rural communities by guaranteeing quality loans. With this authority, the agency guaranteed a total of 515 loans across 47 States, and obligated more than \$1.5 billion in Recovery Act funds. Our analysis of 55 statistically sampled loans found that 68 percent of applications were given unmerited priority for loan approval, and that 65 percent of requests for Recovery Act-funded B&I loan guarantees were reviewed inadequately because key financial data were not documented. As a result, the agency faces significant financial obligations if the borrowers default. Additionally, RD awarded guarantees to at least two loans, valued at \$6.2 million, which do not comply with eligibility regulations. Agency officials agreed with OIG's recommendations to improve how these loans are made.

*Upcoming Recovery Act Reports*

At present, we are starting the final phase of our Recovery Act audit objectives, which emphasizes how agencies are reporting their programs' accomplishments. Specifically, our work focuses on the performance measures being used to report these accomplishments, such as whether the funds contributed to creating or saving jobs.

But the value of our oversight will not expire with the end of Recovery Act funding. When we identify a problem with a program receiving Recovery Act funding, we are often helping to improve the overall program's performance for the future, whether the dollar spent is from a Recovery Act appropriation or not.

Similarly, we anticipate that our investigative work will continue in this area even after Recovery Act funding is no longer available. Our goal remains to timely identify and look into potential fraud involving USDA Recovery Act funds, including the prompt investigation of allegations of whistleblower reprisal, as set forth in the Recovery Act. Since the passage of the act, OIG has received 60 hotline complaints from various sources and initiated several ongoing investigations.

## GOAL 1: STRENGTHEN USDA'S SAFETY AND SECURITY MEASURES FOR PUBLIC HEALTH

One of OIG's most important oversight responsibilities is helping USDA ensure the wholesomeness of the U.S. food supply, and we continue to conduct audits and investigations intended to help USDA reduce the risk of food contamination and food-borne illnesses. For example, when Japan halted U.S. beef imports—worth more than \$1 billion annually—due to the discovery of vertebrae in a shipment of beef product originating from a U.S. company, OIG and the Food Safety and Inspection Service (FSIS) jointly conducted an investigation. As a result of our work, the Government filed a civil complaint charging the company with violations of the Federal Meat Inspection Act. In 2011, permanent injunctive relief and escalating monetary penalties were granted in an effort to prevent the company from committing future violations.

*The Food Emergency Response Network (FERN)*

In our 2011 audit of FERN—a program that was developed to integrate the Nation's food testing laboratories into a network able to respond to emergencies involving biological, chemical, or radiological contaminants, we found that FSIS, in coordination with the Food and Drug Administration, needs to take steps to formalize FERN, ensure that the program's laboratory capacity is sufficient to respond to emergency surges, and implement targeted surveillance of the food supply. Such surveillance should benefit the network by ensuring that emergency response personnel are able to execute their assigned tasks. Generally, FSIS agreed with our recommendations, and took steps to initiate a more robust program of targeted food surveillance.

We are finalizing a second report on efforts to improve how FSIS tests ground beef for *Escherichia coli* O157:H7. In our February 2011 report on this topic, OIG made recommendations to FSIS concerning how it samples beef so that the agency could improve the accuracy of its tests. In Phase 2, we are visiting beef slaughter plants and analyzing how the beef industry's sampling and testing protocols vary among plants and whether they differ from FSIS standards.

In addition to food safety, assuring the personal safety of USDA employees is paramount. In January 2011, an OIG investigation disclosed that, from 2009 through 2010, a USDA official sexually assaulted his female subordinate on multiple occasions. In February 2011, this official was charged in Federal court with four counts of aggravated sexual assault. He pled guilty in March 2011 to one misdemeanor count of sexual assault and in April 2011 was sentenced to 5 months' incarceration.

#### GOAL 2: STRENGTHENING PROGRAM INTEGRITY AND IMPROVING BENEFIT DELIVERY

One of OIG's most important goals is helping USDA safeguard its programs and ensuring that benefits are reaching those they are intended to reach. This year we have made a concerted effort to help improve the integrity of the Supplemental Nutrition Assistance Program (SNAP).

##### *Trafficking in SNAP Benefits<sup>1</sup>*

In fiscal year 2011, OIG devoted about 46 percent of its investigative resources to SNAP-related criminal investigations, and our investigations resulted in 179 convictions and monetary results totaling \$26.5 million. In a recent example, OIG worked jointly with Immigration and Customs Enforcement to determine whether a SNAP retailer was engaged in a conspiracy to defraud SNAP through trafficking, wire fraud, money laundering, and operating an unlicensed money transmitting business. The investigation revealed that the SNAP retailer trafficked at least \$3.1 million in SNAP benefits. In January 2012, the owner was sentenced to 46 months of incarceration, and ordered to pay \$2.5 million in restitution.

OIG also is working to minimize fraud, waste, and abuse within SNAP by performing a series of data mining audits analyzing 10 States' participant databases.<sup>2</sup> We have completed work in seven States—Kansas, Florida, Louisiana, Alabama, Mississippi, Missouri, and Texas—and found a total of 13,936 recipients who were receiving potential improper payments. We estimate that these recipients could be receiving a total of about \$1.9 million a month.

In our reports, we have recommended that the Food and Nutrition Service (FNS) require State agencies to ensure they use a national database to perform death matches and social security number verifications, and that they perform checks to make sure information is entered correctly. Generally, FNS agreed with our recommendations and is taking appropriate action.

Due to congressional interest in the early results of this work, we expanded the scope of our audit work to include evaluating the adequacy of FNS and State tools to prevent and detect SNAP fraud, determining whether the States are using all available tools, and identifying and evaluating the integrity of amounts reported for recipient and retailer fraud.

##### *Improper Payments at USDA*

OIG also continues to work on reducing the rate and volume of improper payments in USDA. In 2011, we released our first required report focusing on "high-dollar" overpayments in high-risk programs. Our review found that USDA submitted its fiscal year 2010 high-dollar overpayment reports after the deadline, did not report all high-dollar overpayments, and did not accurately report its corrective actions. We recommended that the Department and its agencies take steps to formalize and improve their reporting processes, and the Department concurred with our recommendations.

##### *Participants Who Abuse USDA Programs*

In addition to improper payments, we often investigate program participants who provide false information to USDA agencies to obtain payments to which they are not entitled. In one such investigation, OIG found that a large number of farmers in North Carolina concealed their production and then subsequently filed false crop insurance claims based on non-existent losses. This was a far-reaching conspiracy, involving farmers, warehouse operators, insurance agents, and loss adjusters, all of

<sup>1</sup> Trafficking is the illegal exchange of SNAP benefits for cash.

<sup>2</sup> The 10 States are Alabama, Florida, Kansas, Louisiana, Massachusetts, Mississippi, Missouri, New Jersey, New York, and Texas.

whom assisted in filing false claims and concealing the farmers' actual production. To date, 24 individuals have pled guilty to various crimes in Federal court and, in total, have been ordered to pay \$19.8 million in restitution, fines, and forfeiture.

I would also like to note an especially significant case involving mortgage fraud in which employees of a Michigan mortgage company issued 271 guaranteed single family home loans, valued at over \$38 million. OIG's investigation disclosed that at least 63 percent of the loans reviewed were based on false borrower income certifications, fraudulent pay statements, forged application signatures, and altered credit scores. These bogus documents were subsequently provided to RD for loan guarantees. Over 5 years, approximately 40 of these loans defaulted, resulting in RD paying out over \$2.3 million in guarantees. As a result of this case, four individuals received sentences ranging from 2 years of probation to 18 months in prison and have been ordered to pay \$8.7 million in restitution.

#### *Upcoming Work*

OIG has several particularly significant audits in process. First, we are completing fieldwork on participant eligibility and vendor management in the Special Supplemental Nutrition Program for Women, Infants, and Children. The overall objective of this audit is to evaluate implementation of food delivery regulations intended to improve the integrity of vendor management, and assess how FNS determines if participants are eligible for the program.

We are also in the process of completing work on the Farm Service Agency's (FSA) Conservation Reserve Program, which provides incentives to farmers to maintain conservation practices to prevent soil erosion and chemical run-off. Our audit was designed to inform Congress and USDA whether FSA has effective controls in place to ensure that the rates used to pay benefits to these farmers were reasonable.

#### GOAL 3: OIG WORK IN SUPPORT OF MANAGEMENT INITIATIVES

OIG works to improve the processes and systems the Department needs to function. USDA must manage vast amounts of data associated with its many programs and operations, information that ranges from agricultural statistics that drive domestic and global markets to inspection systems that help ensure our food is safe. As you are aware, USDA is facing many challenges to operating information technology (IT) that complies with all Federal requirements.

#### *Security Challenges Concerning Smartphones*

Like other Federal departments, USDA increasingly relies on smartphones and other handheld wireless devices to conduct its day-to-day business, but we found that many of these devices were not secured properly and were vulnerable to security breaches. Of approximately 10,000 wireless handheld devices USDA uses, we reviewed 277 devices and found that all 277 devices were not adequately secured. We recommended that USDA ensure that agencies better understand how to configure their wireless devices to meet Federal standards, and departmental officials agreed.

#### *IT Contracting*

During the course of the fiscal year 2011 Federal Information Security Management Act audit, OIG found that a contracting officer in USDA's Information Technology Contracting Branch signed a contract that exceeded a \$5 million warrant authority and resulted in an unauthorized commitment. We also learned that this contracting officer acted outside of a contracting officer's roles and responsibilities; disclosed sensitive contractual information to vendors; and authorized a contractor to work even though funding was not available. We recommended that USDA take steps to rectify this situation, and also ensure that its contracting officials do not exceed their authority in the future. USDA concurred with our findings and recommendations and has provided a corrective action plan.

#### *Employee Integrity*

While the vast majority of USDA employees go about their work with the highest standards of integrity, OIG investigates allegations of wrongdoing when an employee is accused of breaking the law. In 2011, a former Forest Service accountant was sentenced to 4 years of incarceration for mail fraud, and was ordered to pay restitution of \$1.1 million. These charges resulted from a year-end review that disclosed more than \$600,000 missing from funds the agency collected to provide a service to private vendors in one of the national forests in California. OIG's investigation revealed that the accountant had embezzled approximately \$1.4 million by redirecting funds from multiple private vendor accounts to a corporation she and her husband owned.

*Upcoming Work*

As required by law, OIG has begun conducting a performance audit based on a statistical sample of adjudicated claims from *In re Black Farmers Discrimination Litigation*, the discrimination litigation commonly known as *Pigford 2*.

## GOAL 4: IMPROVING USDA'S STEWARDSHIP OF NATURAL RESOURCES

Our audit of the Natural Resources Conservation Service's (NRCS) Farm and Ranchlands Protection Program—a program that keeps selected parcels of land from being developed for housing or other non-agricultural purposes—found that NRCS accepted conservation easement appraisals even though they did not meet standards or were unsupported. Although appraisals should reflect the current value of the land, we found that the State Conservationist did not note that many conservation easements had appraisals that were too outdated to be accurate. We recommended that the NRCS State office improve its oversight processes to ensure that payments are not made to cooperating entities using invalid appraisals, and take more timely action when a cooperating entity submits appraisals that do not meet standards. Agency officials agreed.

An OIG investigation of this program resulted in a land trust organization in Wisconsin entering into a settlement agreement to pay \$50,000 to partly reimburse NRCS for overpayments caused by false statements submitted by the organization's former executive director. These false statements led to NRCS paying too much to purchase conservation easements from four Wisconsin landowners participating in the program.

*Upcoming Work*

OIG is reviewing how NRCS is using Recovery Act and non-Recovery Act funds to rehabilitate aging dams across the country. In 2009, we reported serious issues with how NRCS was prioritizing dams for rehabilitation—the agency was not always focusing first on dams that, if they failed, might cause serious loss of life. Our current audit will evaluate whether NRCS has implemented the recommendations from our prior audit, and whether NRCS has more effectively used subsequent funds.

## OIG'S FISCAL YEAR 2013 BUDGET REQUEST

Since 2011, OIG has responded to the call to reduce Government spending while building a stronger and more efficient agency. We have taken a number of steps to increase our effectiveness within our limited budget:

- We approved voluntary buyouts and early retirements for 21 employees during the first quarter of fiscal year 2012, and are seeking authority for 30 more to offset the reduction in available funds as OIG's Recovery Act funding expires in December 2012.
- We are using alternatives to Government travel, including teleconferencing and videoconferencing, which allowed us to reduce our travel expenditures by \$1.1 million, or 49 percent, during both fiscal year 2011 and fiscal year 2012.
- We reduced the amount we spend on training by \$203,000, or 33 percent, by relying more on the training that we provide our employees "in-house."
- We have reorganized and restructured to streamline business operations within the agency to better focus on high-priority work. As vacancies arise, we have filled only key positions.
- We have taken steps to reduce our telecommunications costs, including inventorying all phone lines and disconnecting unused lines. We also have consolidated contracts for smartphones and copiers to achieve greater efficiency.

Thanks to this work, we are a leaner and more effective agency that is better able to carry out our mission. For example, our improved efficiency allows us to reinvest in IT infrastructure and obtain more communication services, such as bandwidth, with the same money we used to pay for basic phone lines.

We ask that you support the President's fiscal year 2013 budget request of \$89 million for OIG, which would enable us to provide effective oversight of USDA programs and help ensure that tax dollars are being well spent.

The President's budget request includes modest increases in areas where we should be able to produce a high-value return for a relatively small investment:

- \$800,000 to support statistical samples in audits of improper payments. Statistical sampling allows OIG to project the results of our audit work to the entirety of a program, which multiplies our work's range and effectiveness, especially for very large programs like SNAP.

- \$1,072,000 to fund an OIG initiative to address SNAP fraud. OIG investigative teams plan to more actively engage State and local authorities and pursue the prosecution of both retailers and recipients involved in benefit trafficking.
- \$613,000 to fund enhanced oversight of USDA's international programs.
- \$468,000 to support the Council of the Inspectors General on Integrity and Efficiency by funding Government-wide activities to identify vulnerabilities in Federal programs.

From fiscal year 2006 to 2011, the potential dollar impact of OIG audits and investigations has been \$5.7 billion, while our appropriations have been \$502.5 million. For every \$1 invested, we have realized potential cost-savings and recoveries of about \$11.42. This calculation does not include the value of our food safety work and program improvement recommendations, which are not so easily quantified.

This concludes my remarks. Thank you again for the opportunity to submit a statement to the subcommittee regarding our fiscal year 2013 budget request. I would be pleased to address questions that members and staff may have about our request, and our continuing audit and investigatory activities pertaining to USDA operations.

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#### RELATED AGENCY

##### FARM CREDIT ADMINISTRATION

##### PREPARED STATEMENT OF LELAND A. STROM, CHAIRMAN AND CHIEF EXECUTIVE OFFICER

Mr. Chairman, Members of the Subcommittee, I am Leland A. Strom, Chairman and Chief Executive Officer of the Farm Credit Administration (FCA or Agency). 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 the Agency, I am pleased to provide this testimony.

Before I discuss the Agency'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 or System) 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, the Agency submitted a proposed total budget request of \$64,130,601 for fiscal year 2013. FCA's proposed budget for fiscal year 2013 includes funding from current and prior assessments of \$63,300,000 on System institutions, including Farmer Mac. Almost all this amount (approximately 83 percent) goes for salaries, benefits, and related costs.

A key factor driving the fiscal year 2013 budget is the Agency's need to hire and train qualified individuals to replace the many employees who are expected to retire soon. We must ensure that our staff has the skills it needs to address changes in the agricultural industry and the complexities of agricultural finance. Also, changes in the organization and structure of the System itself are presenting challenges. On January 1, 2012, two System banks merged, representing the largest merger in the history of the FCS. As System institutions continue to merge and grow larger and more complex, the Agency must dedicate more resources to examining and overseeing these institutions. The funding we have requested for fiscal year 2013 will allow us to hire and train the people we need to continue to properly examine, oversee, and regulate the System.

##### MISSION OF THE FARM CREDIT ADMINISTRATION

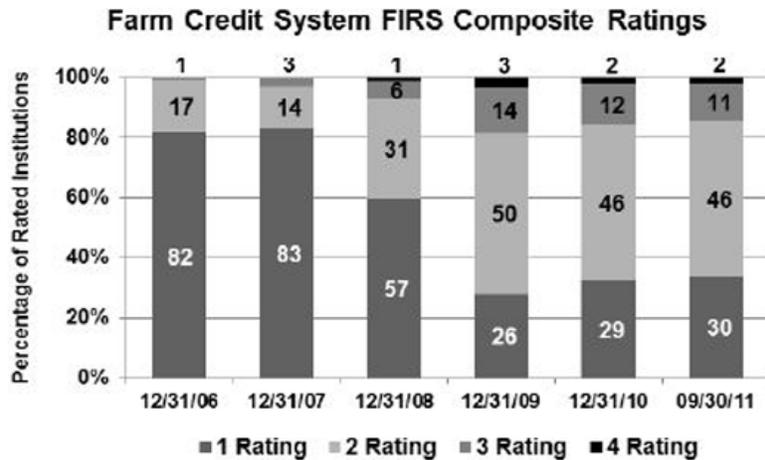
As directed by Congress, FCA's mission is to ensure a safe, sound, and dependable source of credit and related services for agriculture and rural America. The Agency accomplishes its mission in two important ways. First, FCA protects the safety and soundness of the FCS by examining and supervising all 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 a System 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 System institutions conduct their business and interact with customers. FCA's policy and regulation development focuses on protecting System 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 corporate charter changes, System debt issuance, and other financial and operational matters.

EXAMINATION PROGRAMS FOR FARM CREDIT SYSTEM BANKS AND ASSOCIATIONS

To help ensure the safety and soundness of FCS institutions, FCA uses examination and supervision processes to address material risks and emerging issues at the institution level and across the System. The Agency 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. We monitor agricultural, financial, and economic risks that may affect groups of institutions or the entire System. Given the increasing complexity and risk in the System 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.

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 properly manage assets and liabilities, to establish high standards for governance, and to provide transparent disclosures to shareholders. FCA's examination and supervision program promotes accountability in FCS institutions by providing a framework to help institutions identify and manage risks. In addition, FCA is closely watching rapidly rising real estate values in certain sections of the country to ensure that FCS lending practices remain prudent. FCA may use its enforcement powers to effect changes in an institution's policies and practices to correct unsafe or unsound conditions or violations of law or regulations.



Source: FCA's FIRS Ratings Database. The above chart includes only the System banks and their affiliated direct-lender associations. The figures in the bars reflect the number of institutions by FIRS rating.

The Agency uses the Financial Institution Rating System (FIRS) to assess the safety and soundness of each FCS institution. The system provides a framework of component and composite ratings to help examiners evaluate significant financial, asset quality, and management factors. FIRS ratings range from 1 for a sound institution to 5 for an institution that is likely to fail. As the chart above indicates, the System remains financially strong overall. Institutions are well capitalized, and the FCS does not pose material risk to investors in FCS debt, the Farm Credit System Insurance Corporation, or to FCS institution stockholders.

Although the System's condition and performance remain satisfactory overall, several institutions are experiencing stress and now require special supervision and enforcement actions. Factors causing the stress include weaknesses in the Nation's economy and credit markets, a rapidly changing risk environment in certain agricultural segments, and, in certain cases, management's ineffective response to these risks. We have increased supervisory oversight at a number of institutions and dedicated additional resources in particular to those 13 institutions rated 3 or worse. Although these institutions represent about 2 percent of System assets and do not meaningfully affect the System's consolidated performance, they require significantly greater Agency resources to oversee. As of December 31, 2011, seven FCS institutions were under formal enforcement action, but no FCS institutions are in conservatorship or receivership.

#### REGULATORY AND CORPORATE ACTIVITIES

*Regulatory Activities.*—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. The Agency is committed to developing balanced, flexible, and legally sound regulations. 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 make it more consistent with the Basel Accord and with that of other Federal financial regulating authorities;
- Revising regulations to enhance System disclosures and compliance requirements for executive compensation, pension, and other benefit programs;
- Strengthening investment-management regulations to ensure that prudent practices are in place for the safe and sound management of FCS investment portfolios;
- Revising regulations to provide guidance on the statutory and regulatory authority related to rural community investments;
- Revising regulations to provide the parameters under which an FCS institution may organize or invest in LLCs, LLPs, and other unincorporated business entities;
- Clarifying and strengthening standards-of-conduct regulations; and
- Revising regulations related to FCS bank and association mergers and consolidations.

*Corporate Activities.*—Because of mergers, the number of FCS institutions has declined over the years, but their complexity has increased, placing 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 2012, two banks have merged, and two associations have merged. In addition, a new service corporation was chartered. As of January 1, 2012, the System had 83 direct-lender associations, four banks, six service corporations, and two special-purpose entities.

#### CONDITION OF THE FARM CREDIT SYSTEM

The System remained fundamentally safe and sound in 2011 and is well positioned to withstand the continuing challenges affecting the general economy and agriculture. Total capital increased to \$35.9 billion at September 30, 2011, up from \$33.0 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 15.8 percent at September 30, 2011, compared with 15.0 percent the year before, as strong earnings allowed the System to continue to grow its capital base.

Because of stronger agricultural profits, which reduced the need for farmers to borrow, the System experienced slower loan growth. In total, gross loans grew by 1.3 percent over the 12-month period ended September 30, 2011, compared with 3.9 percent during the previous period. Nonperforming loans decreased modestly to \$3.3 billion at the end of fiscal year 2011, representing 9.2 percent of total capital, down

from 11.3 percent a year earlier. However, although credit quality has been improving and is satisfactory overall, volatility in commodity prices, rising input prices, and weaknesses in the general economy pose continued risks to some agricultural operators, creating the potential for a reversal of this trend.

The FCS earned \$3.0 billion in the first 9 months of 2011, a 13.7 percent increase from the same period in 2010. Return on assets remained favorable at 1.7 percent. The System's liquidity position increased from 172 days as of September 30, 2010, to 200 days a year later, remaining significantly above the 90-day regulatory minimum. The quality of the System's liquidity reserves also improved in 2011. Further strengthening the System's financial condition is the Farm Credit Insurance Fund, which holds almost \$3.4 billion. Administered by the Farm Credit System Insurance Corporation, this fund protects investors in Systemwide consolidated debt obligations.

U.S. agriculture just experienced back-to-back years of exceptional profitability. According to U.S. Department of Agriculture estimates, combined net farm income for 2010 and 2011 is 23 percent higher than for 2008 and 2009. Higher farm incomes reflect rising prices for key crops. However, farm prosperity has not been uniform—because of high feed costs, profits were lower for livestock producers than for crop producers. Despite continued financial stress among certain livestock enterprises, such as dairy, farm finances were generally strong going into 2012. While many farmers have significantly increased capital investments, they have done so using excess cash and limited their use of credit. For those farmers borrowing money, they are paying some of the lowest interest rates of their lifetime.

U.S. farm incomes for 2012 may well hinge on the ability of farmers across the globe to expand production enough to alleviate tight world stocks of key crops. Greatly improved weather and higher plantings could turn shortages of key crops such as corn and soybeans into surpluses quickly, thus causing prices to fall. Meanwhile, future world economic growth and, hence, food demand, remains uncertain, as does the exchange value of the dollar and government policies that affect agriculture and energy. As a result, commodity prices will probably remain volatile.

An increasing risk to the farm sector's financial health is the persistent rise in production costs. The surge in farmland prices and rental rates have driven production costs even higher, especially over the past 2 years. This is most notable in the Midwest where corn and soybeans are the main enterprises. In some States, farmland prices now significantly exceed inflation-adjusted records. These prices could drop significantly if grain prices fall or interest rates climb. While the percentage of debt being used to purchase land appears to be modest, FCA continues to closely monitor farmland values and associated risk to loan collateral across the System. In addition, FCA continues to exchange ideas and meet with other banking regulators to determine the most appropriate regulator response to risks associated with rising land values.

The System had full access to the capital markets during 2011, which further increased its overall financial strength and its ability to serve its mission. In addition, as a Government-sponsored enterprise (GSE), the System has benefited from the monetary policies that have helped foster historically low interest rates. Despite continued volatility in the financial markets, investor demand for System debt has remained favorable across the yield curve. Because of low interest rates, the System was able to exercise the options on significant quantities of callable bonds to further reduce the cost of funds. For 2012, the System expects that the capital markets will continue to meet its financing needs.

#### FEDERAL AGRICULTURAL MORTGAGE CORPORATION

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), the Agency 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 U.S. Treasury Department, not to exceed \$1.5 billion, to fulfill the guarantee obligations on Farmer Mac Guaranteed Securities. Farmer Mac is not subject to any intra-System agreements and is not jointly and severally liable for Systemwide debt obligations. Moreover, the Farm Credit Insurance Fund does not back Farmer Mac's securities.

Farmer Mac made financial progress during fiscal year 2011. Although GAAP net income was down from 2010, this decline was largely the result of unrealized gains and losses; however, core earnings, a measure based more on cash flow, was up by 50 percent. As of September 30, 2011, Farmer Mac's core capital totaled \$461.3 million, which exceeded its statutory requirement of \$336.6 million. The result is a capital surplus of \$124.7 million, down from \$183.2 million as of September 30, 2010. The total portfolio of loans, guarantees, and commitments grew 3.2 percent to \$11.8 billion.

Farmer Mac's program-business portfolio shows stress in certain subsectors, but credit risk 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 1.46 percent at September 30, 2011, compared with 1.86 percent a year earlier. Loans more than 90 days delinquent decreased from 1.53 percent at September 30, 2010, to 1.02 percent a year later.

Regulatory activity in 2012 that will affect Farmer Mac includes an interagency joint final 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 final rulemaking on nonprogram investments and liquidity at Farmer Mac; a proposed rulemaking to amend regulatory requirements governing operating and strategic planning; and a proposed rulemaking to amend the Risk-Based Capital Stress Test to reduce its reliance on credit ratings.

#### CONCLUSION

We at FCA remain vigilant in our efforts to ensure that the Farm Credit System 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 2013 budget as presented, and we continue our efforts to be good stewards of the resources entrusted to us. In addition to appointing a Performance Improvement Officer, we have met all of the other requirements of the GPRA Modernization Act that apply to our Agency. Our Budget Proposal identifies our goals and the performance measures we have developed to help ensure that we use our resources judiciously. While we are proud of our record and accomplishments, I assure you that the Agency 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 the Agency, 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 2013**

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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 2013 budget request for programs within the subcommittee's jurisdiction.]

PREPARED STATEMENT OF THE AD HOC COALITION

Mr. Chairman, Members of the Subcommittee, this statement is respectfully submitted on behalf of the ad hoc coalition composed of the organizations listed below. The coalition supports sustained funding for our Nation's food aid programs, including the Public Law 480 Title II Food for Peace Program, McGovern-Dole International Food for Education, and Food for Progress. We strongly oppose USDA's proposal to divert funding away from Food for Peace.

*Food Aid's Unique Role*

The donation of American commodities as food aid has been the cornerstone of U.S. and global foreign assistance programs since their inception, and the need for food aid today is stronger than ever. According to USDA's Economic Research Service, 12 million metric tons of commodities are needed each year to fill food gaps in the 70 most food insecure countries. Food aid, delivered in bags bearing the U.S. flag marked "From the American People" provides a tangible symbol of our Nation's generosity and compassion and builds good will toward the American people.

In recent years, opponents of food aid programs have argued that they are not being administered efficiently, and that we should therefore just transfer these programming funds over to USAID's Emergency Food Security Program (EFSP). Through a variety of reforms, such as prepositioning commodities and application of the Famine Early Warning System, the speed of delivery and accuracy of food aid targeting has been dramatically improved in recent years, leading USAID Administrator Shah to announce last summer that the United States is now the fastest provider of food assistance at times of crisis and emergency. Rather than abandon the demonstrated, life-saving benefits of U.S.-sourced food aid, we should work together across agencies, and across stakeholders, to apply American ingenuity to these programs, and continue to make them the best, most efficient programs they can be while still preserving their unique benefits overseas and here at home.

In contrast to most other foreign assistance programs which just send money overseas, food aid also provides direct economic benefits here at home. U.S. food aid programs not only further our humanitarian and security goals by allowing Americans to share their bounty with the needy, but these programs also provide stable jobs for hundreds of thousands of Americans in our farming, processing, and shipping economic sectors.

*Diversion of Food Aid Funding for Cash Donations*

The U.S. Department of Agriculture's proposed fiscal year 2013 budget includes a request to divert \$66 million in funding away from Food for Peace, instead adding it to the \$300 million already designated for USAID's EFSP.

Mr. Chairman, we are concerned that this back-door diversion of funding will further weaken the Food for Peace Program, which has suffered extraordinary cuts in recent years. Although the program is authorized at \$2.5 billion, funding has fallen in recent years and the current requested level is only \$1.4 billion. This proposal is a replay of USDA's proposals for fiscal year 2007–2009, which would have given authority to USAID to use Food for Peace funding for the purchase of foreign or "local and regional" commodities at its discretion. The U.S. Government and its global partners already have significant cash amounts for local and regional purchases when it is necessary and appropriate. Especially in light of the recent cuts to Title II, it is our belief that the present funding level of EFSP does not need a further infusion of scarce Title II funds. We respectfully request that this Subcommittee again reject USDA's proposal, and preserve the integrity of the Food for Peace program.

*Conclusions and Recommendations*

We respectfully recommend that our food aid programs continue to be funded at responsible, sustainable levels. The Public Law 480 Food for Peace Program is the world's most successful foreign assistance program, has saved countless lives, and has provided valuable jobs to the American people, who take pride in their tangible commitment to relieving global hunger. Its straightforward delivery of American food to the hungry fills a clear and immediate need overseas, and its unique architecture has made it a successful program here at home that has endured for over fifty years. Therefore, we respectfully recommend that USDA's request to siphon money away from Food for Peace be denied as it was in prior years.

America Cargo Transport Corp.	North American Millers' Association
American Maritime Congress	National Corn Growers Association
American Maritime Officers	National Council of Farmer Cooperatives
American Maritime Officers' Service	National Potato Council
APL Limited	National Sorghum Producers
American Soybean Association	Sailors' Union of the Pacific
Central Gulf Lines, Inc.	Seafarers International Union
Hapag-Lloyd USA, LLC	Sealift, Inc.
International Organization of Masters, Mates & Pilots	Transportation Institute
Liberty Maritime Corporation	United Maritime Group, LLC
Maersk Line, Ltd.	U.S. Dry Bean Council
Marine Engineers' Beneficial Association	U.S. Wheat Associates, Inc.
Maritime Institute for Research and Industrial Development	USA Dry Pea & Lentil Council
National Association of Wheat Growers	USA Maritime
	USA Rice Federation
	Waterman Steamship Corporation

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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 fully fund administrative expense funding for the Emergency Food Assistance Program (TEFAP) at \$100 million; to make TEFAP food purchase dollars available for 2 fiscal years; to approve the administration's budget request of \$186,935,000 for the Commodity Supplemental Food Program (CSFP) and provide an increase of \$5 million to begin operations in six additional States approved by USDA, and to evaluate alternative approaches for the Department of Defense Fresh Program.

ACDA is a nonprofit professional trade association, dedicated to the growth and improvement of USDA's 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 over 1.5 billion pounds of USDA-purchased commodity foods annually through programs such as National School Lunch Program, the Emergency Food Assistance Program (TEFAP), Summer Food Service

Program (SFSP), Commodity Supplemental Food Program (CSFP), Charitable Institution Program, and Food Distribution Program on Indian Reservations (FDPIR).

*Fully Fund TEFAP Administrative Funds at \$100 Million*

We urge the subcommittee to fully fund TEFAP Administrative Funds at \$100 million.

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 \$74.5 million for TEFAP Administrative Funds in fiscal year 2010 including ARRA funds, \$49.401 million in fiscal year 2011, and \$48 million in fiscal year 2012. While these resources have been used responsibly, and are sincerely appreciated, food banks around the country are finding that operating expenses are increasing while private sector donations are decreasing. They have had to increasingly depend upon converting food dollars to administrative expense funds in order to maintain their operations.

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 at least the fiscal year 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 essential to maintaining distribution sites, especially in rural distribution sites. In fact, this past year Minnesota was not able to reimburse food bank warehouses for the storage and distribution costs. New Mexico had to restrict food deliveries to remote locations, and had to reduce paid staff by not hiring replacement employees.

*Make TEFAP 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.

ACDA officials have met with FNS and AMS personnel to explore ways to improve the ordering of TEFAP foods. While the agencies of the Department of Agriculture 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 cancelled 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. We are pleased that Under Secretary for Food, Nutrition and Consumer Services Kevin Concannon told the Subcommittee on February 28 that USDA would support making TEFAP food dollars available for a 2 year period.

At the end of fiscal year 2011, Minnesota was at risk of losing \$70,000. Connecticut had nearly \$69,000 at risk. Other States had similar experiences at a time when private donations are fewer, and when available food dollars result in lower food volumes due to higher prices.

As we did last year, we respectfully point out to the subcommittee that 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 committee 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 2013 budget request of \$186,935,000 for the Commodity Supplemental Food Program (CSFP), and urges the Committee 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 overwhelmingly serves elderly individuals, many of whom are homebound. States currently operating CSFP requested 116,350 additional caseload slots for the current program year, clearly showing the need for this program.

*ACDA 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 the Department of Defense 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.

We once again ask the Committee 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 Committee 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 has identified the following nine areas for funding in the fiscal year 2013 Agriculture spending bill:

- Programs that promote animal health;
- Programs that promote conservation;
- Programs that expand export markets for agriculture;
- Programs that enhance and improve food safety and protection;
- Programs that ensure crop protection tools;
- Programs that further develop renewable energy;
- Programs that strengthen rural communities;
- Programs that support wildlife services; and
- Research priorities.

Farm Bureau strongly opposes any cuts to funding of the farm safety net. The farm bill discussion has begun, and the House and Senate Agriculture Committees should continue to have the primary responsibility to ensure farmers and ranchers have a viable farm safety net.

*Programs That Promote Animal Health*

Farm Bureau supports a \$5.3 million increase for the Animal and Plant Health Inspection Service (APHIS) to a total of \$14 million for voluntary Animal Disease Traceability (ADT). The ADT program requires strong Government oversight on the expenditure of funds and is essential for animal health.

Farm Bureau supports \$4.79 million for the Veterinary Medicine Loan Repayment Program (VMLRP) administered by the Department of Agriculture (USDA) National Institute for Food and Agriculture (NIFA). VMLRP veterinarians ensure animal health and welfare, while protecting the Nation's food supply.

Farm Bureau supports \$123.4 million for the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM). The CVM oversees the safety of animal drugs, feeds and biotechnology-derived products.

*Programs That Promote Conservation*

Farm Bureau supports funding for conservation programs but prioritizes working lands programs over retirement-type programs. Farmers and ranchers have made great strides in conserving our natural resources, and these gains can continue through working lands programs.

*Programs That Expand International Markets for Agriculture*

Farm Bureau supports funding at authorized levels for:

- The Foreign Agricultural Service (FAS) to maintain services that expand agricultural export markets. Farm Bureau urges continued support for the Office of the Secretary for trade negotiations and biotechnology resources.
- The Market Access Program, Foreign Market Development Program, Emerging Markets Program and 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.
- 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), which oversees the permit, notification and deregulation process for plant biotechnology products. BRS personnel and activities facilitate agriculture innovation, and ensure public confidence and international acceptance of biotechnology.

Farm Bureau supports continued funding for the U.S. Codex Office. Active U.S. participation in the Codex Alimentarius Commission is essential to improving the harmonization of international, science-based standards for the safety of food and agriculture products.

#### *Programs That Enhance and Improve Food Safety and Protection*

Farm Bureau recommends 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.

Farm Bureau supports funding for a National Antimicrobial Residue Monitoring System (NARMS) to detect trends in antibiotic resistance. NARMS protects human and animal health through integrated monitoring of antimicrobial resistance among foodborne bacteria. Farm Bureau requests that Congress direct that stakeholder involvement and industry input be a priority in the ongoing Federal review.

Farm Bureau supports funding for the Food Animal Residue Avoidance Databank (FARAD) at the authorized level of \$2.5 million. FARAD aids veterinarians in establishing science-based recommendations for drug withdrawal intervals. No other Government program provides or duplicates the food safety information FARAD provides to the public.

Farm Bureau 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 Ensure Crop Protection Tools*

Farm Bureau supports maintaining \$12 million for Minor Crop Pest Management (IR-4) within NIFA Research and Education Activities. Developing pest control tools has high regulatory costs, and public support has been needed to ensure that safe and effective agrichemicals and biopesticides are available for small, orphan markets. The IR-4 Project facilitates Environmental Protection Agency registration of safe and effective pest management technologies where the private sector is unable to cover regulatory cost.

Farm Bureau supports maintaining funding to the National Agricultural Statistical Service (NASS), specifically for the continuation of agricultural chemical-use surveys for fruits, vegetables, floriculture and nursery crops. NASS surveys provide data about the use of agricultural chemicals involved in the production of food, fiber and horticultural products.

#### *Programs That Support the Development of Renewable Energy*

Farm Bureau supports 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.

Farm Bureau supports funding for the Biomass Crop Assistance Program (BCAP). BCAP provides vital financial assistance to farmers who produce and transport eligible biomass feedstocks and helps growers meet the capital-intensive costs of establishing new crops and delivering them to market.

#### *Programs That Strengthen Rural Communities*

Farm Bureau supports USDA implementing a regional approach to give its Rural Development (RD) programs greater flexibility and promote innovation in rural regions.

Farm Bureau supports maintaining the funding at authorized levels for:

- The Value-Added Agricultural Producer Grants, Rural Innovation Initiative, Rural Microentrepreneur Assistance Program, and Business and Industry Di-

- rect and Guaranteed Loans, which all foster business development in rural communities.
- Rural Utilities Service for rural broadband and telecommunications services, and the Distance Learning and Telemedicine Program.
- The Revolving Fund Grant Program for acquiring safe drinking water and sanitary waste disposal facilities.
- The Resource Conservation and Development Program, which helps local volunteers create new businesses, form cooperatives and develop agri-tourism activities.
- The Beginning Farmer and Rancher Development Program, which provides participants with the information and skills needed to make informed decisions for their operations.
- Agriculture in the Classroom, a national grassroots program coordinated by USDA, which helps students gain greater awareness of the role of agriculture in the economy and society.

*Programs That Support Wildlife Service*

Farm Bureau supports maintaining the funding level for Wildlife Service programs. Wildlife Service works to prevent and minimize an estimated \$1 billion worth of wildlife damage, while protecting human health and safety from conflicts with wildlife.

*Research Priorities*

Agricultural research is vital, particularly research focused on meeting the growing challenges of production 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. 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.

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PREPARED STATEMENT OF THE AMERICAN FOREST & PAPER ASSOCIATION

*Introduction*

The American Forest & Paper Association (AF&PA) is the national trade association of the forest products industry, representing pulp, paper, packaging and wood products manufacturers, and forest landowners. Our companies make products essential for everyday life from renewable and recyclable resources that sustain the environment.

The forest products industry accounts for approximately 5 percent of the total U.S. manufacturing GDP. Industry companies produce about \$190 billion in products annually and employ nearly 900,000 men and women, exceeding employment levels in the automotive, chemicals and plastics industries. The industry meets a payroll of approximately \$50 billion annually and is among the top 10 manufacturing sector employers in 47 States. Within the jurisdiction of this subcommittee, continued resources for protecting forest health and providing adequate resources to enforce existing trade laws are essential. Specific recommendations follow.

*Food and Drug Administration—Food Contact Notification Program*

*AF&PA supports continued funding of the Food Contact Notification Program.*—The Food Contact Notification (FCN) program protects consumer health, food safety and quality while providing packaging manufacturers with an efficient process that is less burdensome than the food additive approval process. It has allowed packaging manufacturers to bring new, more environmentally friendly products to market that have extended product shelf life, thereby increasing consumer value.

As Congress begins work on appropriations legislation for FDA in the coming weeks, we would like your support and assistance in ensuring that robust funding is included in the appropriations bills for the Center for Food Safety and Applied Nutrition, and that Congress expresses its intention to continue the operation of the FCN program. AF&PA appreciates that the subcommittee has previously rejected proposals to eliminate the FCN program.

*Animal and Plant Health Inspection Service (APHIS)—Lacey Act Enforcement*

*AF&PA supports \$5.5 million to provide for implementation of the declaration requirement of the Lacey Act, as amended by the 2008 farm bill.*—The 2008 farm bill amended the Lacey Act (16 U.S.C. 3371 et seq.) to make it unlawful to trade wood products or other plants taken in violation of the laws of either a U.S. State or foreign country. This ground-breaking legislation already is beginning to influence the

way companies make sourcing decisions and monitor their supply chains. Full and effective implementation and enforcement of the Lacey Act will enable American forest product companies to compete fairly in the global marketplace, help keep jobs in the United States, deter the destructive impacts of illegal logging on forests and forest-dependent communities in developing countries, and reinforce initiatives to mitigate climate change.

When fully implemented, the law requires U.S. importers of wood and wood products to file a declaration identifying the genus/species name and country of harvest—a critical measure intended by the law’s sponsors to increase supply chain transparency and assist Federal agencies in fair and strong enforcement. The prohibition and the declaration requirement affect a wide array of American industries, so it is critical that the declaration process generates data in a streamlined, cost-effective manner without unduly burdening legitimate trade. To that end, APHIS—which is responsible for implementing the declaration provision—needs \$5.5 million in funding to fully implement congressional mandates, including to establish an electronic declarations database and to add internal capacity to perform data analysis needed for monitoring and enforcement purposes.

*APHIS—Plant Pests*

*AF&PA recommends maintaining at least fiscal year 2012 funding of \$56 million for the “Tree and Wood Pests” category to aid in combating these, and other pests and diseases.*—As world trade continues to expand, global weather patterns shift, and an increasingly affluent world population has the ability to travel to—and demand products from—the far corners of the globe, the inadvertent, yet inevitable introduction of nonnative pests and diseases into the United States continues. Additional funding is vitally needed to aid in combating pests such as the Asian longhorn beetle, the Emerald Ash borer, and the Sirex woodwasp, as well as diseases such as *Phytophthora ramorum*. These are but a sampling of the diseases that harm commercial timber stands, community parks, and private forest landowners. American citizens most certainly will bear the cost of combating these and other emergent threats. We believe a comprehensive, coordinated response to each is more effective and more economical.

*National Institute of Food and Agriculture—McIntire-Stennis Cooperative Forestry Research*

*AF&PA requests \$33 million for the McIntire-Stennis Cooperative Forestry Research Program.*—Approximately one-third of the United States is forested and these forests enhance our quality of life and economic vitality and are an invaluable source of renewable bioproducts, outdoor recreation, clean water, fish and wildlife habitat, and carbon sequestration. Sustaining these forests in a healthy and productive condition requires a strong, continuing commitment to scientific research and graduate education. Foundational financial support for university-based forestry research and graduate education comes from the McIntire-Stennis Cooperative Forestry program, funded through the USDA’s National Institute of Food and Agriculture. Funds are distributed according to a statutory formula to each of the 50 States, Puerto Rico, Guam, and the Virgin Islands, with a dollar-for-dollar match required from the States.

Additional funding is needed to:

- Provide the additional scientific research needed to address critical forest issues such as fires, storms, insects, diseases, urbanization, fragmentation, and lost economic opportunities.
- Develop new knowledge and innovations to sustain healthy, productive forests and address the challenges facing forest owners, forest products manufacturers and all Americans who benefit from our forest resources.
- Support research capacity within each State to address issues that are essential to private forest owners, and develop new opportunities for economic benefit from their forests.

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PREPARED STATEMENT OF THE AMERICAN HONEY PRODUCERS ASSOCIATION, INC.

Chairman Kohl and Members of the Subcommittee, my name is Mark Jensen, and I currently serve as President of the American Honey Producers Association (AHPA). I am pleased today to submit the following statement on behalf of the AHPA, a national organization of commercial beekeepers actively engaged in honey production and crop pollination throughout the country. The purpose of this statement is to bring to your attention the continued threats faced by American beekeepers and the billions of dollars in U.S. agriculture that rely upon honeybee pollination services. With those threats in mind, we respectfully request an appropriate

tion that meets the needs anticipated by the 2008 farm bill for research funds to combat CCD and to conduct other essential honeybee research through the Agricultural Research Service (ARS) and other agencies at the Department of Agriculture, including at least \$11.7 million for bee research at the ARS Honeybee Research Laboratories. And we specifically request that funds and personnel not be diverted from the essential ARS Honeybee Research Laboratory in Weslaco, Texas, which for reasons given below would jeopardize highly valuable research at a critical time for America's beekeepers.

Honeybees are an irreplaceable part of the U.S. agricultural infrastructure. Honeybee pollination is critical in the production of more than 90 food, fiber, and seed crops and directly results in more than \$15 billion in U.S. farm output. One key example is the almond crop. California grows 100 percent of the Nation's almonds and supplies 80 percent of the world's almonds, all of which are 100 percent pollinated by managed bees. Nearly half of the managed colonies in the United States are transported each year from other parts of the country to pollinate those almonds. In addition to this clear commercial benefit, honeybees are also vital to the health of all Americans given the dietary importance of such diverse pollinated crops as almonds, apples, oranges, melons, blueberries, broccoli, tangerines, cranberries, strawberries, vegetables, alfalfa, soybeans, sunflower, and cotton, among others. In fact, honeybees pollinate about one-third of the human diet.

With this in mind, a threat to the existence of managed American honeybees is a threat to all Americans. And unfortunately, the American honeybee continues to face a number of significant threats. While not specifically a topic of relevance for congressional appropriators, complex circumvention and customs fraud schemes continue to disadvantage the American honey producer, stress pollinated crops and even threaten the health and safety of consumers. Producers struggle under the impact of increasingly divergent market prices—one price for legitimate honey and another rock bottom price for illegally transshipped honey. The direct result of these divergent prices is a rapidly shrinking domestic market share for American producers. The shrinking domestic share has, in turn, diminished the available supply of managed bee colonies necessary to pollinate U.S. agriculture, and it has placed American consumers at risk due to increasing volumes of low-cost, often adulterated, food products entering uninspected into the Nation's food supply.

This substantial trade threat is layered on top of the industry's ongoing battle against Colony Collapse Disorder (CCD), a phenomenon that since 2006 has ravaged bee colonies across the United States, moving from one hive to another in unpredictable patterns and causing the death of up to 90 percent of the bee colonies in affected apiaries. The National Research Council at the National Academy of Sciences has, as a result of CCD, characterized the beekeeping industry as being in "crisis mode"—a point echoed and re-emphasized in a USDA action plan regarding honeybee threats. And hundreds of news articles and many in-depth media reports have continued to chronicle the looming disaster facing American beekeepers and the producers of over 90 fruit, vegetable and fiber crops that rely on honeybee pollination.

Unfortunately, despite extensive and coordinated work by experts from Government, academia and the private sector, the definitive causes of and solutions for CCD have yet to be identified. The research is complex, as there are a wide range of factors that—either alone or in combination—may be causes of this serious condition, including stress from the cross-country movement of bees for commercial pollination, stress of pollinating crops, and the impact of certain crop pesticides and genetic plants with altered pollination characteristics. Continuing infestations of the highly destructive Varroa mite, combined with other pests and mites, are also thought to compromise the immune systems of bees and may leave them more vulnerable to CCD. At the same time, researchers will need to focus on the many reported instances in which otherwise healthy, pest-free, stationary bee colonies are also suffering collapse or problems with reproduction.

AHPA, other industry officials, and leading scientists believe that an important contributing factor in the current CCD crisis is the longstanding, substantial underfunding of U.S. bee research, resulting in an inadequate capacity to respond to new research challenges and to take long-term steps to assure honeybee health. In recent years, honeybee research has become overly confined to four ARS laboratories that, while providing the first line of defense against exotic parasitic mites, Africanized bees, viruses, brood diseases, pests, pathogens and other conditions, simply cannot be expected to handle the full range of honeybee research challenges at current funding levels. At the same time, universities and the private sector, despite their ability to provide significant and innovative new research on emerging bee threats, have scaled back their efforts due to a lack of available funds.

In recent years, the Federal Government has spent very modest amounts at each ARS Honeybee Research Laboratory—for a sector that contributes \$15 billion per

year to the U.S. farm economy and exponentially more to ensuring ecological balance and a healthy human diet. Worse still, with the emergence of CCD, funding amounts have not been increased commensurate with growing bee health concerns, resulting in a serious gap between the threats faced by U.S. honeybees and the capacity of our researchers to respond. Closing this gap will require significant new resources. To give a sense of this cost, it is estimated that each new scientist, technician and the support materials that they need will cost an additional \$500,000 per year. Many new scientists are needed.

To address these challenges, the AHPA respectfully requests funding consistent with authorizations provided in the 2008 farm bill. Specifically, the funds should be divided among the following Department of Agriculture agencies and programs: (1) the four ARS Bee Research Laboratories for new personnel, facility improvement, and additional research; (2) the Animal and Plant Health Inspection Service to conduct a nationwide honeybee pest and pathogen surveillance program; (3) the ARS Area Wide CCD Research Program divided between the Beltsville, Maryland and the Tucson, Arizona research laboratories to identify causes and solutions for CCD in affected States; (4) the NIFA to fund extension and research grants to investigate the following: honey bee biology, immunology, and ecology; honey bee genomics; native bee crop pollination and habitat conservation; native bee taxonomy and ecology; pollination biology; sub-lethal effects of insecticides, herbicides, and fungicides on honey bees, native pollinators, and other beneficial insects; the effects of genetically modified crops, including the interaction of genetically modified crops with honey bees and other native pollinators; honeybees, bumblebees, and other native bee parasites and pathogens' effects on other native pollinators; and (5) the additional ARS research facilities in New York, Florida, California, Utah, and Texas for research on honeybee and native bee physiology, insect pathology, insect chemical ecology, and honeybee and native bee toxicology.

Unfortunately, it has come to our attention that ARS, in a unique decision to try and achieve false savings, is planning in fiscal year 2013 to close the Weslaco ARS research facility, including the ARS Honeybee Research Laboratory—perhaps the newest and best of the four honeybee research laboratories in terms of practical, near term results achieved. Our understanding is that funds currently dedicated to the Weslaco honeybee research function would be “re-directed” to honeybee research currently conducted in Beltsville, Maryland, and Tucson, Arizona.

The AHPA strongly opposes the decision to close the Weslaco Honeybee Research Laboratory. While we appreciate that ARS intends to maintain and re-direct funds rather than terminate the research function entirely, it is important to note that each of the four ARS Honeybee Research Laboratories focuses on different problems facing the U.S. honey industry and undertakes research that is vital to sustaining honey production and assuring essential pollination services in this country. And each of the four ARS Honeybee Research Laboratories has unique strengths and is situated and equipped to support independent research programs which would be difficult, and in many cases impossible, to conduct elsewhere. This is particularly true of the Weslaco laboratory.

Thus, given the multi-factor research capacity needed to address the scourge of CCD and the unique contributions made by each of the four laboratories, the AHPA urges Congress to permit Weslaco and each of the other ARS Honeybee Research Laboratories to continue and expand upon their unique strengths in their respective geographic locations. For the following reasons, the AHPA believes that maintaining the laboratory in Weslaco is in the best overall interest of our Nation's honeybee research agenda:

—*Personnel.*—ARS, in its plan to re-direct funds from the Weslaco Honeybee Research Laboratory, does not account for the loss of highly skilled personnel. While ARS appears to believe that the scientific staff in Weslaco are replaceable, we believe this ignores that honeybee research is a unique study with a limited number of dedicated scientists worldwide. Further, even assuming ARS could replace some or all of the scientists, valuable time and years of practical and scientific knowledge and experience will be lost. In fact, some of the key personnel at Weslaco have already resigned or opted for retirement out of concern that the ARS plan for re-direction of funds will come to fruition. And finally, since the ARS plan would re-direct funding to other laboratories with existing research leaders, the result will likely be the loss of a research leader position—a position typically reserved for distinguished scientists. Each research leader position lost diminishes our capacity to attract world class scientific talent to honeybee research.

—*Mission.*—The Weslaco Honeybee Research Laboratory's mission is to research ways to implement integrated pest management principles. As discussed above, each of the four ARS laboratories has a unique focus. Weslaco is the only hon-

eybee laboratory dedicating a significant amount of time, money and expertise to honeybee pest, parasite and disease management—an absolutely necessary endeavor if we intend to preserve colony strength while awaiting the results of research initiatives at other laboratories aimed at longer-term solutions for the same problems. In short, the Weslaco laboratory is the front-line defense. The others represent longer-term hope. For example, in cooperation with pharmaceutical and chemical manufacturing companies, Weslaco scientists have played a key role in bringing to market all of the major chemical controls that have successfully mitigated damage that would otherwise be caused by *Varroa* destructor mites. If the honeybee research laboratory at Weslaco is re-located as proposed, its research focus will necessarily be altered, and possibly even lost since the other laboratories do not have expertise in the same area of research. We cannot afford to take that risk at this particularly challenging time.

- Cost.*—If implemented, the ARS plan will produce an overall cost increase for the agency’s honeybee research program instead of serving as an austerity measure. The Weslaco Honeybee Research Laboratory will realize increased costs associated with travel and other administrative inefficiencies that will be necessary if ARS wishes to continue the current Weslaco research agenda—an agenda that relies on particular geographic and climate qualities not found in Beltsville, Maryland or Tucson, Arizona. Additionally, the receiving facilities will be burdened with new administrative responsibilities and demands for space. Restructuring any research facility requires time and funding. The ARS facilities are no exception. The fiscal year 2012 Senate Appropriations Committee report included the following language: “[W]hile the Committee understands the need to continually look for ways to increase efficiency and improve research outcomes, laboratory closures often cost money in the short-term and do not necessarily provide real savings. Therefore, the Committee directs ARS to evaluate its capital asset requirements for necessary coordination with ongoing and emerging research opportunities. As part of this evaluation, ARS should provide opportunity for public comment in order to incorporate the priorities of all interested stakeholders, including ARS and other scientists, and users of ARS data. Finally, in future budget requests, the Committee directs ARS to identify any costs associated with any proposed laboratory closures, including decommissioning, relocation or other effects on employees, and any other additional costs.” Unfortunately, the ARS plan to re-direct funding does not appear to account for the added costs discussed above and contemplated by Congress just a year ago. Further, while they have communicated with certain stakeholders, ARS has failed to provide formal notice and afford appropriate time for public comment by those most affected by its decision. And finally, ARS has not, to our knowledge, identified “costs associated with any proposed laboratory closures, including decommissioning, relocation or other effects on employees, and any other additional costs.”
- Climate.*—The research currently conducted at the Weslaco Honeybee Research Laboratory relies on more than 450 research-quality bee colonies located near the facility. The scientists at Weslaco have access to such a large bee supply due in substantial part to the unique climate and habitat afforded by the laboratory’s Weslaco, Texas location. Taken together, the warm climate and ample scrub brush ranch land combine for an optimal breeding ground and year-round research—a combination that neither the Beltsville, Maryland or Tucson, Arizona can offer.
- Quality and Divisibility of Facility.*—As a practical matter, closing the Weslaco Honeybee Research Laboratory is unnecessary. As discussed above, the laboratory at Weslaco is among the best and newest in the country, and it remains an ideal geographic location for honeybee research. While we acknowledge that ARS maintains other agricultural research laboratories on the same campus, known collectively as the Kika de la Garza Subtropical Agricultural Research Center, and that those other laboratories are also targeted for closure, we note that the property is easily divisible and that closure of one lab does not necessitate closure of another. Each laboratory on the Weslaco campus operates in a separate building with considerable distance between buildings. Further, each laboratory has its own independent scientific and administrative staff. Thus, ARS can easily close and lease or sell other agricultural research laboratories located on the Weslaco campus without disturbing the important work conducted by the honeybee laboratory. Indeed, this makes good sense given that the ARS plan is to both close and eliminate funding for those other laboratories whereas, in the case of the honeybee laboratory, it is only to close and re-direct funding, a move that the members of our organization believe strongly will actually result in greater costs than benefits.

—*Precedent.*—This is not the first time ARS laboratories have faced this challenge. In the President’s fiscal year 2003 budget proposal, a number of laboratories were proposed for closure, consolidation or reduction. Ironically, those targeted then for closure included all of the ARS Honeybee Research Laboratories except Weslaco. Similar to the current situation, the fiscal year 2003 proposal sought to achieve projected budgetary savings at the expense of science. Congress wisely and emphatically rejected that proposal. The following excerpt is from the fiscal year 2003 Senate Appropriations Committee report: “The Committee does not concur with proposals to close selected research laboratories and consolidate and terminate related ongoing research programs. The Committee directs the Agency to maintain these important research programs and laboratories and maintains funding which was eliminated under the President’s budget.” Then in the fiscal year 2009 omnibus appropriations bill, Congress preserved funding for the Weslaco, Texas ARS research facility despite a recommendation in the President’s budget proposal to close that facility. Congress should again reject closure and consolidation of the ARS Honeybee Research Laboratories in fiscal year 2013, just as it did on two prior occasions in the last decade.

While to date the four ARS Research Laboratories have been the backbone of American Honeybee research, we do not believe that those four facilities alone—even when fully funded—will have the capacity to meet today’s research needs. This is why, after analyzing the new and serious threats to U.S. honeybees, Congress, representatives of the farm sector and leading researchers developed the research priorities that were incorporated into the 2008 farm bill. In addition to increased resources for ARS research, these experts pressed for new funding, through NIFA, for Government, academic and private sector research. They also urged new bee surveillance programs through the Animal and Plant Health Inspection Service to address the alarming lack of accurate information about the condition of U.S. bee colonies

One particularly effective way of adding needed capacity and innovative expertise in the effort to ensure honeybee health would be to reinvigorate private sector and university bee research initiatives. For many years, these sectors played a vital role in honeybee research, and many leading universities have significant bee research capabilities. In recent years, non-Federal agency research has substantially declined due to a lack of support for such initiatives. Fully funding the 2008 farm bill authorization for the Department of Agriculture’s NIFA would go a long way toward achieving this worthy goal.

NIFA is tasked with advancing knowledge for agriculture by supporting research, education, and extension programs. Funds may be channeled through the Department to researchers at land-grant institutions, other institutions of higher learning, Federal agencies, or the private sector. The requested funding for NIFA would provide important flexibility in allocating badly needed Federal dollars among Government, private sector and university researchers. The recipients would provide more widespread research on honeybee biology, immunology, ecology, and genomics, pollination biology, and investigations into the effects on honeybees of potentially harmful chemicals, pests, other outside influences, and genetically modified crops. The result of such funds would be to ensure flexible financing with a comprehensive plan for battling CCD, pests, and other ongoing and future honeybee threats.

Additionally, the same coalition of experts identified a need for a honeybee pest and pathogen surveillance program. Although significant data exists on American honey production, comparably less and lower quality data exists on beekeepers and bees. Providing continued funding under the 2008 farm bill authorizations to the Animal and Plant Health Inspection Service at the Department of Agriculture would allow the Department to utilize such data to better respond to pest and disease outbreaks, and to compile data that may better enable prediction of new threats. Given the roughly \$15 billion added to the U.S. farm economy each year by honeybees, this is certainly a worthwhile investment in the honeybee and pollinator industry.

In conclusion, we wish to thank you again for your past support of honeybee research and for your understanding of the critical importance that Federal funding plays in ensuring a healthy honeybee supply. By way of summary, in fiscal year 2013, the American Honey Producers Association strongly encourages at least \$11.7 million in funding for CCD and other honeybee research spread among the four ARS Honeybee Research Laboratories. The AHPA strongly opposes closure of the ARS Honeybee Research Laboratory in Weslaco, Texas. And, the AHPA supports continued funding for the NIFA at the Department of Agriculture, and the Animal and Plant Health Inspection Service. Only through critical research can we have a viable U.S. beekeeping industry and continue to provide stable and affordable supplies of

bee-pollinated crops, which make up fully one-third of the U.S. diet. I would be pleased to provide answers to any questions that you or your colleagues may have.

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 currently compose the list of 1994 Institutions, thank you for this opportunity to outline our needs and concerns for fiscal year 2013.

This statement is presented in three parts: (a) summary of our fiscal year 2013 funding recommendations, (b) brief background on Tribal Colleges and Universities, and (c) 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 2013 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: \$4,312,000 for the 1994 Institutions' competitive Extension grants program; \$2 million for the 1994 Institutions' competitive Research Grants program; \$3,335,000 for the Higher Education Equity Grants; a doubling of the corpus in the Native American Endowment fund; and in the Rural Development—Rural Community Advancement Program (RCAP), that \$4 million be appropriated for the TCU Essential Community Facilities Grants program (the same level included in the President's fiscal year 2013 budget request) to help the 1994 Institutions address the critical facilities and infrastructure needs that advance their capacity to participate as full land grant partners.

*Background on Tribal Land Grant Institutions*

The first Morrill Act was enacted in 1862 specifically to bring education to the people and to serve their fundamental needs. Today, 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 32 Tribal Colleges and Universities that compose the list of 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 20 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 critically impor-

tant 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 this program include poverty, isolation, health, cultural dissonance, and land use practices by Lakota landowners. To continue such highly successful programs conducted at 1994 Institutions, we request that the Subcommittee appropriate a minimum of \$4,312,000 for this competitive grants program to support 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 Congress is currently functioning. The \$1,801,000 appropriated last year 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 maintain and expand the vital research projects begun at the 1994 Institutions, but only if adequate funds are secured and sustained. A total research program funded at less than \$2 million, for which all 32 of the 1994 Institutions compete for awards, is incredibly 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; ramifications of 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 considerable 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 afford the 1994 Research competitive program a very modest increase, and appropriate \$2 million for these critical grants.

*1994 Institutions' Educational Equity Grant Program.*—This program is designed to assist 1994 Institutions with academic programs. Through the modest appropria-

tions 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 appropriate at a minimum, \$3,335,000 to allow the 1994 Institutions to continue their current 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' treasury endowment was \$4,306,999 and after the USDA NIFA claimed its standard 4 percent administrative fee, \$4,134,719 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 all but 6 of the 32 tribal college (1994) land grant institutions. In other words, about 80 percent of the 1994 institutions receive less of the annual interest yield for program use than the administrative fee paid to the USDA-NIFA.

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 \$97,494, 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. Identifying creative solutions is essential to address so many public funding needs in a time of extreme fiscal austerity. The TCUs propose a one-time doubling of the 1994 Native American endowment, which would result in an increase in the annual interest yield by approximately \$4 million—the same amount as proposed for the TCU Rural Development Essential Community Facilities Grant program. Payments into the endowment remain with the U.S. Treasury, therefore only the interest yield is scored as outlay. Should the endowment corpus be doubled and the agency's administrative fee scaled back, the TCUs could then consider forgoing the Rural Development program. We respectfully request that the Subcommittee consider doubling the current endowment corpus by fiscal year 2015. 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 and address critical infrastructure needs.

*Tribal Colleges and Universities Essential Community Facilities Program (Rural Development).*—The Absent the doubling of the 1994 endowment corpus resulting in an additional interest yield equal to the TCU Essential Community Facilities Program, we strongly urge the Subcommittee to appropriate a minimum of \$4 million, the level included in the President's fiscal year 2013 budget request, each year for the next 3 fiscal years to afford the 1994 Institutions the means to actively 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 2013 appropriations requests.

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PREPARED STATEMENT OF THE AMERICAN PHYTOPATHOLOGICAL SOCIETY

The American Phytopathological Society (APS), the premier educational, professional, and scientific society dedicated to the promotion of plant health and plant disease management for the global good, appreciates the opportunity to provide our views on research, extension, and education provisions of the fiscal year 2013 agricultural appropriations bill. The APS believes that now is the time to make strategic, additional investments in agricultural science to help jumpstart the U.S. economy. Thus, we request the Subcommittee to include in the fiscal year 2013 agricultural appropriations bill, funding for agricultural science and technology at no less than the fiscal year 2012 level for the USDA Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA). We further request the Subcommittee to support strategic investments, above the fiscal year 2012 funding levels, of \$72.9 million for the ARS and NIFA as described below:

- A net increase of \$7.9 million for salaries and expenses for the USDA Agricultural Research Service, (i.e., funding at not less than the President's budget request of \$1,102,565,000);
- A net increase of \$4 million for the Food and Agriculture Defense Initiative (homeland security) under the Integrated Activities account of the National Institute for Food and Agriculture, returning the funding to the fiscal year 2010 level of \$9.83 million with the increase divided equally between the National Plant Diagnostic Network and the National Animal Health Laboratory Network; and
- A net increase of \$61 million (total budget of \$325 million) for the Agriculture and Food Research Initiative (AFRI) competitive grants program of the National Institute for Food and Agriculture.

Agriculture in the United States is highly productive. This productivity was achieved because past investments in agricultural science led to advances that placed our producers, processors, and manufacturers at the cutting edge of agricultural technology. To ensure continued safety and security of our food, feed, fiber, and natural resources, we believe that science-based solutions to the new challenges faced in today's agriculture must be explored and developed. Further, our agricultural economy must be protected from devastating invasive plant diseases and pests by a robust diagnostic network and the development of science based tools and resources. The only way we can achieve these solutions is by providing strategic investments in agricultural science, extension, and education and to make these investments with additional funds and not by reducing funding for other essential programs at ARS and NIFA.

The jobs of 21 million Americans depend on the vitality of the U.S. agriculture and food sector. In Ohio, for example, one in seven jobs is directly tied to agriculture. For every \$1 invested in publicly funded agricultural research, a minimum of \$20 in economic activity is generated. Unfortunately, U.S. Government investments in agricultural innovation have been flat in recent years. As a consequence, the competitive edge that made the U.S. agricultural research sector the envy of the world has declined, and industry is turning to other parts of the world for innovation. The decisions made by the Subcommittee this year will have far-reaching impacts, the downstream implications of decisions made now have far reaching impacts, as the scientific research funded today will be responsible for enhancing the Nation's agricultural productivity and overall economic prosperity in the future.

While an increase of \$100 million would have little impact on the NIH or NSF research budgets, a \$73 million increase in funding for the USDA's ARS and NIFA would be significant in the impact on the Nation's economy, generating almost \$1.5 billion in economic activity.

The added funds we are requesting for the Food and Agricultural Defense Initiative (Homeland Security) would ensure that we have a coordinated network of diagnostic laboratories and experts at land grant universities, State departments of agriculture to protect our crops from diseases such soybean rust, citrus greening, plum pox virus, sudden oak death, Ug99. The slight increase in funding for the ARS would support funding for food safety, crop health, and strengthen long-term agroecosystem research that will be essential for ensuring an abundant supply of safe, high quality, food, feed, and fiber during periods of changing weather patterns.

The 23 percent increase in the AFRI competitive grants program would provide a much needed boost of funding for fundamental, applied, and integrated research

and education that will be used to address critical gaps in food safety science, particularly those related to human pathogens on/in plants and plant associated microbial communities. The AFRI funding increase could also expand opportunities for scientists broadly trained to meet the needs of the various agricultural industries.

We recognize the difficult challenge facing the Subcommittee. However, we believe that investment in science for food and agriculture is essential for maintaining the Nation's food, economic, and national security. Thank you for this opportunity to present our views.

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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 2013 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.

APPA is the national service organization representing the interests of over 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 \$56 million 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 the Commodity Futures Trading Commission (CFTC), a \$102 million increase over fiscal year 2012. As the 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 rulemakings and implementation. Given the direct effect the rulemakings will have on public power utilities and consumers, APPA is supportive of giving the CFTC the resources it needs to complete the rulemakings quickly and thoroughly.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) is pleased to submit the following testimony on the fiscal year 2013 appropriation for food safety and science programs at the U.S. Department of Agriculture (USDA). The ASM is the largest single life science organization in the world with more than 38,00 members.

The administration's fiscal year 2013 budget for research and development (R&D) at USDA would provide \$2.6 billion or a 2.7 percent increase over the fiscal year 2012 level. There is a proposed increase of 23 percent for the USDA's competitive grants program, the Agriculture Food and Research Initiative (AFRI), which funds research at both USDA facilities and land grant universities. Also increased is funding for research in food safety and global food security. The budget would increase support for USDA bioenergy research as well, in part to develop cellulosic and algae-based biofuels. We strongly support these program increases and ask Congress to approve the fiscal year 2013 request for these resources necessary to strengthen USDA research.

Agriculture not only ensures a healthy, plentiful food supply, but contributes significantly to the economy. Agriculture related businesses account for 1-in-12 U.S. jobs. Net farm income is forecast to be nearly \$92 billion this year. Farms and ranches produce food volumes roughly one-third greater than domestic demand, and the U.S. export share of the global ag market is usually about 20 percent. In 2011, exports of agriculture related products reached a record \$136.3 billion, supporting more than 1 million jobs in an economic sector where exports outperform imports.

In 2010, U.S. agriculture generated food products worth \$352 billion, and USDA expects \$410 billion for 2011 when market data are completed. Higher crop yields,

better animal breeding, and new products like genetically modified plants are among the many science based advances involved in the success of U.S. agriculture. R&D efforts have had tangible farm-to-fork results, making U.S. agriculture statistically one of the Nation's most productive economic sectors. USDA research also improves food safety, helps develop sustainable energy, protects animal health, and preserves water quality and the environment. USDA personnel depend upon the best available methods and tools to accomplish public health goals like decreasing foodborne illnesses and crop losses due to microbial pathogens.

*USDA Funding Advances Science-Based Agriculture*

The Agricultural Research Service (ARS) conducts intramural research and the National Institute of Food and Agriculture (NIFA) distributes grants to colleges and universities for extramural research, extension, and education activities. The ARS budget request for discretionary funding is \$1.103 billion, which is \$8 million over the fiscal year 2012 enacted level. The NIFA request is \$1.244 billion or \$37 million over fiscal year 2012. Updated science and technology like genomic databases are critical to USDA's oversight of the agriculture enterprise in this country. For example, one-third of total U.S. ag exports are genetically engineered (GE) crops or products from these crops, and about 80 percent of processed foods sold in the United States contain GE-derived ingredients. Federal regulators test an increasing number of samples resulting from food biotechnology; in fiscal year 2011 alone, testing increased by approximately 28 percent. USDA investigators and educators clearly must access the latest information when assessing the safety of our food supply. USDA researchers also discover best practice approaches to food production, microbial diseases of food animals and plants, and sustainable environments. A 2011 report by the Government Accountability Office called for stronger efforts by USDA in collecting data on antibiotic use in food animals, to better understand the relationship between use and pathogens' drug resistance. These science based activities require adequate funding each year for USDA R&D programs.

ARS maintains over 100 facilities in the United States and abroad with ongoing studies of optimal ag production, food safety and security, and environmental stewardship. ARS scientists are responsible for epidemiological studies of pest and disease transmission to protect crops. The fiscal year 2013 request identifies new proposed research, like the allocation of \$7.6 million to develop management tools for soil-borne plant pathogens and nematodes. One goal is to identify beneficial soil microbes for use as biocontrol tools that stop plant pathogens naturally. ARS also will increase capacity at its overseas biological control laboratories to find new biocontrol agents for use in the United States. Another plant protection program receiving increased funding will develop plant varieties inherently resistant to infectious diseases. Other researchers would focus on livestock protection, such as projects to detect and eliminate tumor and enteric viruses in poultry.

NIFA funds extramural research projects at the States' agricultural experiment stations, land grant universities, State-based cooperative extension system, and other research and education institutions. Federal funds are distributed through grants and other competitive awards, and NIFA administers USDA's primary grants program, the Agriculture and Food Research Initiative. The ASM supports the fiscal year 2013 budget for AFRI of \$325 billion, an increase of \$60.5 million. USDA identified priority areas funded in part by this increase will be developing better feedstocks for biofuel production, minimizing antibiotic resistance transmission among foodborne pathogens, and supporting additional graduate student training through the NIFA Fellows program.

Research results reported in the past year are the best argument for sufficient USDA R&D funding in fiscal year 2013, illustrating the breadth of contributions made by USDA science:

- ARS scientists found that using Fourier transform infrared-attenuated total reflection (FTIR-ATR) spectroscopy can rapidly identify citrus plant leaves infected with citrus greening disease, faster and cheaper than the current DNA method.
- Last year, USDA and the U.S. Department of Energy jointly announced they will invest up to \$30 million over 3 to 4 years to support R&D in biofuels, bioenergy, and high-value bio-based products. In August, they awarded 10 university grants totaling \$12.2 million to improve the efficiency and cost-effectiveness of biofuel and bioenergy crops.
- ARS molecular biologists are identifying genes in the yeast *Saccharomyces cerevisiae* to improve fermentation of fiber from corn, wheat, and other plants into cellulosic ethanol during biofuel manufacture. The genes are likely to improve the yeast's ability to resist deleterious growth inhibitors created during acid pre-treatments.

- Last year, USDA and the U.S. Agency for International Development began construction on a university-associated ARS facility that will specialize in breeding wheat varieties resistant to stem rust disease, which threatens grain crops worldwide.
- An ARS procedure developed to improve polymerase chain reaction (PCR) methods for detecting plant pathogens has increased test sensitivity by 100 to 1,000 fold. Called Bio-PCR, it identified the bacterium responsible for Pierce's disease of grapes in 90 percent of infected samples compared to 13 percent with conventional PCR.
- A team of ARS scientists, screening *Starmerella* yeast for their ability to produce surfactant-like sophorolipids, are identifying green alternatives to the currently used petroleum-based surfactants in products like detergents and paints.

#### *USDA Funding Protects the U.S. Food Supply*

One in six Americans becomes sick each year with foodborne illnesses that could be prevented. USDA cooperates daily with other Federal partners, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to safeguard the U.S. food supply through prevention, public and industry education, site inspections and disease outbreak investigations. The fiscal year 2013 budget for food safety will continue USDA's three part strategy to fulfill its food oversight responsibilities: prioritizing prevention, strengthening surveillance and enforcement and improving response and recovery.

USDA scientists and inspectors are responsible for some important steps in reducing foodborne illness. For example, USDA expects to enforce new, stricter *Salmonella* and *Campylobacter* standards in turkeys and young chickens, which could prevent up to 25,000 human illnesses annually. During 2000–2010, the agency helped achieve the national goal of reducing *E. coli* O157 infection rates by 50 percent. In the past 15 years, the overall rates of six foodborne infections have declined by 23 percent, according to a 2011 CDC report. Both ARS and NIFA sponsor research on safe production, storage, processing, and handling of animal and plant products. For instance, ARS microbiologists are studying the relationship between cattle feed containing corn byproducts of biofuel processing and the persistence of pathogenic *E. coli* on the animals' hides. Other USDA microbiologists are studying yeast extracts as an alternative to using antibiotics in organic turkey farming.

The USDA's Food Safety and Inspection Service (FSIS) enforces the Federal standards for all meat, poultry, and processed egg products, to ensure they are safe, wholesome, and properly labeled and packaged. The fiscal year 2013 budget proposes a decrease in FSIS discretionary funding: at \$996 million, more than \$8 million below fiscal year 2012 and \$11 million less than the fiscal year 2011 level. Volumes of imported foods are steadily increasing and foodborne illnesses persist as major public health threats in the United States. Approximately 8,400 FSIS employees inspect foods and production methods at more than 6,200 slaughtering and processing facilities, import houses, and other federally regulated entities involved in food production. Their workload is daunting: for example, about 40 million cattle inspected yearly by FSIS personnel.

#### *Conclusion*

The ASM encourages Congress to increase the fiscal year 2013 budget in support of USDA's science and food safety programs. USDA research in multiple agriculture sectors has pervasive impacts on our quality of life. The USDA mission reaches far beyond its role in transforming our Nation's farms and ranches into highly productive, economically important businesses. USDA science protects human and animal health, prevents crop losses from disease and climate changes, seeks best practices to preserve the environment, encourages innovation in valuable agriculture based products and supports new generations of agriculture scientists and educators.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY OF AGRONOMY; CROP SCIENCE SOCIETY OF AMERICA; AND SOIL SCIENCE SOCIETY OF AMERICA

The American Society of Agronomy (ASA), Crop Science Society of America (CSSA), and Soil Science Society of America (SSSA) represent over 18,000 members in academia, industry, and Government, and 13,000 Certified Crop Advisers. The largest coalition of professionals dedicated to the agronomic, crop, and soil science disciplines in the United States, ASA, CSSA, and SSSA are dedicated to utilizing science in order to meet our growing food, feed, fiber, and fuel needs. We are pleased to submit the following funding recommendations for fiscal year 2013: ASA, CSSA, and SSSA urge the Subcommittee to support a \$60 million increase from fiscal year

2012 for the Agriculture Food Research Initiative (AFRI), bringing total funding to \$325 million, as requested in the President's fiscal year 2013 budget proposal. This strong level of funding will enable AFRI to continue to target areas that are key to American scientific leadership including: plant health and production, food safety, sustainable bioenergy and global food security. ASA, CSSA, and SSSA further recommend funding the Agricultural Research Service (ARS) at \$1.13 billion in fiscal year 2013 to recognize the essential role of the intramural programs in ensuring the safety of our Nation's food system. In addition, ASA, CSSA, and SSSA recommend funding the United States Department of Agriculture's (USDA) National Institute of Food and Agriculture (NIFA) at \$1.244 billion (an increase of \$37 million over fiscal year 2012) in order to maintain continued support for research, education, and extension programs. Finally, we support a strong commitment to farm bill conservation programs and request that they be funded at levels agreed to in the 2008 farm bill to ensure preservation of our Nation's essential resources—soil and water.

#### *Background*

The success of the agriculture and food industry plays a significant role in the overall health and security of the U.S. economy. In 2010, U.S. farms and ranches spent \$288 billion to produce goods valued at \$369 billion. The value of U.S. food and agriculture exports is expected to be more than \$140 billion in 2011, creating a record trade surplus of \$42.5 billion. Furthermore, the jobs of 21 million Americans depend on the vitality of the U.S. agriculture and food sector.

Investments in publicly funded research are critical for maintaining a successful agriculture and food sector. For every \$1 invested in publicly funded agricultural and food research, \$20 in economic activity is generated. Budgetary decisions made today have far-reaching impacts, as the scientific research funded today will be responsible for enhancing the Nation's agricultural productivity and economic prosperity in the future. A strengthened commitment to investments in science for food and agriculture is essential for maintaining the Nation's food, economic, and national security.

#### *Agricultural Research Service (ARS)*

ASA, CSSA, and SSSA applaud the Agricultural Research Services' (ARS) ability to respond to and address agricultural problems of high national priority. ARS's 2,200 scientists are located at 90+ research locations, managing 800 research projects that help solve current and future crop and livestock production and protection, human nutrition and environmental quality challenges. ARS programs and technologies ensure high-quality, safe food and other agricultural products; assess the nutritional needs of Americans; help to sustain a competitive agricultural economy; enhance the natural resource base and the environment; and, provide economic opportunities for rural citizens and communities. ARS also forms key partnerships that move new technologies to the marketplace.

These partnerships are especially important to leverage during a time when our Nation's economy remains vulnerable and Federal funding is constrained. Such cooperative research and development helps foster American businesses and enhances the position of the United States as a global leader in food, feed, fiber and fuel production.

#### *Highlighting National Institute of Food and Agriculture Programs (NIFA)*

*Agriculture and Food Research Initiative (AFRI).*—ASA, CSSA, and SSSA strongly endorse funding AFRI at \$325 million, which is less than half of what is authorized in the Food, Conservation, and Energy Act of 2008. AFRI is the premier competitive grants program for fundamental and applied research, extension and education in support of our Nation's food and agricultural systems. Investments in AFRI bolster work performed by ARS, America's land grant colleges and universities, the private sector and the American farmer.

*Hatch Act Formula Funding.*—ASA, CSSA, and SSSA support \$236 for Hatch Act formula funds. These funds provide research grants to our Nation's great land-grant colleges and universities. Any additional cuts to academic funding will reduce the ability of our scientists and students to conduct imperative research such as developing drought resistant wheat varieties.

*Sustainable Agriculture Research and Education Programs (SARE).*—ASA, CSSA, and SSSA support the President's budget request for SARE at \$22.7 million. This includes \$4.7 million for the Professional Development Program and \$3.5 million for the creation of a new Federal-State Matching Grant SARE Program. SARE directly supports farmer-led research and development in practices that, in turn, increase food, fuel and fiber sustainability. In 2007, 64 percent of farmer and rancher grantees noted that because of an SARE project, they had achieved higher sales, and another 79 percent had experienced improved soil quality.

*Cooperative Extension System.*—Extension forms a critical part of research, education and extension program integration, a feature unique to NIFA. ASA, CSSA, and SSSA support \$294 million for Smith-Lever 3(b) and 3(c) to support continuing education and research activities.

*Natural Resources Conservation Service*

ASA, CSSA, and SSSA also support farm bill conservation programs that help farmers and ranchers adopt critical conservation practices to reduce soil erosion, conserve water, address nutrient management concerns and contribute to carbon sequestration. NRCS conservation programs are an essential tool to help mitigate and address the challenge of producing the food, feed, fuel and fiber needed for a growing global population. We urge the Subcommittee to fund these programs at levels agreed to in the 2008 farm bill.

*Summary*

A balance of funding mechanisms, including intramural, competitive, and formula funding is essential to maintain the capacity of the United States to conduct both basic and applied agricultural research, to improve crop and livestock quality, and to deliver safe and nutritious food products while protecting and enhancing the Nation's environment and natural resource base.

Thank you for your consideration. For additional information or to learn more about the ASA, CSSA, and SSSA, please visit [www.agronomy.org](http://www.agronomy.org), [www.crops.org](http://www.crops.org), or [www.soils.org](http://www.soils.org).

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PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR NUTRITION

The American Society for Nutrition (ASN) appreciates the opportunity to submit testimony regarding fiscal year 2013 appropriations for the U.S. Department of Agriculture (USDA) National Institute of Food and Agriculture's Agriculture and Food Research Initiative (AFRI) and the USDA Agricultural Research Service (ARS). Founded in 1928, ASN is a nonprofit scientific society with more than 4,500 members in academia, clinical practice, Government and industry. ASN respectfully requests \$1.2 billion for USDA's Agricultural Research Service, and we urge you to adopt the President's request of \$325 million for the Agriculture and Food Research Initiative competitive grants program in fiscal year 2013.

*Agriculture and Food Research Initiative*

The USDA has been the lead nutrition agency and the most important Federal agency influencing U.S. dietary intake and food patterns for years. Agricultural research is essential to address the ever-increasing demand for a healthy, affordable, nutritious and sustainable food supply. The AFRI competitive grants program is charged with funding research, education, and extension grants and integrated research, extension, and education grants that address key problems of national, regional, and multi-state importance in sustaining all components of agriculture. These components include human nutrition, farm efficiency and profitability, ranching, renewable energy, forestry (both urban and agro forestry), aquaculture, food safety, biotechnology, and conventional breeding. AFRI has funded cutting-edge, agricultural research on key issues of timely importance on a competitive, peer-reviewed basis since its establishment in the 2008 farm bill. Adequate funding for agricultural research is critical to provide a safe and nutritious food supply for the world population, to preserve the competitive position of U.S. agriculture in the global marketplace, and to provide jobs and revenue crucial to support the U.S. economy.

In order to achieve these benefits, AFRI must be able to advance fundamental sciences in support of agriculture and coordinate opportunities to build off of these discoveries. Therefore, ASN strongly urges you to adopt the President's request of \$325 million for the Agriculture and Food Research Initiative competitive grants program in fiscal year 2013. ASN also strongly supports funding AFRI at the fully authorized level of \$700 million as soon as practical. Current flat and decreased funding for AFRI hinders scientific advances that support agricultural funding and research.

*Agricultural Research Service*

The ARS is the Department of Agriculture's lead scientific research agency. The ARS conducts research to develop and transfer solutions to agricultural problems of high national priority. It is also the job of ARS to ensure high-quality, safe food, and other agricultural products; assess the nutritional needs of Americans; sustain a competitive agricultural economy; enhance the natural resource base and the envi-

ronment; and provide economic opportunities for rural citizens, communities, and society as a whole.

Nutrition monitoring conducted in partnership by the USDA ARS with the Department of Health and Human Services (HHS) is a unique and critically important surveillance function in which dietary intake, nutritional status, and health status are evaluated in a rigorous and standardized manner. (ARS is responsible for food and nutrient databases and the “What We Eat in America” dietary survey, while HHS is responsible for tracking nutritional status and health parameters.) Nutrition monitoring is an inherently governmental function and findings are essential for multiple Government agencies, as well as the public and private sector. Nutrition monitoring is essential to track what Americans are eating, inform nutrition and dietary guidance policy, evaluate the effectiveness and efficiency of nutrition assistance programs, and study nutrition-related disease outcomes. Because of past funding deficiencies, some food composition database entries don’t reflect the current food supply, which may negatively impact programs and policies based on this information. It is imperative that needed funds to update USDA’s food and nutrient databases and the “What We Eat in America” dietary survey, both maintained by the USDA ARS, are appropriated to ensure the continuation of this critical surveillance of the Nation’s nutritional status and the many benefits it provides.

With the growing need for agricultural research to ensure that the country is healthy, ARS requires access to sufficient funding. Therefore, ASN requests that ARS receive \$1.2 billion in fiscal year 2013. At least \$10 million above current funding levels is necessary to ensure that the critical surveillance of the Nation’s nutritional status and the many other benefits ARS provides continue. With such funding, the ARS will be able to continue its vision of leading America toward a better future through agricultural research and information.

USDA AFRI and ARS programs are both equally important to the nutrition field because together they provide the infrastructure and the investigator-initiated, peer-reviewed research that generates new knowledge and allows for rapid progress toward meeting national dietary needs. These programs allow USDA to make the connection between what we grow and what we eat. Through strategic nutrition monitoring, we can also learn how dietary intake affects our health.

Thank you for your support of USDA ARS and AFRI, and thank you for the opportunity to submit testimony regarding fiscal year 2013 appropriations. Please contact John E. Courtney, Ph.D., Executive Officer, at [jcourtney@nutrition.org](mailto:jcourtney@nutrition.org), if ASN may provide further assistance.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS

On behalf of the American Society for the Prevention of Cruelty to Animals (ASPCA) and our 2.5 million supporters nationwide, thank you for the opportunity to submit this written testimony. Founded in 1866, the ASPCA was the first humane organization in North America. Our mission, as stated by founder Henry Bergh, is “to provide effective means for the prevention of cruelty to animals throughout the United States.” The ASPCA works to rescue animals from abuse, pass humane laws, and share resources with other animal protection groups nationwide.

The fiscal year 2013 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations bill presents opportunities to not only cut unnecessary and wasteful Federal spending, but also to ensure that programs to protect animals are being effectively implemented. As you craft the fiscal year 2013 appropriations bill, the ASPCA asks that you please consider the following provisions to ensure that Federal funds are being effectively and responsibly spent to protect animals.

*Reinstatement of the Ban on Federal Funding for Horse Slaughterhouse Inspections*

The fiscal year 2012 Agriculture Appropriations bill failed to include a provision that barred Federal funding of USDA inspectors at horse slaughter plants in the United States. Added as an amendment to the Agricultural Appropriations bill in 2005, the original measure was supported by huge, bipartisan votes (69–28 in the Senate and 269–158 in the House). Each successive appropriations bill included the provision until last year. This provision effectively prevented horse slaughter in the United States for human consumption and saved taxpayers up to \$5 million a year. Now that the ban on inspections has been removed, horse slaughterhouses could resume operations on American soil, even though horsemeat is not sold for human consumption in the United States.

This is distressing on two counts. First, at a time when Congress is cutting funds for many vital programs across the entire Federal budget, it is outrageous that taxpayers would be asked to spend \$5 million for something as senseless as horse slaughter. Second, since Americans do not eat horsemeat, this action will benefit only foreign markets in Asia and Europe, where horsemeat is considered a delicacy.

Contrary to what some may claim, horse slaughter does not create jobs. The last three remaining slaughter plants in the United States only created a handful of physically dangerous and low paying jobs. Nor is horse slaughter a humane way to end a horse's life. Horses are ill-suited for commercial slaughterhouses due to their biology. They often endure repeated blows to the head and remain conscious during slaughter and dismemberment. The USDA has documented, at length, the cruel treatment of horses at domestic slaughterhouses.

Ending horse slaughter enjoys mainstream, bipartisan support in Congress. The American Horse Slaughter Prevention Act, which would permanently ban horse slaughter in this country and the export of horses for slaughter abroad, has overwhelmingly bipartisan support in Congress with 26 cosponsors in the Senate and over 160 in the House. Beyond Congress, efforts to end horse slaughter enjoy strong mainstream support with the American public. A 2012 poll commissioned by the ASPCA and conducted by Lake Research Partners found that 80 percent of American voters are opposed to the slaughter of horses for human consumption.

The ASPCA requests that the Committee make the fiscally responsible and humane decision to reinstate the ban on Federal funding for horse slaughterhouse inspections by the USDA by inserting the following language:

“None of the funds made available in this Act may be used to pay the salaries or expenses of personnel to—

“(1) inspect horses under section 3 of the Federal Meat Inspection Act (21 U.S.C. 603);

“(2) inspect horses under section 903 of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 1901 note; Public Law 104–127); or

“(3) implement or enforce section 352.19 of title 9, Code of Federal Regulations.”

*Maintain or Increase Animal Welfare Act Enforcement Funding for the Inspection of Puppy Mills*

One of the functions of the USDA's Animal and Plant Health Inspection Service (APHIS) is to ensure the humane care and treatment of animals by enforcing the requirements of the Animal Welfare Act of 1966 (AWA). Included in this mandate is the inspection of large-scale commercial dog breeding operations, which prioritize profit over welfare. Dogs raised in these facilities, commonly known as puppy mills, spend their entire lives in small, crowded cages without adequate veterinary care, food, water, and socialization. These dogs receive no exercise or basic grooming. To minimize waste cleanup, dogs are often kept in cages with wire flooring that injures their paws and legs. Because these cages are often stacked, waste falls through wire floors onto the animals housed below. Female dogs usually have little to no recovery time between bearing litters. When, after a few years, they can no longer reproduce, the dogs are often abandoned or killed.

In 2010, the USDA's Office of the Inspector General (OIG) released a report detailing the lax and ineffective enforcement of the AWA for puppy mills. In response, the House Appropriations Committee late last year, recognizing the importance of inspecting “problematic dog dealers,” repurposed \$4 million for puppy mill inspection enforcement. The same OIG report recommended closing a loophole in the AWA that exempts from regulation breeders selling directly to customers over the Internet. In compliance with that request, the USDA is currently drafting regulations that would close that loophole, thereby increasing the number of entities regulated and inspected under the AWA. These rules will likely be final by 2013 and will require increased funding for pre-licensing inspections of these new entities and for continued, annual inspections of these breeding facilities once licensed. The ASPCA is disappointed that the President's fiscal year 2013 budget request includes a reduction in funding for APHIS's AWA enforcement from \$28 million in the previous year to \$25 million. For fiscal year 2012, Congress approved a 20 percent increase in the USDA's annual budget to strengthen inspections and enforcement of the AWA. This is on top of \$4 million in reprogrammed fiscal year 2011 funds approved in October by House Agriculture Appropriations leaders to address problematic dog dealers. We encourage the Committee to continue this trend of prioritizing AWA enforcement. The ASPCA requests that the Committee maintain or increase the previous year's funding for APHIS's Animal Welfare Act enforcement, build upon the advancements of last year's repurposing of funds, and encourage the USDA to improve its inspections of puppy mills.

*Exceed the Statutory Funding Cap for Horse Soring Enforcement*

In addition to enforcing the Animal Welfare Act, APHIS is charged with protecting horses through its enforcement of the Horse Protection Act (HPA) of 1970. USDA inspectors enforce the HPA by conducting surprise inspections at walking horse shows by examining horses for soring and the presence of harmful and illegal chemicals. Horse soring is a cruel practice in which trainers use painful chemicals and other devices to cause such agony to a horse's front limbs that any contact with the ground makes the horse quickly jerk up its leg, producing the pronounced gait prized by the walking horse industry. Recently, the USDA's Office of Inspector General and the U.S. Attorney's Office for the Eastern District of Tennessee successfully obtained guilty pleas from four individuals arrested for horse soring in Tennessee.

While the ASPCA applauds these successful prosecutions, in most cases the cruelty of horse soring goes unnoticed because USDA officials do not have the resources to oversee most shows. In 2011, USDA inspectors had the resources to attend just 62 of approximately 700 walking horse shows nationwide. Other shows were overseen solely by inspectors trained and hired by the horse industry itself. Although present at only 8–10 percent of shows, USDA inspectors found over 50 percent of reported violations last year. One of the defendants in the recent case in the Eastern District of Tennessee testified that "every Walking Horse that enters into a show ring is sored . . . They've got to be sored to walk." Clearly the problem is endemic and industry self-regulation is not effectively exposing violators. A greater USDA presence is necessary to root out the bad actors and hold them accountable.

Since passage of the HPA in 1970, effective USDA enforcement of horse soring has been frustrated by a \$500,000 statutory funding cap on activities under the authority of HPA. Though Congress can choose to ignore the cap and fund the program at higher levels, only once, in fiscal year 2012, did the Committee choose to do so. If APHIS is to eradicate soring, the program must be adequately funded so that it can assert a strong and frequent presence at horse shows. It must also have proper funding to sample horses for the presence of foreign substances, such as those documented in the most recent criminal soring prosecutions. Finally, HPA enforcement should not have to rely on lax and inadequate industry self-regulation. The agency requires increased funding in order to certify independent veterinarians who are not biased by their involvement in the walking horse industry. APHIS has now begun this process and needs greater resources for the program to be effective.

The President's fiscal year 2013 budget request includes only \$493,000 for HPA enforcement, which is below the statutory cap and below the \$696,000 that this Committee provided last year. The ASPCA requests that the Committee continue to furnish the USDA with the proper resources and continue to exceed the statutory funding cap to allow the USDA to properly enforce the Horse Protection Act and prevent the cruel practice of horse soring.

*Ensure Proper Enforcement of the USDA Ban on Double-Deck Transport of Horses Bound for Slaughter*

Double-deck trailers are dangerous and inhumane when used to transport horses. The USDA bans the use of these trailers for horses bound for slaughter, stating: "We do not believe that equines can be safely and humanely transported on a conveyance that has an animal cargo space divided into two or more stacked levels." The USDA's Veterinary Services (VS) program is charged with enforcing this regulation.

Double-deck trailers are designed for cattle and other short-necked livestock—not horses. Because horses are significantly taller and require more head room, these trailers cannot physically provide enough space to stand upright, leading to unstable footing, falls, injuries, trampling, and death. As long as Congress allows horses to be transported and exported for slaughter, VS should take proper steps to ensure that horses are not transported in cramped and inhumane double-deck trailers during their final journeys. Currently, VS does not employ sufficient inspectors in the field or at the border to ensure that horses are not being transported to slaughter in double-deck trailers.

The ASPCA requests that the Committee direct Veterinary Services to properly and effectively enforce the ban on the use of double-deck trailers to transport horses bound for slaughter.

*Defund Licensing and Relicensing of Class B Dealers*

Currently, two types of animal dealers are licensed by the USDA to sell animals for research: Class A "purpose-bred" dealers and Class B "random source" dealers. Class A dealers are highly regulated businesses that raise their own animals. Class B dealers, on the other hand, routinely obtain animals from suppliers with unknown or suspicious backgrounds. Many of these suppliers obtain the dogs and cats

through theft, or by posing as adopters and responding to “free to good home” advertisements. Class B dealers pay suppliers for each animal, creating a financial incentive for individuals to steal pet dogs and cats from owners’ properties. Class B dealers then sell the pets to researchers. As a result, many lost or stolen family pets could end up as part of an experiment.

The USDA spends hundreds of thousands of taxpayer dollars each year unsuccessfully trying to regulate Class B dealers. The process is both lengthy and time consuming; the USDA must do lengthy “tracebacks” to try to determine the source of the animals. At one point, the USDA estimated that it spent as much as \$300,000 to regulate approximately 10 Class B dealers, or about \$30,000 per license. Even so, the department acknowledges that it is unable to guarantee that dogs and cats are not being illegally acquired for use in experiments. Five of the only eight dealers currently in operation are under investigation by the USDA, and one was recently indicted on a number of Federal charges, including identity theft. Additionally, the inability to effectively regulate Class B dealers leads to animals often being kept in deplorable and inhumane conditions.

Removing animals sourced from Class B dealers would have little impact on our Nation’s research capabilities. In May 2009, a National Academies report released on the Class B dealer system concluded that “Class B dealers are not necessary for supplying dogs and cats for NIH-funded [National Institutes of Health] research.” The NIH began implementing a pilot program in March 2011 to eliminate the use of Class B sourced dogs in favor of other more reputable sources for NIH-supported research.

Since the NIH is already taking steps to phase out the use of random sourced animals in research, there is no need or justification for the USDA to continue to spend Federal funds to support the inhumane and corrupt system of Class B dealers. The Committee has an opportunity to not only save tax dollars but to also put an end to its tacit endorsement of inhumane and possibly illegal businesses.

The ASPCA requests that the Committee insert the following language to prohibit the USDA from spending funds on new licensing or relicensing of Class B Dealers:

*“Provided, That appropriations herein made shall not be available for any activities or expense related to the licensing of new Class B dealers who sell live, random source dogs and cats for use in research, teaching, or testing, or to the renewal of licenses of existing Class B dealers who sell live, random source dogs and cats for use in research, teaching, or testing”.*

#### *Defund Wildlife Services’ Lethal Predator Control*

The USDA’s Wildlife Services (WS) division is a little-known Federal agency that uses tax dollars to kill wildlife species considered by private landowners and ranchers to be problematic or nuisances. Unattended traps and poisons—and even helicopter hunting—are all routine features of WS’s campaign to kill wildlife. Their work is often carried out without oversight, fiscal accountability, or public notification. The methods they employ are often indiscriminate and ineffective. In some cases, WS traps and poisons have unintentionally killed beloved family pets.

The WS lethal predator control program is a waste of taxpayer dollars. Not only does WS provide a subsidized service for private landowners, but also its indiscriminate and random targeting of predators is not based on sound science. The USDA estimates that it spends \$10 million on its lethal predator control program. By cutting this wasteful and unnecessary program, Congress can ensure that U.S. taxpayers will stop subsidizing risky wildlife control methods for the benefit of private property owners.

The ASPCA requests that the Committee act in a fiscally sound and humane manner and reduce funding for Wildlife Services Damage Management by \$10 million.

#### *Direct APHIS Veterinary Services To Prioritize Twenty-Eight Hour Law Enforcement*

Passed in 1873, the Twenty-Eight Hour Law states that animals cannot be transported interstate via “rail carrier, express carrier, or common carrier” for more than 28 hours consecutively without being unloaded for rest, food, and water. It was not until 2005 that the USDA agreed to extend the statute to interstate truck transport, which comprises the overwhelming majority of modern farm animal transport. The Twenty-Eight Hour Law is an important protection for livestock, as many travel great distances en route to livestock auctions and slaughter facilities. However, enforcement of this act is still lacking. APHIS Veterinary Services (VS) program is charged with enforcing the Federal Twenty-Eight Hour Law. Like its lax enforcement of the ban on double-decked trailers for horses bound for slaughter, VS has not made enforcement of the Twenty-Eight Hour Law an enforcement priority.

The ASPCA requests that the Committee direct APHIS Veterinary Services to prioritize Twenty-Eight Hour Law enforcement.

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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 Agriculture and Food Research Initiative (AFRI) of \$325 million as well as the requested level of the Agricultural Research Service (ARS) at \$1.13 billion.

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.

Despite the fact that foundational plant biology research—the kind of research funded by agencies such as USDA—underpins vital advances in practical applications in agriculture, health, energy, and the environment, the amount of money invested in understanding the basic function and mechanisms of plants is relatively small. In his 2012 annual letter Bill Gates wrote, “Given the central role that food plays in human welfare and national stability, it is shocking—not to mention shortsighted and potentially dangerous—how little money is spent on agricultural research.”<sup>1</sup> This is especially true considering the significant positive impact crop plants have on the Nation's economy and in addressing some of our most urgent challenges like food and energy security.

Understanding the importance of these areas and in order to address future challenges, ASPB organized the Plant Science Research Summit held in September 2011. With funding from the National Science Foundation, USDA, Department of Energy, and the Howard Hughes Medical Institute, the Summit brought together representatives from across the full spectrum of plant science research to identify critical gaps in our understanding of plant biology that must be filled over the next 10 years or more in order to address the grand challenges facing our Nation and our planet. The grand challenges identified at the Summit include:

- In order to feed everyone well, now and in the future, advances in plant science research will be needed for higher yielding, more nutritious varieties able to withstand a variable climate.
- Innovations leading to improvements in water use, nutrient use, and disease and pest resistance that will reduce the burden on the environment are needed and will allow for improved ecosystem services such as clean air, clean water, fertile soil, and biodiversity benefits such as pest suppression and pollination.
- In order to fuel the future with clean energy—and to ensure that our Nation meets its fuel requirements—improvements are needed in current biofuels technologies including breeding, crop production methods, and processing.
- For all the benefits that advances in plant science bestow—in food and fiber production, ecosystem and landscape health, and energy subsistence—to have lasting, permanent benefit they must be economically, socially, and environmentally sustainable.

In spring 2012, a report from the Plant Science Research Summit will be published. This report will further detail priorities and needs to address the grand challenges.

*Recommendations*

Because of our membership's extensive expertise and participation in the academic, industry and Government sectors, ASPB is in an excellent position to articu-

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<sup>1</sup> <http://www.gatesfoundation.org/annual-letter/2012/Pages/home-en.aspx>.

late the Nation's plant science priorities as they relate to agriculture. Our recommendations are as follows:

- Since the establishment of NIFA and AFRI, interest in USDA research has increased dramatically, a trend ASPB hopes to see grow in the future. 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 2013 for AFRI, which, although far short of the authorized level of \$700 million, provides sound investment in today's fiscal environment.
- The Agricultural Research Service (ARS) provides vital research to serve USDA's mission and objectives and the Nation's agricultural sector. The need to bolster ARS efforts to leverage and complement AFRI is great given the challenges in food and energy security. ASPB is supportive of a strong ARS and supports the \$1.13 billion request for ARS in fiscal year 2013.
- USDA has focused attention in several key priority areas including childhood obesity, climate change, global food security, food safety, and sustainable bioenergy. Although ASPB appreciates the value of such strategic focus, ASPB also emphasizes the importance of robust support for AFRI's Foundational Program because 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.
- 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 and calls for additional 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 focused on the use of plant biomass for energy production. However, if crops are to be used to their full potential, extensive 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. Please do not hesitate to contact ASPB if we can be of any assistance in the future. For more information about the American Society of Plant Biologists, please see [www.aspb.org](http://www.aspb.org).

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PREPARED STATEMENT OF THE ANIMAL WELFARE INSTITUTE

Thank you for the opportunity to submit testimony as you consider fiscal year 2013 funding priorities. Our testimony addresses the U.S. Department of Agriculture's Animal Care Program of the Animal and Plant Health Inspection Service, and the Food Safety and Inspection Service. AWI has also joined several horse show industry organizations, other animal protection groups, and the key association of equine veterinarians on a separate statement calling for sufficient funding to enable USDA to do a better job enforcing the Horse Protection Act.

*Animal Care/Animal Welfare Act Enforcement/Class B Random Source Dealers*

In 1966, Congress passed the Animal Welfare Act (AWA) to prevent the mistreatment of animals and to assure families that their pets would not be sold for laboratory experiments after an exposé revealed the widespread theft of pets for that purpose.

Unfortunately, 46 years later, this is still a problem. Despite the well-meaning intent of the AWA and the enforcement efforts of the U.S. Department of Agriculture

(USDA), the AWA routinely fails both to reliably protect pet owners against the actions of Class B dealers who sell random source dogs and cats for use in research (also known as “random source” dealers), and to ensure that these dealers provide humane care for the dogs and cats kept on their premises.

In response to repeated requests from Congress, the National Institutes of Health (NIH) funded a study by the National Academy of Sciences (NAS) of the use of Class B dogs and cats in NIH-funded research. The NAS’s 2009 report “Scientific and Humane Issues in the Use of Random Source Dogs and Cats in Research” describes a “complicated tangle of trade” in animals sold for use in experiments, and notes that “loopholes in the AWR [Animal Welfare Regulations] permit pets to enter the research pipeline via Class B dealers.” Furthermore, “. . . USDA could not offer assurances that pet theft does not occur, and agreed that such a crime is exceedingly difficult to prove . . .” That difficulty notwithstanding, the report stated that there are “descriptions of thefts provided by informants in prison . . . and documented accounts of lost pets that have ended up in research institutions through Class B dealers.” (p.84)

[As part of its mandate, the NAS report assessed whether there is a scientific rationale for recipients of research grants from NIH to purchase dogs and cats from random source Class B dealers. The report concluded that there is not.]

Across the Nation, these random source Class B dealers—and the middlemen who work for them, known as “bunchers”—use deceit and fraud to acquire dogs and cats. Their tactics include tricking animals’ owners into giving away their dogs and cats by posing as someone interested in pet adoption, and the outright theft of family pets left unattended. The treatment of the animals sold by these random source Class B dealers is shocking and cruel. Hundreds of animals are kept in squalid conditions and are denied much needed veterinary care. Again, the NAS report cited a variety of problems with regard to animal welfare and enforcement.

USDA has had to implement a lengthy and time-consuming enforcement protocol for these random source dealers, involving quarterly inspections (more than any other licensees) and “tracebacks,” in order to attempt to verify the source of their animals. While it is exceedingly difficult to put a price tag on this exaggerated level of oversight, USDA did estimate for the NAS report, at a time when 11 random source Class B dealers were still in business, that it was spending as much as \$300,000 per year to regulate that small number of dealers. There are now eight dealers left, with one’s license still suspended and four others under investigation. One dealer who recently gave up his license had been indicted on a number of Federal charges, including conspiracy, aggravated identity theft, mail fraud, and making false statements to a Federal agency.

Congress, too, has spent an inordinate amount of time reviewing the actions of Class B dealers and prodding USDA and NIH to address their respective Class B dealer problems. NIH long ago banned its intramural researchers from using Class B dealers but had until recently ignored Congress’ repeated calls for it to do likewise with respect to outside researchers.

As a result of the NAS report, ongoing congressional interest, enhanced (but disproportionate to their numbers) oversight by USDA, and evaporating demand for their dogs and cats, very few of these dealers remain, and with NIH’s phased-in ban on the use of Class B dealers by its extramural researchers, the Class B dealer system has become a cruel and expensive anachronism. Those who continue to operate are an unjustifiable drain on USDA’s resources. However, as long as it is possible to issue and renew licenses for such dealers, there is the risk that this anachronism will continue to limp along, wasting taxpayer money and perpetuating the inhumane treatment of animals and the trade in illegally acquired dogs and cats.

For this reason, we respectfully request that Congress prohibit any further spending by USDA both to grant new licenses and to renew existing licenses for Class B dealers selling dogs and cats for research purposes by including the following language in the report accompanying the fiscal year 2013 agriculture appropriations:

*“Provided, That appropriations herein made shall not be available for any activities or expense related to the licensing of new Class B dealers who sell dogs and cats for use in research, teaching, or testing, or to the renewal of licenses of existing Class B dealers who sell dogs and cats for use in research, teaching, or testing”.*

While this step in and of itself will not immediately save much money, it will lead to more significant savings later as USDA’s enforcement load with respect to these entities is eliminated.

*Food Safety and Inspection Service/Humane Methods of Slaughter Act Enforcement*

We appreciate the generous support provided by Congress during the past decade for enforcing the Humane Methods of Slaughter Act (HMSA). While USDA’s enforce-

ment of the law has increased recently, attention to the issue remains uneven among Federal regional districts.

An analysis of Humane Activities Tracking System (HATS) data reveals that in calendar year 2010, some USDA districts spent 10–20 times the number of hours on humane enforcement, per animal slaughtered, as other districts. Overall, USDA continues to allot an extremely small percentage of its resources to humane slaughter. For example, in calendar year 2010, only 0.5 percent of all noncompliance records written by FSIS were for humane violations.

Repeat violators present a major enforcement problem for FSIS. Of the 205 federally inspected plants that have been suspended for humane slaughter violations since January 1, 2008, 32 percent have been suspended more than once within a 1 year period. Moreover, 32 plants have been suspended on three or more occasions during the past 4 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 (DVMS) 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 work load 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. No fewer than 140 full-time equivalent positions should be employed for purposes dedicated solely to inspections and enforcement related to the HMSA. In addition, the number of DVMS positions should be increased to a minimum of two per district. It is essential that the DVMS role, and humane slaughter enforcement overall, not be weakened as a consequence of the planned consolidation of FSIS districts. 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.

*Animal Care/Horse Protection Act Enforcement/Requested: \$891,000*

We request that you support \$891,000 for strengthened enforcement of the Horse Protection Act (HPA). Congress enacted the HPA in 1970 to make illegal the abusive practice of “soring,” by which unscrupulous trainers deliberately inflict pain on Tennessee Walking Horses’ hooves and legs to exaggerate their high-stepping gait and gain unfair competitive advantage at horse shows. They use such abominable practices as applying caustic chemicals and then using plastic wrap and tight bandages to “cook” those chemicals deep into the horse’s flesh for days; attaching heavy chains to slide up and down the horse’s sore legs; inserting metal screws or other foreign objects into the sensitive areas of the hooves; cutting the hooves down to expose the live tissue; and using salicylic acid or other painful substances to slough off scarred tissue in an attempt to disguise the sores areas.

A report released in October 2010 by USDA’s Office of Inspector General documents significant problems with the industry self-monitoring system on which the seriously understaffed APHIS inspection program relies, recommends its abolition, and calls for funding to enable the agency to more adequately enforce the law.

We greatly appreciate the appropriation last year of \$696,000 for Horse Protection Act enforcement. Under its historic levels of funding, Animal Care inspectors were able to attend only about 10 percent of the more than 500 Tennessee Walking Horse shows held annually. Sustained support at the requested level of \$891,000 will help ensure that this program doesn’t lose ground now that it is finally beginning to address the need for additional inspectors, training, security (due to threats of violence against inspectors), and advanced detection equipment (thermography and gas chromatography/mass spectrometry machines).

*Horse Slaughter*

In 2006, the U.S. House of Representatives and U.S. Senate overwhelmingly approved language that prevented tax dollars from being used to inspect horse slaughter facilities. This language remained in effect until it was removed in conference last year, despite having been approved by the full House Appropriations Committee. Allowing horse slaughter to resume will only bring this well-documented abuse to U.S. soil at great expense to the horses and the American public.

Given the financial troubles facing the Nation, we encourage the Committee to accept this bipartisan language while the full Congress moves to pass a ban on horse slaughter:

“None of the funds made available in this Act may be used to pay the salaries or expenses of personnel to—

(1) inspect horses under section 3 of the Federal Meat Inspection Act (21 U.S.C. 603);

(2) inspect horses under section 903 of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 1901 note; Public Law 104–127);

(3) implement or enforce section 352.19 of title 9, Code of Federal Regulations;

(4) promulgate or implement a fee-for-service-based Federal horsemeat inspection scheme.”.

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PREPARED STATEMENT OF CATHOLIC RELIEF SERVICES

On behalf of Catholic Relief Services (CRS) I thank the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee for this opportunity to testify on fiscal year 2013 appropriations under your jurisdiction.

CRS is the relief and development agency of the U.S. Catholic Church. The Catholic Church’s social teaching informs the work of CRS and our focus on the poorest people in the poorest parts of the world. The Church has broad and deep experience combating poverty and CRS has direct experience as an implementer of foreign assistance projects for almost 70 years, and is currently operating in 100 countries around the world. CRS programs address HIV and AIDS, health, education, civil society, food security, agriculture, emergency relief, WASH, and peace building. The Catholic Church in the United States also has abiding relationships and regular contact with the church in developing countries, where our worldwide community serves the needs of the poorest members of the human family. In fact, CRS counts institutions of the local Catholic Church as important local partners in many countries, and works through the church’s network abroad to reach significantly more people, and often in communities inaccessible to the local government or other actors.

CRS acknowledges the difficult fiscal challenges that Congress faces, including fulfilling our obligations to future generations. We welcome thoughtful efforts to reduce our Nation’s deficit and debt. But even in this context, the most poor and vulnerable must have adequate access to our Nation’s limited resources. We therefore urge Congress to be fiscally responsible in morally responsible ways. We urge Congress and the Subcommittee in particular, not to make cuts to international poverty-focused humanitarian relief and development assistance.

CRS has five specific requests related to the Agriculture appropriations that we ask you to consider:

—CRS is advocating for a reauthorization of Title II of Public Law 480, the Food for Peace Program, of at least \$2 billion per year before the Senate and House Agriculture Committees. We encourage the Agriculture Appropriations Subcommittee to meet our recommended authorized funding levels, but in light of the tight fiscal climate, we consider \$1.5 billion the absolute minimum that should be appropriated to Title II in fiscal year 2013.

—Within the amounts appropriated for Title II, CRS requests that the Agriculture Appropriations Subcommittee direct a minimum of \$450 million to development programs, and that the existing waiver system safe guarding these funds remain unchanged and intact.

—To make more efficient use of resources, CRS encourages the Agriculture Appropriations Subcommittee to direct additional Title II funding to cash resources, which we believe will help to address the inefficiencies of commodity monetization.

—Similarly, to make more efficient use of resources, CRS encourages the Agriculture Appropriations Subcommittee to direct the use of Title II funds toward Local and Regional Procurement (LRP), which has proven to be an effective tool in the implementation of emergency and development programs under certain circumstances.

—CRS requests that the Agriculture Appropriations Subcommittee appropriate \$250 million for the McGovern-Dole Food for Education Program.

For the duration of the testimony, I will explain our justifications for these requests.

Title II should be reauthorized for at least \$2 billion per year, and CRS supports yearly appropriations that match this level, but at minimum \$1.5 billion should to be appropriated to Title II in fiscal year 2013.

It is estimated that around 100 million people will require emergency food assistance<sup>1</sup> and more than 925 million people will continue to suffer from chronic hunger worldwide.<sup>2</sup> CRS estimates it would take more than \$12 billion annually to effectively address these needs. While this global need exceeds the budgetary constraints of the U.S. Government, we believe it is our moral imperative to provide as much assistance as we can to the world's poor.

Title II has been, and continues to be, the U.S. Government's premier mechanism to fight chronic hunger and meet the food needs of those in emergency situations. In 2011, Title II funding helped CRS respond to the devastating drought and famine in the Horn of Africa that affected more than 12 million people.<sup>3</sup> CRS worked in consortium with other international and local organizations to provide life-saving food to more than 2 million Ethiopians, while also helping households protect productive assets, particularly livestock, which is an important source of food and serves as a savings mechanism that is available when absolutely necessary.

Looking ahead to 2012, the Famine Early Warning System has predicted food shortfalls in the Sahel region of West Africa for the coming year. Much like the Horn of Africa, the Sahel has faced in recent years cyclical periods of food deficit due to increasingly inadequate rainfall and farmers' unfamiliarity with cultivation practices tailored to such dry conditions. CRS's current development programs in the region help the poor and vulnerable prepare for impending food crises through interventions like dry season market gardening projects.<sup>4</sup> In areas where no development programs exist, Title II will likely be needed to fund any potential emergency response in the Sahel to meet impending acute food needs. Title II will also continue to be a necessary source of funding for other unexpected global emergencies stemming from natural disasters and human conflict.

Within the amounts appropriated for Title II, a minimum of \$450 million should be directed to development programs and the existing waiver system protecting these funds should be preserved.

As mentioned above, more than 925 million people suffer from chronic hunger worldwide, yet there are insufficient resources to meet these needs. Title II development programming is the primary U.S. Government funded program to directly address the underlying causes of chronic hunger. These programs distribute U.S. food commodities and use complementary programming to address all aspects of food security, including agricultural production, health, and nutrition.

Development programs are designed to promote self reliance, long-term sustainability, resilience in poor communities, which in the long-run can reduce their need for emergency assistance. For example, in the recent drought and famine in the Horn of Africa in 2011, CRS worked alongside other aid providers, the U.S. Agency for International Development, and the Government of Ethiopia, to implement a national Productive Safety Net Program (PSNP). The program, funded in large part by Title II development resources, distributed food and cash to the most vulnerable, giving communities the means to withstand the drought's affects and making more costly emergency assistance unnecessary for 7 million Ethiopians.<sup>5</sup>

The United States response to chronic hunger through Title II continues to be disproportionately low compared to the need, and compared to resources provided for emergencies. Prior to the 2008 farm bill, 75 percent of Title II resources were allocated to development programs, but a weak waiver system allowed these resources to be diverted for emergencies. Ultimately, development program funding during this period was whittled down to only a small fraction of overall Title II funding.

<sup>1</sup> World Food Program USA, *Emergency Response*, at <http://usa.wfp.org/advocate/emergency-response>, last visited March 21, 2012.

<sup>2</sup> United Nations Food and Agriculture Organization, *The State of Food Insecurity in the World* (2010), at 8, available at <http://www.fao.org/docrep/013/i1683e/i1683e00.htm>.

<sup>3</sup> Drought and Famine in the Horn of Africa, Testimony of Assistant Administrator, Bureau for Democracy, Conflict, and Humanitarian Assistance, U.S. Agency for International Development (USAID), Nancy E. Lindborg, Before the Committee on Foreign Relations Subcommittee on African Affairs, Washington, DC, August 3, 2011.

<sup>4</sup> Nancy Lindborg, Assistant Administrator, Democracy, Conflict, and Humanitarian Assistance, USAID, *Responding Early and Building Resilience in the Sahel*, The Huffington Post, March 3, 2012, available at [http://www.huffingtonpost.com/nancy-lindborg/responding-early-and-build\\_b\\_1316234.html](http://www.huffingtonpost.com/nancy-lindborg/responding-early-and-build_b_1316234.html). The article focuses on a CRS market garden program in Burkina Faso that was funded through 2009, and is still in operation under its own accord.

<sup>5</sup> Nancy Lindborg, Assistant Administrator, Democracy, Conflict, and Humanitarian Assistance, USAID, *Building Resilience in the Horn of Africa*, USAID IMPACT blog, Dec. 19, 2011, available at <http://blog.usaid.gov/2011/12/building-resilience-in-the-horn-of-africa/>.

To address this siphoning of development funding, the 2008 farm bill authorized specific funding levels each fiscal year<sup>6</sup> and established a stronger waiver mechanism.<sup>7</sup> Both of these additions have greatly aided development programming by ensuring a reliable funding source, and are generally referred to as the “safebox.”

It is critical that development programs have steady and reliable funding because they require a multiyear approach to achieve a sustainable impact on chronic hunger. When funding levels shift dramatically from year to year, it is hard to ensure program objectives, like improved agricultural production or behavior changes around nutrition practices, are met. Funding for development programs should remain consistent with recent authorized and appropriated amounts. CRS therefore requests that the Subcommittee direct \$450 million to development programs in fiscal year 2013, the same level authorized in fiscal year 2012. Furthermore, CRS requests that the Subcommittee protect the integrity of the safebox by maintaining the current waiver provision. We believe it is a common sense approach to ensuring development funding is not siphoned off for emergencies unless other emergency funding sources have been exhausted.

To make more efficient use of resources, CRS encourages the Agriculture Appropriations Subcommittee to consider making more cash resources available within Title II funding.

Improving food security requires more than just food. Essential complementary activities in development programs ensure that gains made by food distribution programs can be sustained.<sup>8</sup> For example, some development programs provide new mothers with nutrition and sanitation education so that good health practices continue even after programs are completed. Programs also distribute food in exchange for community work. These programs contribute to long-term food security by building roads for better access to markets and by digging irrigation systems to grow crops.

Complementary programs require cash funding to acquire basic inputs such as tools, seeds, and building materials, as well as to hire technical staff to train, mentor and support beneficiaries. However, Title II does not provide cash funding to cover these expenses. Rather, implementers like CRS engage in the practice of monetization, which is the sale of U.S. in-kind food donations abroad to generate proceeds that go to pay for program costs. Monetization is considered an inefficient mechanism to pay for development programs because the costs incurred to buy, ship, and sell U.S. commodities overseas are often greater than the proceeds raised. In the absence of cash resources, CRS values the use of monetization to support program activities, but to address the inefficiencies of monetization CRS believes more cash resources should be made available within Title II, which can be used to fund the necessary complementary activities that are vital in development programming.

One option to increase cash resources is to increase funding available under the existing 202e provision of Title II, and broaden the allowable uses of this funding source. Under the current authorization of the farm bill, 202e permits up to 13 percent of Title II funding to be provided in cash and used for a discrete set of purposes related to program implementation.<sup>9</sup> However, the limitations placed on the use of 202e hamstring the ability of this mechanism to provide necessary flexibility in program budgets. The Committee could address this by expressly directing additional Title II funding to be used for 202e, and allowing 202e to cover any type of program cost. If the Agriculture Appropriations Subcommittee pursued this course, CRS recommends that appropriations directed to 202e should be to up to 25 percent of overall Title II funding. Further, other options for providing additional cash resources do exist, and CRS would be happy to discuss these with the Subcommittee.

To make more efficient use of resources, CRS encourages the Agriculture Appropriations Subcommittee to consider allowing the use of Local and Regional Procurement (LRP) as a tool to implement emergency and development programs under Title II.

<sup>6</sup> 7 U.S.C. § 1736f(e)(1).

<sup>7</sup> This waiver requires following to occur before funds protected by the development safebox can be used for emergencies: (1) the President to determine that an extraordinary food emergency exists; (2) resources from the Bill Emerson Humanitarian Trust be exhausted; and (3) the President has to submit a request for additional appropriations to Congress equal to the reduction in the safe box and Emerson Trust. See, 7 U.S.C. § 1736f(e)(2).

<sup>8</sup> Bonnard, P., et al. *Report of the Food Aid and Food Security Assessment: A Review of the Title II Development Food Aid Program* (2002).

<sup>9</sup> 7 U.S.C. 1721(e)(1).

The 2008 farm bill authorized a small 5-year pilot program for Local and Regional Procurement (LRP) of food assistance.<sup>10</sup> Recent analysis conducted through Cornell University and implementing organizations demonstrates that program activities undertaken as part of the pilot can be cost-efficient, effective in saving lives during emergencies, and enables communities to improve long-term food security through development activities.<sup>11</sup> More specifically, the pilot showed that LRP can save money, varying by commodity, with the most cost savings at 53 percent for cereals when compared to U.S. commodities. LRP can also save time, reducing the transportation costs relative to U.S. in-kind shipments by an average of 13.8 weeks. Further, several development LRP interventions funded through the pilot program showed that LRP has multiple potential benefits, including linking smallholder food producers to markets, building local capacity for food processing, milling and fortification, and expanding availability and access to highly nutritious foods.<sup>12</sup>

CRS's LRP pilot program in Mali successfully integrated into an existing school feeding initiative, and realized cost savings of 46 percent for peas and 62 percent for grains. In our program, LRP was also timely by having food available at the beginning of the school year. The program also had noteworthy developmental impacts; for instance, through farmer field trainings, the program improved local production and storage of harvests, and by purchasing locally sourced foods the program helped develop a source for locally led school feeding programs in the future.

The evidence to date demonstrates that LRP can have significant benefits, though it also shows that LRP isn't necessarily appropriate in all situations. The context of any food crisis should frame the decision of which food assistance tool should be used. We simply encourage the Agriculture Appropriations Subcommittee to allow LRP programming to be used as a tool within Title II, so that LRP can, where appropriate, achieve cost savings in some Title II programs.

CRS requests that the Agriculture Appropriations Subcommittee appropriate at minimum \$250 million for the McGovern-Dole Food for Education Program.

The McGovern Dole Food for Education (FFE) program supports education, child development, and food security initiatives for some of the world's poorest children through donations of U.S. food commodities, as well as financial and technical assistance for school feeding and nutrition projects. FFE has successfully increased school enrollment by feeding school children. CRS recently implemented a FFE program in Mali, serving 45,000 individuals over 3 years. In this program more than 5 million meals, as well as vitamins and medications, were distributed among 120 schools. Our program increased school enrollment in targeted communities for boys from 26 percent to 32 percent and for girls from 39 percent to 55 percent. As education and nutrition are inextricably linked to a promising future for all children, CRS requests \$250 million be appropriated for the FFE program. By targeting the most poor and vulnerable early in their lives, we hope to curb their need for U.S. assistance in the future.

Thank you for your many years of partnership with CRS and for this opportunity to reiterate our values and report back to you on our experiences.

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#### PREPARED STATEMENT OF THE COLORADO RIVER BASIN SALINITY CONTROL FORUM

Waters from the Colorado River are used by approximately 35 million people for municipal and industrial purposes and used to irrigate approximately 4 million

<sup>10</sup>Currently USAID provides a limited level of assistance for local and regional purchase in emergencies through the Emergency Food Security Program funded in the International Disaster Assistance (IDA) Account. Unlike the LRP Pilot Program, IDA funded LRP cannot be used for non-emergency purpose.

<sup>11</sup>Erin C. Lentz, Christopher B. Barrett, and Miguel I. Gómez, "The Impacts of Local and Regional Procurement of U.S. Food Aid: Learning Alliance Synthesis Report, "Final Report: A Multidimensional Analysis of Local and Regional Procurement of U.S. Food Aid," January 2012, available at [http://dyson.cornell.edu/faculty\\_sites/cbb2/papers/LRP%20Ch%201%20Lentz%20et%20al%2011Jan2012Update.pdf](http://dyson.cornell.edu/faculty_sites/cbb2/papers/LRP%20Ch%201%20Lentz%20et%20al%2011Jan2012Update.pdf). Formally, this collaboration was known as the Local and Regional Procurement (LRP) Learning Alliance, which began as a collaboration among organizations implementing LRP programs (Catholic Relief Services, Land O'Lakes, Mercy Corps, World Vision) and Cornell University, to monitor and analyze the market impacts of LRP. Since the closing of the LRP Pilot Program, the Learning Alliance continues to work on knowledge sharing to improve the efficacy of LRP as a whole, and has welcomed other LRP implementers, including Fabretto Children's Foundation, International Relief and Development, ACDI/VOCA, CARE and the United Methodist Committee on Relief.

<sup>12</sup>At present, food assistance programs authorized through the farm bill allow implementing partners to purchase enriched, nutritious products only if they are produced in the United States. By supporting the development and production of locally procured foods, including those used for therapeutic and targeted feeding programs, LRP can address this gap.

acres in the United States. Natural and man-induced salt loading to the Colorado River creates environmental and economic damages. The U.S. Bureau of Reclamation (BOR) has estimated the current quantifiable damages at about \$300 million per year. Congress authorized the Colorado River Basin Salinity Control Program (Program) in 1974 to offset increased damages caused by continued development and use of the waters of the Colorado River. Modeling by BOR indicates that the quantifiable damages would rise to more than \$500 million by the year 2030 without continuation of the Program. The USDA portion of the Program, as authorized by Congress and funded and administered under the Environmental Quality Incentives Program (EQIP), is an essential part of the overall effort. A funding level at approximately \$18 million annually is required to prevent further degradation of the quality of the Colorado River and increased downstream economic damages.

Congress concluded that the Colorado River Basin Salinity Control Program should be implemented in the most cost-effective way. The Program is funded under EQIP, the U.S. Bureau of Reclamation'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,

Congress authorized a program for the United States Department of Agriculture (USDA) through amendment of the Colorado River Basin Salinity Control Act (Act) in 1984. With the enactment of the Federal Agriculture Improvement and Reform Act of 1996 (FAIRA), Congress directed that the Program should continue to be implemented as part of the newly created Environmental Quality Incentives Program. 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 the Program within EQIP. In 2008, Congress passed the Food, Conservation and Energy Act (FCEA). The FCEA addressed 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.

The Program, as set forth in the act, 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 downstream by high salt levels in the water source. There are also local benefits from the Program in the form of soil and environmental benefits, improved water efficiencies and lower fertilizer and labor costs. Local producers 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 the act that provides that the seven Colorado River Basin States will also cost share with the appropriated funds for this effort. This has brought together a remarkable partnership.

After longstanding urgings from the States and directives from Congress, 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 1,400 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 specific 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 the Program. The Colorado River Basin Salinity Control Forum (Forum) appreciates the efforts of NRCS leadership and the support of this Subcommittee. Colorado River water quality standards have been prepared by the Forum, adopted by the States, and approved by the United States Environmental Protection Agency (EPA). The Forum has taken the position that funding for the EQIP portion of the Program should be consistent with the 3-year funding plan submitted by the three NRCS State Conservationists for Colorado, Utah and Wyoming. This amount for 2013 is \$18 million and includes both farm and technical assistance. Over the last few fiscal years, funding has reached the needed level. State and local cost-sharing is triggered by the Federal appropriation. In fiscal year 2013, it is anticipated that the States will cost share with about \$7.7 million and local agriculture producers will add about \$5.5 million. Hence, it is anticipated that in fiscal year 2013 the State and local contributions will be about 42 percent of the total cost. 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 the Program, and specifically for the USDA portion of the effort which was added by

amendments to the act in 1984. 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.

The Forum is composed of gubernatorial appointees from Arizona, California, Colorado, Nevada, New Mexico, Utah and Wyoming. The Forum is charged with reviewing the Colorado River's water quality standards every 3 years. In so doing, it adopts a Plan of Implementation consistent with these standards. The level of appropriation requested in this testimony is in keeping with the adopted Plan of Implementation. 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 salt in the River cause approximately \$300 million in quantified damages and significantly more in unquantified damages in the United States and result in poor water quality for United States users. 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.

Over the years, NRCS personnel have developed a great working relationship with farmers within the Basin. Maintaining salinity control achieved by implementation of past practices requires continuing education and technical assistance from NRCS personnel. Additionally, technical assistance is required for planning and design of future projects. Last, the continued funding for the monitoring and evaluation of existing projects is essential to maintaining the salinity reduction already achieved.

In summary, implementation of salinity control practices through EQIP has proven to be a very cost effective method of controlling the salinity of the Colorado River and is an essential component to the overall Colorado River Basin Salinity Control Program. Continuation of EQIP with adequate funding levels will prevent the water quality of the River from further degradation and significantly increased economic damages to municipal, industrial and irrigation users.

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PREPARED STATEMENT OF THE COLORADO RIVER BOARD OF CALIFORNIA

This testimony is in support of funding for the U.S. Department of Agriculture (USDA) and its on-farm Colorado River Basin Salinity Control Program (Program) for fiscal year 2013. This program has been carried out through the Colorado River Basin Salinity Control Act (Public Law 93-320) (Act), since it was enacted by Congress in 1974. Further, with the enactment of the Federal Agricultural Improvement and Reform Act (FAIRA) in 1996 (Public Law 104-127), Congress directed that the Program should continue to be implemented as one of the components of the Environmental Quality Incentives Program (EQIP). Finally, Congress passed the Food, Conservation, and Energy Act (FCEA) in 2008, that addressed the cost-sharing required from the Basin Funds, and redesignated the cost-sharing requirement as the Basin States Program (BSP). Currently, the BSP provides approximately 30 percent of the total amount that will be spent each year by the combined EQIP and BSP efforts.

The Salinity Control Program benefits both the Upper Basin water users through more efficient water management and the Lower Basin water users, through reduced salinity concentration of Colorado River water. For example, California's Colorado River water users continue to suffer economic damages in the hundreds of million of dollars per year due to the current salinity of the Colorado River.

The Colorado River Board of California (Colorado River Board) is the State agency charged with protecting California's interests and rights in the water and power resources of the Colorado River system. In this capacity, California participates along with the other six Colorado River Basin States through the Colorado River Basin Salinity Control Forum (Forum), the interstate organization responsible for coordinating the Basin States' salinity control efforts. In close cooperation with the U.S. Environmental Protection Agency (EPA) and pursuant to requirements of the Clean Water Act (Public Law 92-500), the Forum is charged with reviewing the Colorado River's water quality standards every 3 years. The Forum adopts a Plan of Implementation consistent with these water quality standards. The level of appropriation being supported in this testimony is consistent with the Forum's 2011 Plan of Implementation. If adequate funds are not appropriated, significant damages associated with increasing salinity concentrations of Colorado River water will become more widespread in the United States and Mexico.

Currently, the salinity concentration of Colorado River water causes about \$300 million in quantifiable damages in the United States annually. Economic and hydrologic modeling by U.S. Bureau of Reclamation (Reclamation) indicates that the quantifiable damages could rise to more than \$500 million by the year 2030 without the continuation of the Salinity Control Program as identified in the 2011 Plan of Implementation. For example, salinity 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 fewer opportunities for recycling due to groundwater quality deterioration; and
- Increased use of imported water for leaching and the cost of desalination and brine disposal for recycled water.

In recent fiscal years, the Natural Resources Conservation Service (NRCS) has directed that about \$18 million of EQIP funds be used for the Salinity Control Program. The Colorado River Board respectfully urges the Subcommittee to support funding for the Colorado River Basin Salinity Control Program for fiscal year-2013 at least at this level.

The Forum has taken the position that funding for the Program should be consistent with the 3-year funding plan submitted by the three NRCS State Conservationists for Colorado, Utah and Wyoming. The NRCS funding plan for 2013 is \$18 million and includes both farm and technical assistance program elements. It should also be pointed out that State and local cost-sharing is triggered by Federal appropriations. In fiscal year 2013, it is anticipated that the States will cost-share with about \$7.7 million and that local agriculture producers will add another \$5.5 million. Consequently, it is anticipated that the fiscal year 2013 State and local contributions are expected to be approximately 42 percent of the total Program costs.

In conclusion, the Colorado River Board of California recognizes that the Federal Government has made significant commitments to the seven Colorado River Basin States with regard to the delivery of Colorado River water. In order for those commitments to continue to be honored, it is essential that Congress continue to provide funds to the USDA to allow it to provide needed technical support to agricultural producers for addressing salinity control activities in the Colorado River Basin. Over the past 28 years, the Colorado River Basin Salinity Control program has proven to be a very cost-effective and collaborative approach to help mitigate the impacts of the salinity of Colorado River water. Continued Federal funding of the USDA elements of this important Basin-wide program is essential to maintaining this effort.

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PREPARED STATEMENT OF COLORADO STATE UNIVERSITY

Mister Chairman, Ranking Member and Members of the subcommittee, thank you for the opportunity to submit testimony for the record. I am writing to share my concerns regarding a recently recognized fungal canker disease that poses an enor-

mous economic and ecological risk to our Nation's walnut resources. Over the past decade, thousand cankers disease (TCD) has caused the death of thousands of black walnut trees in nine western States (Arizona, California, Colorado, Idaho, Oregon, New Mexico, Tennessee, Utah, and Washington) and recently has been discovered in Tennessee, Virginia and Pennsylvania. The negative economic impacts of TCD are felt by our Nation's timber, nut and nursery producers, furniture manufacturers, and private landowners. While States are attempting to stop the spread of TCD through surveys and quarantines, greater Federal oversight and funding are needed. I request dedicated funding be allocated to the U.S. Department of Agriculture's Plant Protection and Early Detection and Rapid Response programs for fiscal year 2013 for the study and management of TCD.

*What is TCD?*

TCD results from the combined activity of a fungus (*Geosmithia morbida*) and the walnut twig beetle (*Pityophthorus juglandis*). As the beetle moves through a tree's twigs, branches and main stem it creates galleries beneath the bark of the branches and introduces the fungal spores. Numerous cankers develop and disrupt the flow of nutrients throughout the tree. Over time the tree is unable to store and move nutrients and starves. The most likely pathway for transmission of TCD is through the movement of raw wood (logs, firewood, stumps, burls and wood packaging materials) with bark attached. It is not known whether transmission to the eastern United States occurred through natural dispersal or by human transport of twig beetle infested walnut products.

*Need for Greater Federal Funding and Oversight*

At the Federal level, pests and diseases similar to TCD are addressed by the USDA's Animal and Plant Health Inspection Service (APHIS) and the U.S. Forest Service (USFS). Within APHIS, the Plant Protection and Quarantine (PPQ) program is primarily responsible and has the regulatory authority for all pests coming to the Nation's borders and the interstate movement of regulated pests. The USFS oversees the Early Detection and Rapid Response (EDRR) program, which detects new invasive species infestations and support the infrastructure necessary to rapidly contain or eradicate these infestations.

To date, USDA has provided some funding and technical assistance for TCD, mainly through fiscal year 2010 farm bill funding for survey, detection and mitigation methods. However, it has not identified TCD as an actionable pest as was done with the emerald ash borer and Asian long horned beetle and it has determined that Federal regulatory oversight of TCD would be challenging due to the interstate movement of products, poor detection capability and the widespread distribution of the disease. I believe that it is for these reasons that greater Federal oversight and funding is needed.

*Funding Needs*

Funding for basic research to study the life history, biology and behavior of the walnut twig beetle and the fungus is needed and would inform and improve management of the disease. Examples of priority research needs include developing an effective lure for the walnut twig beetle, the development of data and maps that would inform where the pest is most likely to migrate, and evaluating methodologies on survival of the insect and the pathogen after debarking and kiln drying or other treatments.

I thank the committee for this opportunity to provide testimony on this important subject. Please do not hesitate to contact me/us if you should require additional information.

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PREPARED STATEMENT OF COPPERHEAD HILL RANCH—JOHN A. AND KAREN M. BUCHANAN, OWNERS

Mister Chairman, Ranking Member and Members of the subcommittee, thank you for the opportunity to submit testimony for the record. I am writing to share my concerns regarding a recently recognized Thousand Cankers Disease (TCD) that poses an enormous economic and ecological risk to our Nation's black walnut resources. Over the past decade, TCD has caused the death of millions of black walnut trees in nine western States (Arizona, California, Colorado, Idaho, Oregon, New Mexico, Nevada, Utah, and Washington) and recently has been discovered in the native walnut range (Tennessee, Virginia and Pennsylvania). The USDA-APHIS has estimated the standing value of walnut timber as being \$539 billion. This does not include potential loss of: Jobs related to logging, transportation, and domestic milling; derivatives of the domestic milling industry to make veneer and lumber for fur-

niture, cabinetry, paneling, flooring, and gun stocks; export market accounts for about 60 percent of the harvested logs; and nuts are shelled into nutmeats and the shells are processed for many industrial uses.

The negative economic impacts of TCD will be felt by private landowners with immature walnut timber and by home owners with millions of walnut trees in residential areas of the Midwest and Eastern States. It will be any ugly site and very expensive to safely remove all the walnut trees as they succumb to TCD over the next couple of decades if this disease is not contained, suppressed, and locally eradicated. Research efforts to date have been limited to monitoring, ecological studies of the walnut twig beetle, epidemiology of the fungal pathogen, and development of phytosanitation treatment of walnut logs harvested in quarantined areas. Insecticide and fungicide application is not feasible or practical as a means of controlling the spread of TCD. Development of biological insect control of the walnut twig beetle is expected to be the most effective and feasible technique in stopping the advancement of TCD through the native range of black walnut.

While States are attempting to stop the spread of TCD through surveys and quarantines, greater Federal assistance and funding are needed. I request dedicated funding be allocated to the USDA-ARS for leadership in the development of biological insect control techniques of the walnut twig beetle and to the USDA-FS for continued efforts in monitoring for TCD for fiscal year 2013.

*What is TCD?*

TCD is a recently recognized disease in which a tiny walnut twig beetle (*Pityophthorus juglandis*) spreads a fungal organism (*Geosmithia morbida*) that causes cankers under the bark which prevents nutrient flow to the foliage leading to dieback of branches and ultimately death to the tree. While the walnut twig beetle advances only a mile or two per year, humans are the vector that spread TCD great distances within days by hauling walnut slabs with fresh bark attached that harbor the tiny beetles and fungal spores. Such shipments are believed to be the reason TCD moved into the native walnut range from the western States. Movement of firewood, logs, stumps, and burls with fresh bark attached can spread the disease great distances.

*Need for Greater Federal Funding and Specific Directives*

The USDA-APHIS considers both the walnut twig beetle and the fungal pathogen to be indigenous to the USA (historical evidence shows them to reside on a different walnut species in Arizona and New Mexico). Since neither is considered exotic to the USA, APHIS is not productively serving any role in combating TCD.

Federal funding needs to be directed to the USDA-ARS to lead research and development of techniques that will contain, suppress, or potentially locally eradicate the walnut twig beetle. Additional funding needs to be directed to the USDA-FS for continued effort in monitoring and development of phytosanitization treatment of walnut logs harvested in quarantined areas.

I thank the committee for this opportunity to provide testimony on this important subject. Please do not hesitate to contact me if you should require additional information.

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PREPARED STATEMENT OF THE CYSTIC FIBROSIS FOUNDATION

On behalf of the Cystic Fibrosis Foundation and the approximately 30,000 people with cystic fibrosis (CF) in the United States, we are pleased to submit the following testimony to the Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies requesting sufficient funding for the Food and Drug Administration in fiscal year 2013. This testimony urges the Committee to provide the Food and Drug Administration the funding it needs to quickly and efficiently review treatments for CF and other rare diseases and encourages the FDA to reach out on a more systematic basis to outside experts early in the drug development process. Additionally, the CF Foundation urges the Committee to support collaborative efforts by the FDA and the National Institutes of Health, such as the Regulatory Science Initiative and the FDA-NIH Joint Leadership Council. Collaboration between the NIH and FDA has the potential to help move innovative new drugs more quickly through the development process and into the hands of patients.

In particular, the Foundation wishes to commend the speed with which the FDA approved Kalydeco™, a breakthrough treatment for cystic fibrosis that is the first to address the underlying genetic cause of the disease for 1,200 people with CF who carry a specific genetic mutation. The agency reviewed and approved Kalydeco's New Drug Application in only 3 months—one of the fastest approvals of any drug

in the history of the agency. The speed with which this review was conducted is a testament to the FDA's commitment to collaboration with Vertex Pharmaceuticals, Kalydeco's developer, and the Cystic Fibrosis Foundation, as well as its commitment to the patients who are already benefiting from the drug. The science behind Kalydeco has opened exciting new doors to research and development that may eventually lead to a cure for all people living with CF.

#### *About Cystic Fibrosis*

Cystic fibrosis is a life-threatening genetic disease for which there is no cure. People with CF have two copies of a defective CFTR gene, which causes the body to produce abnormally thick, sticky mucus that clogs the lungs and results in life-threatening lung infections. This mucus also obstructs the pancreas, preventing pancreatic enzymes from assisting in the breakdown of food and the absorption of nutrients.

The mission of the Cystic Fibrosis Foundation is to find a cure for cystic fibrosis and improve the quality of life for people living with the disease. This is accomplished by funding life-saving research and working to provide access to quality care and effective therapies for people with CF. Through the Foundation's efforts, the life expectancy of a child with CF has doubled in the last 30 years. Although real progress toward a cure has been made, the lives of young people with CF are still cut far too short.

The promise for people with CF lies in research. The CF Foundation has raised and invested hundreds of millions of dollars in private money to help develop CF drugs and therapies and nearly every CF drug available today was made possible because of the Foundation's support. The Foundation accredits a nationwide network of over 110 CF care centers that has been widely recognized as a national model for specialized treatment of a disease.

#### *Sustaining Funding for Rare Disease Drug Review at the FDA*

##### *Funding for Rare and Orphan Disease Drug Review*

In order to encourage swift review of drugs for CF and other rare diseases, we urge the Committee to recommend sufficient funding for the Food and Drug Administration, particularly the Center for Drug Evaluation and Research (CDER)'s Office of New Drugs, in fiscal year 2013.

To be effective, the FDA needs an adequate number of reviewers with the appropriate skills and expertise to evaluate therapies for rare diseases like cystic fibrosis. Additional support for the FDA through increased funding not only ensures 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 therapies that treat small populations and serve specific unmet medical needs.

It is more critical than ever that Congress significantly increase funding for the Center for Drug Evaluation and Research (CDER) at the FDA and for the agency as a whole in fiscal year 2013 so that it can meet its statutory obligations in a timely manner.

##### *Accelerating the Rare Disease Drug Review Process at the FDA*

The Cystic Fibrosis Foundation 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.

As we reap the benefits of the mapping of the human genome, treatments like Kalydeco are being developed that target smaller and smaller populations. This aspect of personalized medicine holds the promise to treat or cure rare diseases and subsets of more common diseases that plague millions of Americans.

However, as the scientific landscape changes, it is important that the FDA has access to the expertise it needs to swiftly review innovative new treatments. FDA review officials have taken steps to improve access to scientific expertise during the review of therapies that treat rare diseases, and FDA leaders and review staff have been willing to engage in constructive dialogue to address the challenges of rare disease review. The agency has taken part in productive conversations with researchers and patients at the CF Foundation, including with many of the world's foremost experts on cystic fibrosis, on the development and review of potential therapies to treat cystic fibrosis and on topics separate from specific drug review, such as improving tools for Patient Reported Outcomes (PROs). In particular, the collaboration showcased during the review of Kalydeco is an excellent example of how the FDA, a drug sponsor, patients and external experts can work to effectively evaluate new drugs and accelerate the approval process.

However, in some 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. While FDA review di-

visions do conduct some consultations with external experts separate from the advisory committee process, the complexity and diversity of applications for rare disease therapies suggest that the agency would benefit from more regular consultation with extramural experts early in the review process. The Cystic Fibrosis Foundation asks that the Committee encourage the FDA to reach out on a more systematic basis to outside experts early in the drug development process.

One such strategy the House of Representatives is considering is the proposed Expanding and Promoting Expertise in Review of Rare Treatments (EXPERRT) Act, H.R. 4156. CFF strongly supports the EXPERRT Act, which establishes a program to facilitate FDA outreach to external experts earlier and throughout the drug review process on issues such as unmet medical need, genetically targeted treatments, disease severity, clinical trial design and patient demographics.

Additionally, the CF Foundation urges the Committee to support collaborative efforts by the Food and Drug Administration and the National Institutes of Health, such as the Regulatory Science Initiative and the FDA-NIH Joint Leadership Council. Collaboration between the NIH and FDA has the potential to help move innovative new drugs more quickly through the development process and into the hands of patients by ensuring that the FDA has the resources, strategies, and tools it needs to efficiently review and regulate drugs in this ever changing scientific landscape. As treatments like Kalydeco are being developed to target specific genetic mutations and smaller and smaller populations, it is important that the FDA has the expertise it needs to quickly move these drugs through the review process.

The Cystic Fibrosis Foundation's unique and successful drug development model for creating treatments for a rare disease has helped create a robust pipeline of potential therapies to fight cystic fibrosis. The Food and Drug Administration has played a critical role in this process, working with the Foundation as they review treatments and move them into the hands of patients. Encouraged by our successes, we believe the experience of the CF Foundation 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 the Cystic Fibrosis Foundation, we thank the Committee for its consideration.

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#### PREPARED STATEMENT OF THE FARMERS MARKET COALITION

The Farmers Market Coalition (FMC) represents more than 2,700 farmers markets across the United States, as well as the more than 30,000 farmers that depend upon them. We seek to build viable agricultural economies by expanding farmers' marketing choices while expanding consumers' opportunities to purchase fresh, locally grown foods. Herein, we urge you to fully fund both the Farmers Market Promotion Program and the WIC Farmers Market Nutrition Program.

Farmers markets have grown in response to consumer demand in recent years, emerging as cornerstones in more than 7,100 communities across the United States. Markets are extending their seasons into winter months, too, offering farmers income throughout the year. Uniquely, they have the potential to bridge urban and rural divides, strengthening the fabric of our country while addressing the nutritional needs of Americans at every income level. The percentage of SNAP dollars redeemed at farmers markets, for example, is increasing as more markets become EBT-equipped and program participants choose to use their benefits there. For this reason, FNS and AMS programs that facilitate the sector's growth are of critical importance not just to farmers, but to families, and community economies. FMC urges the following:

*Reauthorize and increase funding for the Farmers Market Promotion Program.*—The ripple effects of the FMPP program are impressive, providing small infusions of funding to communities and groups of farmers in all 50 States since 2006. These awardees grow capacity, increase farmer income, help new entrepreneurs get started in feeding their local communities, and build local partnerships for long-term viability. However, the program is highly competitive, funding only 444 of the Nation's 7,100 farmers markets since 2006. With rural jobs on the line, and the nascent local food sector in need of training, capacity building, and technical assistance, now is not the time to turn our backs on a program with such far-reaching positive impacts, as illustrated in recent Senate Agriculture Committee briefings and testimonies.

We urge you to reauthorize funding for the Farmers Market Promotion Program, and increase funding to \$20 million annually so that it can fully serve farmers markets and the many farmers choosing to begin marketing to consumers in their local communities.

*Restore full funding to the WIC Farmers Market Nutrition Program (WIC FMNP).*—In 2010, WIC FMNP served more than 2.1 million WIC families, bringing more than \$22 million in income directly to more than 18,000 small and mid-scale produce farmers. Proposed cuts of \$3.5 million to this important program threaten access to fresh local produce for WIC eligible clients in 45 State agencies, Territories and Indian Tribal Organizations. For example, in Wisconsin alone, WIC FMNP provided fresh fruits and vegetables to approximately 100,000 women and their children in 2011, simultaneously providing \$864,037 in additional income to 1,552 participating Wisconsin produce farmers. Proposed cuts to this effective win-win program would mean thousand fewer families in need having access to nutritious, locally grown produce, and many hardworking farmers unable to serve them.

New York State, which serves almost 400,000 WIC mothers and their children, calculated the devastating impact of these proposed WIC FMNP cuts on their agricultural sector. They estimate that small family farmers in the State would lose approximately \$1.1 million in revenues.

We urge you to restore WIC FMNP funding to \$20 million for fiscal year 2013. Thank you for your consideration of this testimony, and, on behalf of the Farmers Market Coalition Board of Directors and members, thank you for all you do on a daily basis to support America's family farmers.

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PREPARED STATEMENT OF FLORIDA HOME PARTNERSHIP, INC.

On behalf of Florida Home Partnership, I wish to thank you for accepting this testimony on Rural Housing Funding for fiscal year 2013. Florida Home Partnership, Inc. (FHP) is a nonprofit Community Housing Development Organization (CHDO). Our mission is to provide low and moderate income families affordable, quality-built, energy efficient homes in communities that offer long-term value and comfort. I am urging the Appropriations Subcommittee to fund the following USDA Rural Housing Programs at the higher of fiscal year 2012 levels or the President's fiscal year 2013 budget request: (1) \$900 million for Section 502 Family Direct Homeownership Loans, (2) \$30 million for Section 523 Self-Help Housing Program, and (3) \$13 million for the Rural Community Development Initiative. The Section 502 Loans provide affordable mortgage opportunities for low-income rural Americans, while the Section 523 funds allow Self-Help Housing grantees across Rural America provide technical assistance to Rural Americans engaged in building their own homes through USDA's Mutual Self-Help Housing Program.

FHP administers the USDA Mutual Self-help Program in the rural areas of Hillsborough and Pasco Counties in Florida. The impact of this service asserts a positive result in four areas: Affordable quality housing for low- to moderate-income families; Green Built and Energy Star certified homes conserve precious resources; safe and affordable housing instills higher goals for the future of youth and teens; and the Mutual Self-help Program sustains and stimulates the local economic environment.

With the support of the USDA Mutual Self-Help Program, Florida Home Partnership guides groups of 6 to 10, low- to moderate-income families to work together to help build each other's homes. In the past 15 years, over 500 homes and 5 communities have been built. Leveraging dollars from the USDA Mutual Self-Help Program, the State of Florida's Home Ownership Pool and down payment assistance through Hillsborough and Pasco Counties, Federal funds enable FHP to efficiently operate a very complex yet effective program. FHP has successfully administered over \$65 million to implement this USDA affordable housing program.

Family members of the groups share the common goal of homeownership and commit themselves to share in the work that will make that goal a reality. When all homes in the construction group are completed, all homeowners are authorized to move into their new homes on the same day, creating an instant community.

Families and individuals contribute a minimum of 600 hours of "sweat equity" in the construction of their new homes in exchange for their down payment. Hard work is the key, along with a willingness to work cooperatively with other participants. No construction experience is necessary! Participants perform a variety of unskilled and semi-skilled tasks from digging the foundation, to carpentry, painting, electrical and plumbing activities through construction clean-up and landscaping—along with everything in between! Our knowledgeable family construction coordinators (who themselves have gone through the program) guide participants through the construction process all the while teaching the participants many new skill sets. Friends, family, church members, and others help these families accomplish the labor requirements. Therefore, it becomes a community endeavor to complete all the homes in a group.

Each Self Help Home is currently being built as a GREEN Certified home, and is constructed to Exceed Energy Star Standards. To date, FHP has constructed over 150 GREEN and Energy Star Certified homes. These homes conserve energy resources for our country, and just as importantly, conserve the precious financial resources of the low-income rural clients we serve. Many of the Self-Help Housing organizations across America build their homes to these same GREEN and Energy Conserving Standards.

FHP provides services before, during and after to assure the success of the families. Services provided “during” the application process include homeownership education, improving credit, and understanding the responsibilities of homeownership. Once the home is built, homeowners are also educated and encouraged to become active with their homeowners association to assure their community remains a quality and safe neighborhood. FHP recently hosted a Parliamentary Procedure Training class for interested homeowners and to train new and seasoned HOA board members.

While FHP provides safe housing and encourages community involvement, the groundwork is being laid to support a positive outlook for youth and teens in the community. The youth of our communities have witnessed the hard work of their parents leading to the accomplishment of the American Dream, homeownership. We have had multiple experiences where children growing up in our decent affordable self help housing communities, have gone on to build self help homes of their own. These children have learned that hard work and perseverance do pay off.

The USDA Mutual Self-help Program has also had a positive impact on the local economy. In addition to a staff of 17 employees, in which 58 percent are Self Help Homeowners, FHP has been able to regularly subcontract with small family owned, mid-size and chain store businesses. A great portion of the \$65 million has been circulated to these various businesses since our inception in 1993. Consequently, as a primary client for many businesses, including Home Depot, in the Ruskin, Florida area, FHP has contributed to supporting jobs throughout its rural service area.

The value of the Mutual Self-Help Housing Program has inherent benefits that provide answers to other social problems in our society by meeting the needs of affordable, quality and energy-efficient housing that provides safe environments for our rural families. Accordingly, the program also prepares the children of these homeowners with the tools to change their collective destinies; all while creating and maintaining meaningful jobs for rural Americans.

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PREPARED STATEMENT OF THE FEDERATION OF AMERICAN SOCIETIES FOR  
EXPERIMENTAL BIOLOGY

The Federation of American Societies for Experimental Biology (FASEB) respectfully requests a fiscal year 2013 appropriation of \$325 million for the Agriculture and Food Research Initiative (AFRI) within the National Institute of Food and Agriculture. This funding level matches the recommendation made in the President’s fiscal year 2013 budget request. FASEB’s broader goal is to support sustainable growth so that AFRI funding reaches its authorized level of \$700 million as soon as feasible.

As a federation of 26 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 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 premier competitive grants program, AFRI supports agricultural research, education, and extension projects at public land grant universities and other institutions nationwide. In order to optimize the effectiveness of its resources, AFRI facilitates collaborative, interdisciplinary research to address key societal problems and build foundational knowledge in high-priority areas of the food and agricultural sciences. AFRI also encourages young scientists to pursue careers in agricultural research by providing research funding for over 1,700 of the Nation’s most promising pre- and postdoctoral scholars.

According to the results of a recent study published in the Proceedings of the National Academy of Sciences, global food demand is expected to double by the year 2050. The world must meet the increasing need for food while simultaneously providing better nutrition, new biofuel materials, sustainable farming practices, and greater food safety. The effective coordination of research, education, and extension activities like those supported by AFRI enables efficient translation of scientific dis-

coveries into a broad range of applications to overcome some of our most daunting food and agriculture challenges. For example, a team of scientists supported by AFRI are discovering the biological processes that determine how warm temperatures affect corn seed development and crop production. With this knowledge, researchers can develop hardier genetic variants of corn that are able to overcome the negative effects of heat stress and produce higher yields—advances which will be important for maintaining an adequate food supply. Other AFRI-funded scientists are studying the genomes of soilborne microorganisms responsible for damaging soybeans and other crops. By understanding the pathogen’s ability to harm plants, research and extension specialists can develop methods to manage the disease, increase crop production, and assist farmers, who lose an estimated \$300 million to soybean root and stem rot diseases each year. AFRI also makes critical contributions to improving human health; scientists are using multidisciplinary approaches to examine the process by which disease-causing *E. coli* are released from the digestive tracts of cattle into the food supply. Research on the genetic, microbial, and environmental factors that cause the bacteria to spread throughout livestock populations enables scientists to devise new strategies for reducing cattle infections and preventing food contamination.

Robust AFRI funding will also help attract talented young scientists to careers in agricultural research. A new AFRI-sponsored fellowship program has been established to help train and develop the next generation of agricultural, forestry, and food scientists and educators. In its first year of funding, the program awarded a total of \$6 million to 54 students from 32 universities across the country. Fellows are already advancing important research projects, including a study to identify sources of microbial contamination in imported foods.

Agricultural research directly benefits all sectors of society and every geographic region of the country. Furthermore, the private sector relies on public investments in USDA research to increase productivity, improve crops, and train future cohorts of agricultural scientists. The estimated value of U.S. agricultural exports increased 32.2 percent between fiscal year 2007 and fiscal year 2010, illustrating the growing demand for agricultural products worldwide, and yet the AFRI budget has stagnated since the program was established with an authorized funding level of \$700 million in the 2008 farm bill. In fiscal year 2010, AFRI’s limited resources could only support 40 percent of project proposals recommended for funding by review panels, and the program remains significantly underfunded relative to its current capacity. The fiscal year 2012 AFRI budget of \$264 million is woefully inadequate to ensure viability of a research enterprise at the core of human prosperity.

Thank you for the opportunity to offer FASEB’s support for AFRI.

FASEB is composed of 26 societies with more than 100,000 members, making it the largest coalition of biomedical research associations in the United States. Celebrating 100 Years of Advancing the Life Sciences in 2012, FASEB is rededicating its efforts to advance health and well-being by promoting progress and education in biological and biomedical sciences through service to our member societies and collaborative advocacy.

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PREPARED STATEMENT OF FRIENDS OF AGRICULTURAL RESEARCH—BELTSVILLE, INC.

Mister Chairman and Members of the Subcommittee, thank you for this opportunity to present our statement supporting funding for the USDA’s Agricultural Research Service (ARS), and especially for its flagship research facility, the Henry A. Wallace Beltsville Agricultural Research Center (BARC), in Beltsville, Maryland. We strongly recommend full fiscal year 2013 funding support for research programs at Beltsville.

We begin our recommendations, Mr. Chairman, by drawing attention to Agriculture Secretary’s Tom Vilsack’s February 13, 2013, remarks on the proposed fiscal year 2013 budget: “USDA has supported farmers, ranchers and growers so that last year they enjoyed record farm income. . . . To help sustain record farm income, we will invest in research and development to improve agricultural productivity. [And continue] support for in-house research and the land grant universities. We’ll continue our efforts to combat destructive pests and disease that threaten crops and livestock.

Following a Department-wide review of operations, we created a Blueprint for Stronger Service to make USDA work better and more efficiently for the American people. We found savings in areas like technology, travel, supplies and facilities. We’ve been able to avoid the interruptions in service that come with furloughs and employee layoffs.

The Blue Print for a Stronger Service holds out substantive agency-wide impacts for the Agricultural Research Service as a whole as well as for Beltsville in particular. The agency is streamlining its business operations, consolidating activities such as human resources and procurement into three “business service centers.” In fiscal year 2011, ARS cut its travel costs by approximately 28 percent from the past year, and the ARS printing fund has been cut by more than half. While continuing to serve the research needs of American agriculture and the Nation, ARS is committed to “doing more with less.”

We strongly endorse the remarks of Secretary Vilsack and the purposes and goals of the Blue Print for a Stronger Service. Overall, ARS will close 12 of its research programs at 10 locations in 2012, none of them at Beltsville—a recognition of the outstanding research conducted at Beltsville.

Beltsville—the Nation’s premier agricultural research center—has spearheaded technical advances in American agriculture for over 100 years. Beltsville celebrated 100 years of research leadership and technical advances in 2010. The long list of landmark research achievements over that time is truly remarkable. Still at the threshold of its second century, Beltsville stands unequalled in scientific capability, breadth of agricultural research portfolio, and concentration of scientific expertise. Under the leadership of Director Dr. Joseph Spence and with its powerful scientific capability, the Beltsville Agricultural Research Center is distinctively, indispensably prepared for the challenges that lie ahead.

Toward that end, the scientists of Beltsville have developed a new, bold vision for the future. Titled *Innovation and Integration: Agricultural Research for a Growing World*, this visionary document stems from the realization that broader, multidisciplinary approaches will be needed to address new, perhaps unforeseeable agricultural challenges of the future. New approaches will be needed to reach beyond the confines of traditional research approaches tied to narrow issues or specific commodities. Traditionally, for instance, plant scientists may have worked in some combination with animal scientists or with human nutritionists. Only rarely, however, have scientists combined efforts across many disciplines to solve problems. Given its broad research portfolio and its many disciplines, Beltsville is perfectly situated for broad, multidisciplinary approaches to flourish. Thus, in every way, Beltsville remains and will continue to be a national Center of Excellence for the highest agricultural research priorities.

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 Beltsville. We would respectively suggest that adequate funding for the Agriculture Department’s flagship research center is central to maintaining national and world food security.

*Priorities in the President’s Fiscal Year 2013 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.

We were pleased to see that the fiscal year 2013 budget includes increases for environmental stewardship; crop breeding and protection; animal breeding and protection; food safety; and human nutrition. Obviously, these are areas of great concern to all Americans, and they are certainly among the highest priorities for agricultural research today. All of these research areas are strengths of the Beltsville Agricultural Research Center and they will benefit well from the unique facilities and scientific expertise at the Center. We encourage you to seriously consider funding the proposed budget and to ensure that Beltsville receives the funding that it needs to address these critical research needs.

Although funds are not requested for major facilities projects in the fiscal year 2013 budget, we would like to bring to your attention the urgent need for renovation of Building 307 on the Beltsville campus. The Center has aggressively moved to consolidate space and reduce costs and has been very successful at doing so. However, these plans require the renovation of a building—Building 307—that was vacated some years ago in anticipation of a complete renovation. In the past, Congress approved partial funding for this renovation, and those monies were retained pending appropriation of the full amount required for the renovation. Unfortunately, those funds now have been lost to ARS. Consequently, renovation of this vacant, highly useful building is on indefinite hold. While we realize that funding is extremely tight, we confirm that Beltsville urgently needs a renovated Building 307 for ade-

quate, high quality lab space. Moreover, a renovated Building 307 would not only yield substantial energy savings, but also would allow Beltsville to move forward with other long-delayed relocation and consolidation plans.

In summation, we would highlight these spheres of excellence:

*Animal Breeding and Protection.*—Beltsville conducts extensive research on animal production and animal health. The research center is the foundation of genetic improvement in dairy cow production. Beltsville is examining ways to prevent resistance to drugs for animal parasite prevention and control.

*Crop Breeding and Protection.*—Beltsville scientists have an extensive record of ongoing research relating to protecting crops from pests and emerging pathogens. Beltsville has distinctive expertise for identifying pathogens, nematodes, and insects that destroy crops or make crops ineligible for export. Beltsville houses the Germplasm Resource Information Network, the United States coordinating body to identify and catalog plant germplasm.

*Child and Human Nutrition.*—The Beltsville Human Nutrition Research Center (BHNRC) is the Nation's largest, most comprehensive Federal human nutrition research center; unique activities include the What We Eat in America survey, which is the Government's nutrition monitoring program, and the National Nutrient Databank, which is the gold standard reference of food nutrient content that 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.

*Global Climate Change.*—Beltsville became actively engaged in climate change research long before climate change became a topic of intense media interest. 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 detrimental plants (such as weeds.) A central aim is finding ways to mitigate negative effects of climate change on crops. Beltsville houses unequalled facilities for replicating past climates or climates that may exist in the future.

*Plant, Animal, and Microbial Collections.*—Beltsville houses matchless national biological collections that are indispensable to the well-being of American agriculture. In addition to the actual collections, Beltsville scientists are internationally recognized for their expertise and ability to quickly and properly identify insect pests, fungal pathogens, bacterial threats, and nematodes. This expertise is crucial to preventing loss of crops and animals, ensuring that invasive threats to American agriculture are identified before they can enter the country, thus helping to protect homeland security, and ensuring that American exports are free of pests and pathogens that could prohibit exports. Also, Beltsville houses the National Animal Parasite collection and has the expertise to identify parasites that are of importance to agricultural animals.

Mr. Chairman, this concludes our statement. Thank you for consideration and support for the educational, research, and outreach missions of the Beltsville Agricultural Research Center.

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PREPARED STATEMENT OF THE GLOBAL HEALTH TECHNOLOGIES COALITION

Chairman Kohl, Ranking Member Blunt, and members of the Committee, thank you for the opportunity to provide testimony on the fiscal year 2013 appropriations funding for the U.S. Food and Drug Administration (FDA). We appreciate your leadership in global health, and we hope that your support will continue. I am submitting this testimony on behalf of the Global Health Technologies Coalition (GHTC), a group of nearly 40 nonprofit organizations working together to advance U.S. policies that can accelerate the development of new global health innovations—including new vaccines, drugs, diagnostics, microbicides, multi-purpose technologies, and other tools—to combat global health diseases and conditions. The GHTC members strongly believe that to meet the world's most pressing global health needs, it is critical to invest in research today so that the most effective health solutions are available now and in the future. We also believe that the U.S. Government has a historic and unique role in doing so. My testimony reflects the needs expressed by our member organizations, which include nonprofit advocacy organizations, policy think-tanks, implementing organizations, product development partnerships (PDPs), and many others.<sup>1</sup> We strongly urge the Committee to continue its established support for global health research and development (R&D), as well as product safety

<sup>1</sup>Global Health Technologies Coalition. <http://www.ghtcoalition.org/coalition-members.php>.

by (1) sustaining and supporting the U.S. investment in global health research, product development, and global regulation; (2) instructing the FDA to prioritize the review and licensure of global health technologies; and (3) requiring leaders at the FDA to put plans in place to ensure that global health product regulation is efficient, coordinated, and streamlined.

*Critical Need for New Global Health Tools*

Every day, more than 35,000 people die from AIDS, tuberculosis (TB), malaria, and other neglected diseases. The health detriments these diseases cause, even when not fatal, have profound implications in other areas such as economic stability and access to education. This highlights the urgent need for sustained investment in global health research to deliver new tools to combat these devastating diseases. While drugs and other health technologies exist for these diseases, many have grown ineffective due to increasing drug resistance and toxicity or are costly and difficult to administer in poor, remote, and unstable settings. While we must increase access to proven, existing drugs, vaccines, diagnostics, and other health tools to tackle global health problems, it is just as critical to develop the next generation of tools to fight existing disease and address emerging threats such as malaria, dengue, and drug-resistant TB. There are several very promising technology candidates in the R&D pipeline; however, these tools will never be available if the support needed to continue R&D is not supported and sustained.

*Innovation as a Smart Economic Choice*

Global health R&D brings lifesaving tools to those who need them most; however, the benefits are much broader than preventing and treating disease. It is also a smart economic investment in the United States, where it drives job creation, spurs business activity, and benefits academic institutions. Biomedical research, including global health, is a \$100 billion enterprise in the United States. In Washington State, \$4.1 billion is generated annually from global health activities, including R&D. In North Carolina, the economic impact from global health is roughly \$2 billion. It is important that the U.S. Government support industries, such as global health R&D, which exhibit such strong potential to build the economy at home and abroad. Global health R&D has been an important legacy of USAID's work for over three decades, and should be supported and protected. History has shown that investing in global health research not only saves lives but also produces cost-savings and efficiencies. In the United States alone, for example, polio vaccinations during the last 50 years have resulted in a net savings of \$180 billion. New therapies to treat drug-resistant TB have the potential to reduce the price of treatment by 90 percent and cut health system costs significantly. The United States has made smart investments in research in the past that have resulted in lifesaving breakthroughs for global health diseases, as well as important advances in diseases endemic to the United States. It is essential that we keep this momentum going and not allow this research to lag behind, in order to maximize the resources we have put into these programs. We must now build on those investments to turn those discoveries into new vaccines, drugs, tests, and other tools.

*Advancing Global Health Product Development*

Because private industry does not invest significantly in the development of products for diseases for which there are no lucrative markets, a host of new organizational models and incentive mechanisms have emerged to address this challenge, with varying success.

One organizational model that has proven promising is the product development partnership (PDP). PDPs are a unique form of a public-private partnership established to drive greater development of products for neglected diseases. Currently, there are more than 26 PDPs developing drugs, vaccines, microbicides, and diagnostics that target a range of infectious and neglected diseases, including HIV/AIDS, malaria, TB, Chagas disease, dengue fever, and visceral leishmaniasis.

While each PDP operates differently depending on its disease area(s) of focus, they typically employ a portfolio approach to R&D to accelerate product development by pursuing multiple strategies for the same disease area. They also work in close partnership with academia, large pharmaceutical companies, the biotechnology industry, and with regulatory and other Government agencies in developing countries.

PDPs are delivering on their promise to develop lifesaving products for use in countries where disease burdens are highest and no viable commercial markets exist. To date, PDPs have developed and licensed 16 products to combat neglected diseases in low- and middle-income countries. More can be expected from PDPs in the future with sustained and additional support: in 2009, PDPs had more than 120 biopharmaceutical, diagnostic, and vector-control candidates in various stages of de-

velopment, including 32 in late-stage clinical trials. In the next 5 years, it is anticipated that several new technologies could be ready for use or in final stages of clinical development.

For example the RTS,S/AS01 malaria vaccine candidate, manufactured by GlaxoSmithKline and co-developed with the PATH Malaria Vaccine Initiative, has produced positive results in clinical trials thus far, and could be available for general implementation for infants in Africa within 5 years or so. Such a vaccine would significantly reduce the burden of sickness and death from malaria. Additionally, six TB vaccine candidates are in clinical trials worldwide, including the first late-stage infant study of a TB vaccine in more than 80 years. There are also several new TB drug candidates in testing, which, if approved, would become the first new TB drugs in nearly 50 years. These therapies could help reduce the 8 million new TB infections and nearly 1.7 million TB-related deaths that happen each year. Also, a vaccine candidate and drug candidates are currently in clinical trials to prevent and treat visceral leishmaniasis, a neglected disease whose current treatments are costly and toxic. Additionally, two artemisinin combination therapies—the gold standard of malaria drug treatment—developed in partnership with Medicines for Malaria Venture have recently been approved and will be reaching those in need in the near future.

#### *Global Health Product Development Challenges*

Developers of products intended for the developing world face challenges in three key areas:

First, capacity to conduct as well as adequately regulate clinical trials does not exist or is often weak in countries where diseases are endemic. Second, there is a lack of financing for late-stage clinical trials, which are necessary for testing the efficacy and safety of new tools. And third, the approval process for new products for neglected diseases is poorly coordinated and involves multiple, complex steps. Global regulatory systems are not sufficiently streamlined and the capacity of regulatory authorities to approve products for the developing world is frequently weak. Therefore, regulatory review and introduction of new safe and effective products takes longer than necessary.

The FDA has demonstrated through a number of recent actions that it can have an impact on the introduction of global health tools. These include:

- The FDA's program to review HIV/AIDS drugs delivered in the developing world through the U.S. President's Emergency Plan for AIDS Relief.
- The release of guidance documents that outlined the FDA's willingness to review vaccines and other products for diseases not endemic to the United States.
- The agency's partnership with global bodies, such as the World Health Organization (WHO), to enhance access to medicines for the developing world and assist other countries in bolstering their regulatory capacity.
- The FDA's Priority Review Voucher Program, which awards a voucher for future expedited product review to the sponsor of a newly approved drug or biologic that targets a neglected tropical disease (NTD).
- The FDA's Office of Critical Path Initiatives, which supports the development of regulatory science such as biomarkers and animal models to better evaluate and register new TB tools.
- The FDA's issuance of a guidance for testing new anti-TB drugs in combination, which accelerates the development of new, safe, and highly effective treatment regimens with shorter therapy durations.

The FDA's efforts in these areas are to be applauded. The agency can and should continue to increasingly leverage its expertise to benefit the millions of people affected by infectious diseases around the world.

#### *Recommendations*

Support for global health research that saves lives around the world—while at the same time promoting innovation, creating jobs, and spurring economic growth at home—is unquestionably one of the Nation's highest priorities. In keeping with this value, the GHTC respectfully requests that the Committee do the following:

- Sustain and support U.S. investments in the FDA's funding resources, as well as its capacity to provide technical advice to other regulatory bodies and review and license health products for diseases not usually endemic to the United States, and its authority to fund research and development for global health technologies, including but not limited to those created through the Critical Pathways Initiative.
- Instruct all U.S. agencies in its jurisdiction involved in global health to prioritize R&D within all development programs by creating actions plans, including metrics to measure progress. We request that leaders at the FDA to

work with leaders at other U.S. agencies, including the State Department, U.S. Agency for International Development, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense to ensure that efforts in global health R&D are coordinated, efficient, and streamlined. This should include establishing transparency mechanisms designed to show what global health R&D efforts are taking place and how U.S. agencies are collaborating with each other to make efficient use of the U.S. investment, and align with the goals and intentions of the recently released Health and Human Services Global Health Strategy.<sup>2</sup>

- Direct that the results of these initiatives should be reported on to Congress and be made publicly available. Past reports of the health R&D activities at U.S. agencies have helped coordinate efforts between agencies and transparently inform the public about the investment of taxpayer money. These reports must be continued in the future and should include information on all U.S. Government agencies involved in global health R&D.

We respectfully request that the Committee consider inclusion of the following language in the report on the fiscal year 2013 Agriculture and FDA appropriations legislation: “The Committee recognizes the critical contribution that the U.S. Food and Drug Administration’s (FDA) funding for new global health tools and its leadership in reviewing and licensing global health technologies makes to the impact of new global health technologies, and also recognizes the need to sustain and support U.S. investment in this area by fully funding the FDA to carry out this work. The Committee acknowledges the FDA’s essential role in capacity-building abroad to help build strong regulatory authorities in other nations, and asks that the FDA continue and expand on this work. New global health products are cost-effective public health interventions that play an important role in improving global health and are vital in protecting the lives of Americans and populations abroad. The Committee directs the FDA to expand its outreach and information-sharing activities with product developers—including but not limited to industry groups, nonprofit organizations, and other product development partnerships (PDPs)—to support the development of safe and effective global health tools. Further, the Committee directs the FDA to submit a report to Congress and the public outlining the monitoring, evaluation, and progress of its ‘Pathway to Global Product Safety and Quality’ as it pertains to products outlined in paragraphs (2) and (3) of section 740(c) of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010 (Public Law 111–80). In its review of drugs and other products for neglected diseases, the Committee requests that FDA:

- Maximize the use of priority review where feasible and appropriate.
- Work with sponsors to facilitate expanded access to investigational products.
- Increase coordination and interaction with the World Health Organization, European Medicines Agency, and other international regulatory agencies.
- Implement mechanisms for enhanced collaboration between the FDA and national regulatory authorities in developing countries.
- Increase coordination among individual drug, biological product, and device review divisions across FDA centers to support the development and monitoring of safe and effective medical products for rare and neglected diseases.

The Committee is also aware that Chagas disease is not on the list of neglected diseases as currently defined by the FDA. The Committee urges the FDA to make the necessary modifications to include Chagas disease in its list of neglected diseases in line with the World Health Organization (WHO) list of neglected tropical diseases. The Committee is pleased with FDA’s current activities in the areas of regulatory capacity-building and the promotion of sound regulatory science practices abroad, and recommends that the FDA explore how to expand on such activities.”

On behalf of the members of the GHTC, I would like to extend my gratitude to the Committee for the opportunity to submit written testimony for the record.

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PREPARED STATEMENT OF THE HOUSING DEVELOPMENT ALLIANCE, INC.

On behalf of Housing Development Alliance, Inc. and the communities we serve, I wish to thank the Subcommittee for the opportunity to submit testimony on fiscal year 2013 Appropriations for the Department of Agriculture (USDA) Rural Housing Programs. I urge this subcommittee to fund USDA Rural Housing’s Section 502 Single Family Direct Loan Program at \$900 million (the fiscal year 2012 level); Section

<sup>2</sup> HHS Global Health Strategy. <http://www.globalhealth.gov/global-programs-and-initiatives/global-health-strategy/>.

504 Very-Low Income Rural Housing Repair Loans at \$28 million; and Section 504 Very-Low Income Rural Housing Repair Grants at \$29.5 million.

Housing Development Alliance, Inc. (HDA) serves Perry, Knott, Leslie and Breathitt Counties in Kentucky. These are among four of the poorest counties in the Nation with poverty rates ranging from 24 percent to over 33 percent. In these four counties over 12,650 households have annual incomes of less than \$25,000 including over 5,100 households with incomes less than \$10,000. Furthermore, these counties suffer from persistent poverty (having more than 20 percent of population in poverty for more than five decades) which has resulted in a poor housing stock and a broken housing market. In short, our community has a critical need for safe, decent and affordable housing.

Since 1996, the Housing Development Alliance has constructed 90 new homes which were sold to qualified low and very-low income homebuyers who received financing through the Section 502 Single Family Direct Loan Program. In this same period, the Housing Development Alliance has repaired nearly 180 homes using Section 504 Loan and Grants. These programs often serve the poorest of the poor. In fact, the average annual income of our Section 502 Direct Loan homebuyers was \$14,252 and the average annual income of our Section 504 Loan and Grant repair client was \$10,660 per year.

In many cases the living conditions of the households prior to receiving assistance are deplorable. These homes often lack an adequate heat source; have little or no insulation; often have major structural defects including collapsing foundations, rotting floors and walls and leaking roofs; have unsafe electrical wiring; and lack complete plumbing. For example recently the Housing Development Alliance encountered an elderly woman whose gas water heater was spewing potentially deadly levels of carbon monoxide into her home and another elderly woman whose tub/shower was not hooked to the sewer and was draining directly under her home.

However, the benefits of these programs are not limited to just to the households purchasing the new home or receiving the affordable home repair. The programs provide jobs and other needed economic activity to our community. For example, in 2011 the constructed seven homes financed in part by the Section 502 Single Family Direct Loan Program. Using the National Association of Home Builders' estimate that each home constructed creates/preserve 3 construction job per year, in 2011 the Housing Development Alliance's use of Section 502 Direct Loans created/preserved 21 construction jobs. Even more jobs were created/preserved through our use of the Section 504 Repair Loans and Grants which funded 14 home repairs. While these numbers may seem modest, as they are repeated in rural communities throughout America these programs have a huge impact on jobs in rural America.

Furthermore the Section 502 Single Family Direct Loan Program is the most cost effective Federal housing program. Despite serving low and very-low income households, the average lifetime cost of a Section 502 Single Family Direct Loan is just \$7,200 while the average cost of Section 8 Housing Assistance is nearly \$7,000 per year. This low cost is due in part to the fact that Section 502 Direct portfolio maintains an excellent repayment history with a foreclosure rate of just over 4 percent.

The administration and others have suggested that the Section 502 Guarantee Program is a suitable alternative to the Section 502 Direct Loan Program; this is simply not true in our community. We completed a study of our 502 Direct Loan Program recipients and found that only 1 out of 10 would have been able to afford the higher interest cost associated with a Section 502 Guarantee Loan.

Thank you again for the opportunity to provide testimony on the critically important programs. Without adequate funding for these programs low income households will remain trapped in substandard, if not outright deplorable, housing and construction and other related jobs will be lost across rural America.

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#### PREPARED STATEMENT OF THE HUNGER TASK FORCE

I am writing to provide comments on the fiscal year 2013 Agriculture Appropriations bill.

Hunger Task Force is a nonprofit, independent food bank located in Milwaukee County. We have been feeding emergency food free of charge to needy people in southeastern Wisconsin since 1974. Last year we distributed 9.8 million pounds of food to programs in our network.

Currently, our network of 81 food pantries, soup kitchens and homeless shelters is providing food to over 35,000 people per month in our food pantry network, and we are serving over 60,000 hot meals in our soup kitchen network each month. We have seen an 11.9 percent increase in the number of people using our food pantries in the last 12 months. The numbers do not surprise us as 1-in-3 City of Milwaukee

residents continue to live at or below the poverty level, and 1-in-2 Milwaukee children live at the poverty level. Milwaukee County's 2-1-1 IMPACT emergency hotline says that the number one reason people call them (27 percent of all calls) is to connect to an emergency food provider. A record 272,661 Milwaukee County residents (1-in-5 residents in the county) now receive FoodShare benefits. In Wisconsin, a record 831,000 people now receive FoodShare benefits. A recent report by our State's Department of Public Instruction notes that the percentage of children in Wisconsin receiving free and reduced-price meals has increased 8 consecutive years—a record 41 percent of Wisconsin's children now receive free and reduced-price meals, and in the City of Milwaukee a record 83 percent of students now receive subsidized meals.

The increasing poverty and ongoing demand for emergency food in southeastern Wisconsin and throughout the State make the Federal nutrition and commodity programs more important than ever.

Hunger Task Force continues to be involved in many of the Federal nutrition programs. We have been a contracted provider of TEFAP foods since 1999, and we have implemented the CSFP (we call it StockBox) since 2003. TEFAP and CSFP commodity foods now account for 75 percent of the food we distribute every year. We coordinate 100 StockBox sites in southeastern Wisconsin at which 9,300 low-income seniors receive monthly box deliveries to their doorstep. The CSFP boxes are incredibly important to the seniors we serve. A recent survey of our StockBox beneficiaries told us that 39 percent of recipients would eat less, go hungry or have a hard time obtaining enough food in they could no longer obtain a StockBox. Another 21 percent of StockBox beneficiaries mentioned that they would have to look for additional assistance, such as meal sites or food pantries, if they did not receive a StockBox each month.

Hunger Task Force has also administered the Senior Farmers Market Nutrition Program since 2004. Last year we distributed 3,200 vouchers to needy seniors in Milwaukee County. We know Milwaukee's seniors value these vouchers, as 91 percent of the vouchers were redeemed in 2011.

Hunger Task Force has also been actively involved in improving and expanding participation in programs such as SNAP (Supplemental Nutrition Assistance Program), School Lunch and School Breakfast, WIC (Women, Infants and Children), CACFP after-school suppers, and the SFSP (Summer Food Service Program). For example:

- We worked with the Milwaukee Public School district to pilot and then expand a universal-breakfast-in-the-classroom program. This program now provides free breakfast every day to all MPS schoolchildren in 87 schools—over 25,000 children per day now receive this benefit.
- We have spearheaded a local coalition that provides summer meals (including suppers) to low-income children in Milwaukee. This summer feeding initiative, which is in large part subsidized by the Kohl's Corporation, provided over 720,000 meals (including 89,000 suppers) to needy children last summer.
- We continually strive to “modernize” FoodShare programming in Milwaukee County. Since 2009, through our three satellite self-service locations, we have helped over 47,000 people apply for FoodShare or retain benefits. We also have received Federal/state SNAP Outreach Grant funding to ensure that all people eligible for SNAP benefits receive them.
- We worked with Senator Kohl's office to bring the CACFP after-school supper program to Wisconsin in 2009. Currently, 36 MPS schools provide more than 40,000 after-school suppers each month to schoolchildren.
- We have been a member of the Wisconsin WIC Advisory Committee since 2000. As a member, we work with local practitioners and State officials to ensure that WIC participation is maximized for those who are eligible. We also have begun attempting to work with State officials on a transition to EBT, and we have conducted outreach in our network around the new WIC food package.

Our experience with the Federal nutrition programs is diverse and extensive. We see the value of these programs to the people who need benefits, as well as to the service providers and local economy. In general, we are very pleased with President Obama's fiscal year 2013 Proposed Budget for USDA's nutrition programs. In particular:

- We support continued investment in the SNAP, including a continuation of State options to suspend time limits on SNAP for able-bodied adults without dependent children and restoration of cuts to SNAP benefits made in the 2010 child nutrition bill.
- We support the increased investment in the SFSP and WIC Program, including an increase in the cash value vouchers for fruits and vegetables for children from \$6 to \$8 per month.

- We support the competitive grants to fund school meal equipment needed for the implementation of the new school meal standards and expansion of the School Breakfast Program.
- We are supportive of the \$187 million provided to support the existing CSFP caseload, but disappointed that CSFP is not made into a seniors-only program. We also would like to see a seniors-only CSFP expanded to all 50 States.
- We are supportive of the increased funding for TEFAP (both commodity purchases and administrative funding).
- We are disappointed that the budget does not provide increased investment in the Senior Farmers Market Nutrition Program and WIC FMNP. Although we provided SFMNP vouchers to 3,200 needy seniors last year, poverty among the elderly continues to grow and we could easily triple the number of distributed vouchers with additional Federal funding. Also, the WIC FMNP is proposed to receive a 30 percent reduction, which will impact families who need healthy and nutritious produce as well as small farmers at farmers markets that operate in low-income communities.

As an experienced emergency food provider and advocacy-driven organization, we ask that you consider our comments as you move forward with fiscal year 2013 budget deliberations. Thank you for your consideration.

Sincerely,

JON JANOWSKI,  
*Director of Advocacy.*

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PREPARED STATEMENT OF THE IZAAK WALTON LEAGUE OF AMERICA

The Izaak Walton League of America appreciates the opportunity to submit testimony concerning appropriations for fiscal year 2013 for various agencies and programs under the jurisdiction of the Subcommittee. The League is a national, non-profit organization founded in 1922. We have more than 39,000 members and 250 community-based chapters nationwide. Our members are committed to advancing common sense policies that safeguard wildlife and habitat, support community-based conservation, and address pressing environmental issues. The League 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.

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 a thousand 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. The League strongly opposes the administration's proposal to cut essential conservation programs, unilaterally reducing the farm bill baseline for fiscal year 2013 and beyond.

The League is concerned that the administration's budget would deprive farmers and ranchers of conservation and environmental stewardship assistance in fiscal year 2013 and 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.

The League and its members across the country are especially focused on the following core conservation programs:

*Conservation Reserve Program (CRP).*—The Conservation Reserve Program (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 fiscal year 2013 budget for CRP proposes a reduction in the farm bill authorized acreage limit from 32 million to 30 million. It is encouraging to see the announcement of a general sign-up in fiscal year 2012, and the special provision for 1 million acres of wetland and grassland restoration, but that does not alter the proposed cut to CRP's mandatory authorization for fiscal year 2013.

*Wetlands Reserve Program (WRP).*—The Wetlands Reserve Program (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 U.S. Department of Agriculture. Unfortunately, the administration takes no action to request new farm bill funding for WRP, which expires with the current farm bill authorization in fiscal year 2012. The League

urges Congress to continue the decades-long commitment made to the goals of the program.

*Grassland Reserve Program (GRP).*—The Grassland Reserve Program (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. Again, the League is disappointed that the administration has not proposed continuing GRP or any form of the program beyond fiscal year 2012. The League opposes this reduction because it will undermine efforts to protect one of the country's most threatened natural resources.

*Conservation Stewardship Program (CSP).*—The Conservation Stewardship Program (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 2013 budget is proposing to cut the mandatory spending for CSP by \$68 million. The League 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).*—The Wildlife Habitat Incentives Program helps agricultural landowners develop habitat for upland wildlife, wetland wildlife, threatened and endangered species, fish, and other wildlife. The President's fiscal year 2013 proposal also seeks to permanently reduce the mandatory commitment established for WHIP in the farm bill. The budget would cut fiscal year 2013 funding for WHIP by \$12 million. The League 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.

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PREPARED STATEMENT OF THE LITTLE DIXIE COMMUNITY ACTION AGENCY, INC.

LDCAA is requesting adequate funding provided to support \$900 million in lending authority for the Section 502 Single Family Direct Loan Program. It is disappointing to see the USDA relinquish the section 502 direct loan program. The section 502 direct loan program has far exceeded in successful outcomes any other Federal homeownership program. No other Federal program can equal the profile of families served: approximately 60 percent of the families receiving section 502 loans have incomes of less than 60 percent of the median income, and 40 percent of families participating in the program have incomes that do not exceed 50 percent of the median income.

Despite serving families with limited economic means, the section 502 direct loan program is the most cost effective affordable housing program in the Federal Government. In fiscal year 2010, the total per unit cost for a homeownership loan to a low income family was less than \$5,000. This stands in significant contrast to the Section 8 Rental Assistance program with the annual per unit costs exceeding the total Federal expense of a section 502 direct loan.

*Section 523 Mutual Self-Help Housing Program*

LDCAA is requesting national funding of \$30 million for the Section 523 Mutual Self-Help Housing Program. Currently, more than 100 organizations across America participate in the self-help housing program. These organizations unite groups of 8 to 10 self-help families who work collectively in the construction of each family's home. They perform approximately 65 percent of the overall construction labor. This "Sweat Equity" results in each homeowner earning and gaining instant equity in their homes. It also makes a significant investment in their community often resulting in the building of homes and neighborhoods together. And despite the fact that self-help families constitute the lowest incomes of participants in the section 502

portfolio, data demonstrates that these families prove to have the lowest rates of default and delinquency.

For the past 3 years, self-help housing organizations have constructed almost 3,500 homes. This construction has in turn led to more than 11,000 jobs, more than \$738 million in local income and \$77 million in taxes and revenue in rural communities across the Nation as evidenced from economic impact numbers from the National Association of Homebuilders.

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#### PREPARED STATEMENT OF THE LUMMI NATION

Mr. Chairman and subcommittee members, thank you for the opportunity to provide testimony on the fiscal year 2013 Agriculture, Rural Development, Food and Drug Administration and Related Agencies appropriations. The following are the requests and priorities of the Lummi Nation.

#### BACKGROUND INFORMATION

The Lummi Nation is located on the northern coast of Washington State, and is the third largest Tribe in Washington State serving a population of over 5,200. The Lummi Nation is a fishing Nation. We have drawn our physical and spiritual sustenance from the marine tidelands and waters for hundreds of thousands of years. Now the abundance of wild salmon is gone, and the remaining salmon stocks do not support commercial fisheries. Consequently, our fishers are trying to survive off the sale of shellfish products. In 1999 we had 700 licensed fishers who supported nearly 3,000 tribal members. Today, we have about 523 remaining. This means that over 200 small businesses in our community have gone bankrupt in the past 15 years. This is the inescapable reality the Lummi Nation fishers face without salmon. We were the last surviving society of hunters/gatherers within the contiguous United States, but we can no longer survive living by the traditional ways of our ancestors.

#### GOVERNMENT-TO-GOVERNMENT PROTOCOL

*Executive Order No. 13175.*—The United States has a unique legal and political relationship with Indian tribal governments, established through and confirmed by the Constitution of the United States, treaties, statutes, executive orders, and judicial decisions. In recognition of that special relationship, pursuant to Executive Order 13175 of November 6, 2000, executive departments and agencies (agencies) are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications, and are responsible for strengthening the government-to-government relationship between the United States and Indian tribes.

#### LUMMI SPECIFIC REQUESTS

##### *Rural Development Loan Fund*

*Tribal Financing and Access.*—It is critical that Tribal governments acquire affordable and assessable financing for infrastructure development, to build facilities that provide tribal governmental services to our member and other governmental projects. Tribes must have equitable access and the same loan eligibility criteria as counties and States. Currently, existing loan criteria is inequitable and obligates valuable Tribal financial resources that otherwise would be allocated to providing needed services to our community.

*Water Supply.*—Phase 1 funding of +\$2 million, for a new Water Supply System—Increase in funding for Hatchery construction, operation and maintenance. Funding will be directed to increase hatchery production to make up for the short-fall of wild salmon.

The Lummi Nation currently operates two salmon hatcheries that support tribal and non-tribal fishers in the region. The tribal hatchery facilities were originally constructed utilizing Federal funding from 1969–1971. Understandably most of original infrastructure needs to be repaired, replaced and/or modernized. Lummi Nation Fish Biologists estimate that these facilities are currently operating at 30 percent of their productive capacity. Through the operation of these hatcheries the Tribe annually produces 1 million fall Chinook and 2 million Coho salmon. To increase production, we must pursue a “phased approach” that addresses our water supply system first. The existing system only provides 850 GPM to our hatchery. To increase production to a level that will sustain tribal and non-tribal fisheries alike, we need to increase our water supply four-fold. A new pump station and water line will cost the Tribe approximately \$6 million. We are requesting funding for the first phase of this project. Our goal is to increase fish returns by improving

aquaculture and hatchery production and create a reliable, sustainable resource to salmon fishers by increasing enhancement.

Lummi Nation needs financial resources to develop comprehensive water resources conservation and utilization plans that accommodates the water needs of its residents, its extensive fisheries resources.

To ensure related to the removal of wild stocks from the salmon available for harvest are compensated through increased hatchery construction, operations and maintenance funding.

*Job Development.*—The Lummi Nation needs support of its comprehensive Fisherman's Cove Harbor and Working Water Front Project which addresses Indian Energy, Economic and Workforce Development needs of the Lummi Nation membership.

Unemployment on the reservation has been very difficult to address with limited on-reservation jobs. Tribal governments need to be able to meet the employment and training needs of our membership as well as the business development needs of our communities. This is the objective of the Lummi Nation Fisherman's Cove Harbor and Working Waterfront Project. We need financial assistance to enable our membership to get the job skills the local (Reservation and Non-Reservation) labor market demands. We ask the Committee to direct the Bureau to require this Office to work with the Lummi Nation to fully develop the Working Waterfront Project for the benefit of the Lummi Nation fishers, members and others invested in the marine economy of the extreme northwest corner of the United States.

*USDA—Natural Resources Conservation Service*

*Treaty Reserved Rights.*—The Lummi Nation and other western Washington tribes are in danger of losing our treaty reserved rights. At risk are our constitutionally protected treaty reserved rights to harvest salmon. Because of the diminishing salmon populations and subsequently constrained tribal harvests—all due to the inability to restore salmon habitat faster than it is currently being destroyed and limitation on hatchery production to mitigate for lost natural production. To stop this habitat degradation, we are requesting that our Federal trustee to implement their fiduciary duties by better protecting salmon habitat. By fulfilling these essential Federal obligations, it is our hope that our salmon resource—the foundation of our cultures, our economies, and our rights—will be restored. We are urging the following action:

- Require that all Federal funding for agricultural BMPs are contingent upon agreement to implement full suites of NMFS/USFWS/EPA's western Washington BMP performance standards.
- Consult with NMFS regarding the impacts of agricultural subsidy programs on western Washington salmon.
- Fund tribal riparian easement and fee simple habitat conservation acquisitions.
- Make the production of traditional tribal foods eligible for agricultural subsidy and conservation programs.

#### FAMILY AND CHILDREN WELLNESS

*Healthy, Hunger-Free Kids Act of 2010.*—Lummi Nation needs assistance to develop and implement our tribal program to take full advantage of the National School Lunch Program reimbursement by having our tribal traditional foods eligible for reimbursement/subsidy.

*Child Abuse and Neglect.*—Poverty is the primary factor in predicting incidents of child abuse and neglect. When the whole family is living in a car or a camper or in a low income house sparsely furnished house stimulation for positive mental, physical and emotional child development is absent. Poverty starts a downward spiral that is further fueled by the lack of traditional teachings, which values working together, not competing with one another. The first and most important step in reversing this trend is a job. Jobs not only change the life of the one who gets the job, but the lives of everyone in their family and positive impact to the community. The reverse is also true when jobs are lost. Over the last 10 years over 300 hundred small fishing businesses operated by members of the Lummi nation have financially failed. The people employed and families supported by these businesses are unemployed without access to unemployment insurance. Most of these people have replaced their employment with access to TANF, GA and other related income transfer programs. Lummi Nation needs financial assistance to insure that every Lummi Nation members who needs a job has access to a job.

*Domestic Violence.*—Poverty starts a downward spiral that is further fueled by the lack of traditional teachings, which values working together and not competing with one another. Domestic Violence is a function of poverty and a lack of traditional values about the most prominent difference in our lives is the difference between men

and women. Traditionally both are considered sacred functions and cannot be preempted by the other. The first and most important step in reversing this trend is a job.

*Elder Abuse.*—Lummi Nation is concerned that incidents of elder abuse have been identified in our community. The Lummi Nation is committed to identify conditions which lead to and support elder abuse and eliminating those conditions from the community. Those elders who have secured social security payments are often the only family member with cash income. As the head of a family they are looked to support others who do not have a cash income. When the available resources do not match required expenditures month after month tension builds and tragic incidents result. Lummi Nation needs financial assistance to insure that all of its members who need jobs have jobs. This is the best way to insure that our elders may live in our community without harm.

Thank you again for this opportunity to provide you with the priorities and requests of the Lummi Nation.

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#### PREPARED STATEMENT OF THE MASSACHUSETTS VEGETABLE & FLOWER GROWER

U.S. agriculture is made up of hundreds of crops of which only a dozen or so are considered major crops. The rest are referred to as minor or specialty crops and form the backbone and bloodline of our country's food supply. The commodity groups supporting this letter represent those who grow all the high quality vegetables and fruits we eat, the herbs and spices that add flavor to our lives, and the flowers and landscape plants that make America a beautiful place to live. All crops require pest control whether grown organically or conventionally. Due to cost of meeting EPA standards, which ensure all pest control compounds are safe to both human health and the environment, it is often economically unfeasible to commercialize pest control products for minor markets without public support. The limited acres on which these crops are grown do not provide the economic incentive for the private sector to register these products on our crops. Recognizing the need for the Government to assist with pest management in specialty crops, the IR-4<sup>1</sup> Project was created nearly 50 years ago to help America's specialty crop growers. The IR-4 Project is widely considered to be a model program with a history of successfully providing specialty crop growers with needed production tools and has deep support throughout the agricultural community.

We believe the IR-4 Project has become one of the most efficient, indispensable and reliable Government programs ever developed. Simply put, specialty crops cannot economically survive without the IR-4 Project. Since the IR-4 Project is so crucial to our existence, we felt great alarm and deep concern when the fiscal year 2013 President's budget proposal for the USDA National Institute Food and Agriculture (NIFA) was proposing to transfer the IR-4 budget line item (Minor Crop Pest Management in Research and Education Activities) into a proposed new Crop Protection Program which includes five integrated pest management (IPM) programs. This proposed elimination of dedicated funding for the IR-4 Project will have profound negative impacts on production costs for all specialty crops and will result in unsustainable economic losses to growers, food processors and, ultimately, the consumers.

We support the logic and financial considerations behind the proposal to consolidate five similar Integrated Pest Management Programs into the proposed Crop Protection Program. However, we believe that the Crop Protection Program is not the appropriate place to merge IR-4 due to its distinct objectives, which do not dovetail into the other IPM programs.

We offer the following reasons why we are adamantly opposed to this move:

—The five Focus Areas for the proposed Crop Protection program, as documented in the Explanatory Notes, which was submitted to Congress in the President's budget, do not include the primary IR-4 mission of "supporting the development of appropriate data to facilitate registration of sustainable pest management technologies for specialty crops and minor uses". Thus, it appears that USDA does not intend to continue to support the regulatory approvals of new crop protection chemicals and biopesticides for food and nonfood specialty crops in the proposed Crop Protection Program. We consider this change to be a serious threat to specialty crop agriculture in the United States.

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<sup>1</sup>The Friends of IR-4 is a large diversified assemblage of commodity/agricultural organizations that rely upon and support the IR-4 Project as it currently exists. For more information, go to [www.saveir-4.org](http://www.saveir-4.org).

- IR-4 is exempt from indirect cost recovery by the host land-grant universities under 7 U.S.C. 450i(e), the NIFA grant currently provided to fund IR-4. The proposed Crop Protection Program transfers funds to Integrated Activities which would allow up to 30 percent indirect cost recovery. If IR-4 is included as part of the Crop Protection program, it means a 30 percent decrease in funds available for IR-4 project. This funding decrease is a very threatening proposition for specialty agriculture and is something that we cannot accept.
- IR-4 does much more than crop protection chemical testing. IR-4 collaborates with:
  - USDA-Foreign Agricultural Service*.—To reduce the impact of pesticide residues in/on specialty crops from being a barrier of trade for U.S. grown exports.
  - Department of Defense*.—To prevent sickness/death within deployed U.S. military forces who are exposed to insect pests which transmits diseases to humans by facilitating the availability of public health pesticides.
  - USDA-APHIS*.—To perform collaborative research to combat invasive pests.
  - USEPA*.—To review IR-4 submitted data to help with their priorities to provide new technology to reduce the risk from pesticides.
  - Department of Commerce/OMB*.—IR-4 is involved in a critical project supporting the U.S.-Canada agreement to accomplish key objectives of the Regulatory Cooperation Council.
- IR-4 food residue research often takes 3 to 5 years to complete, involves highly trained staff that are proficient with USEPA's Good Laboratory Practices regulations, and requires expensive analytical instruments. This is vastly different from NIFA's typical research grants. Restructuring or eliminating IR-4 and abandoning numerous ongoing studies would be extremely expensive and a waste of already appropriated taxpayer money.
- Investment in IR-4 has yielded a huge return on investment. Since its inception, IR-4 has facilitated the registration of over 25,000 crop uses. The Michigan State University Center for Economic Analysis (Dec. 2011) determined that for a total budget of \$18 million (USDANIFA and other public/private sources), IR-4 efforts contribute over \$7.2 billion to annual U.S. Gross Domestic Product and supports 104,650 U.S. jobs.

These comments are on behalf of the 88 undersigned commodity associations/grower groups who represent American specialty agriculture. Collectively, we represent growers with operations in almost every congressional district of every State. Our operations are a huge driver in American agriculture; the farm gate value of specialty crops is over \$67 billion annually. For more information on this topic please see: [www.saveir-4.org](http://www.saveir-4.org).

In summary, the proposed consolidation of the IR-4 Project into the Crop Protection Program significantly hurts growers of food and non-food specialty crops and our food systems. It will lead to higher prices for the food that enhances health, and plants that enhance the environment. Consolidating IR-4 with the proposed Crop Protection Program will substantially increase costs to the taxpayer or result in a much smaller program providing significantly less service to American growers and ultimately the American public. We urge the Senate Appropriations Committee Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies to continue to dedicate at least \$12 million net dollars for Minor Crop Pest Management (IR-4) in fiscal year 2013 USDA-NIFA Research and Education Activities. Simply put, the United States specialty crop growers ask Congress to let the IR-4 Project continue to do the excellent job it has done for the past 49 years.

The following commodity associations/grower groups support the above written testimony:

(WHILE LOOKING AT THIS LIST, CONSIDER THE BREADTH OF CROPS, REGIONS AND STATES REPRESENTED)

Ag Matters, LLC	California Garlic and Onion Research
American Farm Bureau Federation	Advisory Board
American Mushroom Institute	Cherry Marketing Institute, Inc.
American Nursery & Landscape Association	Center for Applied Horticultural Research
Ball Horticultural Company	Cranberry Institute
California Apple Commission	Dill Growers of Oregon and Washington
California Asparagus Commission	Engage Agro USA
California Blueberry Commission	Essex County Fruit Growers
	Florida Blueberry Growers Association

Florida Fruit and Vegetable Association	New England Vegetable & Berry Growers Association
Florida Strawberry Growers Association	North American Blueberry Council
Ginseng board of Wisconsin	North American Greenhouse/Hothouse Vegetable Growers Association
Great Lakes IPM, Inc.	North American Strawberry Growers Association
Hawleys Florist	North California Garlic & Onions Growers
Hoogasian Flowers, Inc.	North Carolina Blueberry Council
Hop Growers of Washington, Inc.	North Carolina Nursery & Landscape Association
Hop Growers of American, Inc.	North Carolina Strawberry Association
Idaho Grain Producers Association	Oregon Blueberry Commission
Idaho Hop Commission	Oregon Essential Oil Growers League
Idaho Hop Growers Association	Oregon Fine Fescue Commission
Idaho Sugar Beet Growers Association, Inc.	Oregon Hop Commission
Iwasaki Bros, Inc.	Oregon Mint Commission
Kona Perfect Estate Grown Coffee	Oregon Ryegrass Commission
Lavender Growers of Oregon	Oregon Seed Council
Maine Vegetable & Small Fruit Growers Association	Oregon Tall Fescue Commission
Massachusetts Fruit Growers Association	Pacific Northwest Christmas Tree Association
MGB Marketing	Pacific Northwest Vegetable Association
Meister Media Worldwide-Publisher of:	Pickle Packers International
American Western Fruit Grower	Rudd Farm
American Vegetable Grower	Society of American Florists
Florida Grower	Texas Citrus Mutual
Greenhouse Grower	Texas Vegetable Association
CropLife	Tulelake Growers Association Mint Research Advisory Committee
Michigan Asparagus Advisory Board	U.S. Apple Association
Michigan Cherry Committee	U.S. Dry Pea & Lentil Council
Michigan Mint Growers Association	U.S. Hop Industry Plant Protection Committee
Minor Crop Farmers Alliance	Washington Asparagus Commission
Mint Industry Research Council	Washington Blueberry Commission
Montana Mint Committee	Washington Hop Commission
Nash Produce	Washington Mint Growers Association
National Asparagus Council	Washington Red Raspberry Commission
National Barley Growers Association	Washington State Commission on Pesticide Registration
National Greenhouse Manufacturers Association	Western Alfalfa Seed Growers Association
National Onion Association	Wisconsin Mint Industry
National Potato Council	Wisconsin Muck Farmers Association
National Watermelon Growers Association	
NC Commercial Blackberry & Raspberry Growers Association	
NC Pickles Packers Association	
NH Vegetable & Small Fruit Growers Association	

PREPARED STATEMENT OF THE METROPOLITAN WATER DISTRICT OF SOUTHERN CALIFORNIA

The Metropolitan Water District of Southern California (Metropolitan) encourages the Subcommittee's support for fiscal year 2013 Federal funding of about \$18 million from the U.S. Department of Agriculture's Environmental Quality Incentives Program for the Colorado River Basin Salinity Control Program.

The concentrations of salts in the Colorado River cause approximately \$300 million in quantified damages in the lower Colorado River Basin States each year and significantly more in unquantified damages. Salinity concentrations of Colorado River water are lower than at the beginning of Program activities by over 100 milligrams per liter (mg/L). Modeling by the U.S. Bureau of Reclamation indicates that the quantifiable damages would rise to more than \$500 million by the year 2030 without continuation of the Colorado River Basin Salinity Control Program (Program).

Water imported via the Colorado River Aqueduct has the highest level of salinity of all of Metropolitan's sources of supply, averaging around 630 mg/L since 1976, which leads to economic damages. For example, 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 cost of cooling operations, and the cost of water softening, and a decrease in equipment service life in the commercial 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 fewer opportunities for recycling due to groundwater quality deterioration; and
- Increased use of imported water for leaching and the cost of desalination and brine disposal for recycled water.

Concern over salinity levels in the Colorado River has existed for many years. To deal with the concern, the International Boundary and Water Commission approved Minute No. 242, Permanent and Definitive Solution to the International Problem of the Salinity of the Colorado River in 1973, and the President signed into law the Colorado River Basin Salinity Control Act in 1974 (Act). High total dissolved solids in the Colorado River as it enters Mexico and the concerns of the seven Colorado River Basin States regarding the quality of Colorado River water in the United States drove these initial actions. To foster interstate cooperation and coordinate the Colorado River Basin States' efforts on salinity control, the seven Basin States formed the Colorado River Basin Salinity Control Forum.

The salts in the Colorado River system are indigenous and pervasive, mostly resulting from saline sediments in the Basin that were deposited in prehistoric marine environments. They are easily eroded, dissolved, and transported into the river system, and enter the River through both natural and anthropogenic sources.

The Program reduces salinity by preventing salts from dissolving and mixing with the river's flow. Irrigation improvements (sprinklers, gated pipe, lined ditches) and vegetation management reduce the amount of salt transported to the Colorado River. Point sources such as saline springs are also controlled. The Federal Government, Basin States, and contract participants spend over \$40 million annually on salinity control programs.

The Program, as set forth in the act, benefits both the Upper Colorado River Basin water users through more efficient water management and the Lower Basin water users, hundreds of miles downstream from salt sources in the Upper Basin, through reduced salinity concentration of Colorado River water. California's Colorado River water users are presently suffering economic damages in the hundreds of millions of dollars per year due to the river's salinity.

These Federal dollars will be augmented by the State cost sharing of 30 percent with an additional 25 percent provided by the agricultural producers with whom the U.S. Department of Agriculture contracts for implementation of salinity control measures. Over the past years, the Colorado River Basin Salinity Control program has proven to be a very cost effective approach to help mitigate the impacts of increased salinity in the Colorado River. Continued Federal funding of this important Basin-wide program is essential.

Metropolitan urges the Subcommittee to support funding for fiscal year 2013 of about \$18 million from the U.S. Department of Agriculture's Environmental Quality Incentives Program for the Colorado River Basin Salinity Control Program.

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PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

The National Association of County and City Health Officials (NACCHO) is the voice of the approximately 2,800 local health departments across the country. City, county, metropolitan, district, and tribal health departments work every day to ensure the safety of the water we drink, the food we eat, and the air we breathe. Local health departments work with State, local, and national partners to prevent, identify, and respond to outbreaks of foodborne illness.

The Nation's current financial challenges are compounded by those in State and local governments further diminishing the ability of local health departments to address community health and safety needs. Repeated rounds of budget cuts and layoffs continue to erode local health department capacity. NACCHO surveys have found that since 2008, local and State health departments have lost 52,000 jobs due to budget reductions. In the area of food safety, that means there are fewer inspec-

tors and trained food safety and food service professionals—from restaurants and school cafeteria workers to street fair vendors—able to identify risks and prevent foodborne illness.

Local health departments have wide ranging responsibilities including measuring population-wide illness and organizing efforts to prevent disease and prolong quality of life. In the area of food safety, local health department responsibilities are focused on preventing foodborne illness and investigating the cause and spread of illness. Local health departments represent two-thirds 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.

Despite the best efforts of public officials, over 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. Foodborne illness causes an estimated 128,000 hospital visits and 3,000 deaths annually. Foodborne illness has significant costs associated with direct medical expenses, lost productivity, and decreased revenue for food manufacturers and retail establishments. Salmonella, which causes 1 million cases of foodborne illness, costs \$365 million a year in direct medical expenses. The 2009 salmonella outbreak saw a double digit decline in the amount of peanut products purchased.

In 2011, the United States experienced the deadliest foodborne illness outbreak in 90 years, an outbreak of listeria in cantaloupe that killed 32 people and infected 146 people in 28 States. This outbreak was quickly contained and the loss of life limited because of coordinated action between local, State and Federal public health agencies, including local and State health departments.

Local health departments are on the front lines conducting food safety inspections and have the expertise to educate food handlers in their communities. Local health departments inspect restaurants, grocery stores, daycare facilities, hospitals, schools, and some food manufacturing plants to ensure safe food handling practices and sanitary conditions. Local health departments investigate citizen complaints and when necessary, will take action to ensure that a food establishment complies with sanitation standards.

In 2010, Congress passed the Food Safety Modernization Act (FSMA), which recognized the importance of protecting the public from foodborne illness and the need to strengthen our current system for prevention of these costly illnesses. In the 21st century, our global food supply system is more complex than ever before and has an increased risk of accidental or intentional contamination. In FSMA, the Federal Government made a commitment to foster coordination and increase capacity at the local, State and Federal level to prevent and respond to foodborne illness. The return on Federal investment in food safety training, surveillance and investigation capacity can be measured in improved health and lower health care costs and lost productivity. In fiscal year 2012, Congress made a down payment on the implementation of FSMA by providing \$39 million. NACCHO recommends Congress take further steps in fiscal year 2013 to fully implement FSMA and fund the Food and Drug Administration's food safety programs as outlined below.

FOOD AND DRUG ADMINISTRATION—CENTER FOR SAFETY AND APPLIED NUTRITION

*NACCHO Request: \$1.0 Billion*

*President's Fiscal Year 2013 Budget: \$1.0 Billion*

*Fiscal Year 2012: \$883 Million*

FDA's Center for Safety and Applied Nutrition (CFSAN) supports partnerships at the local, State and Federal level to protect consumers from, and quickly respond to and track, foodborne illness outbreaks. CFSAN also oversees the food safety training program which helps to maintain uniform standards in food inspection and the retail food safety initiative which provides best practices for retail food handlers.

A national food safety training system, including a certification system, will ensure that officials at all levels of government have consistent, up-to-date knowledge, as well as the necessary skills, to do their jobs. Without a robust national training system, there is less capacity to consistently and continuously improve knowledge and skills based on the latest science and risk assessments. It is crucial that regulators and public health partners have the appropriate knowledge and training to carry out their duties to safeguard the public from foodborne illness. Food safety training requires continued funding to increase capacity and adequately train our Nation's food protection workers.

FDA's dedicated retail food safety initiative supports research and distribution of technologies that prevent, mitigate, or detect foodborne illness hazards in the retail environment. FDA resources allow local health departments to learn about and

adopt best practices for prevention of foodborne illness in the retail setting and to utilize products developed by FDA to educate the public and food service workers in their communities.

As you draft the fiscal year 2013 Agriculture-Rural Development—FDA Appropriations bill, we urge consideration of these recommendations for FDA programs that are critical to ensuring the safety of our Nation's food supply and protecting our Nation's people.

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PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE ENERGY OFFICIALS

Chairman Kohl and Ranking Member Blunt, I am David Terry, Executive Director of the National Association of State Energy Officials (NASEO) (dterry@naseo.org), and I am testifying in support of funding for the energy title of the farm bill. Specifically, we support funding of at least \$39 million in discretionary funds for the Rural Energy for America (REAP) program (Section 9007 of the farm bill), in addition to any mandatory funding. The REAP program was created in the 2002 farm bill and it has been a huge success. Over 9,600 energy efficiency and renewable energy projects have been implemented in every State since 2003. With a required \$3 match of non-Federal funds for every Federal dollar invested in REAP, over \$1.6 billion in matching funds have been provided. This program has specifically benefitted farmers, ranchers and rural small businesses. NASEO members work directly with eligible entities, as well as State agricultural agencies and rural interests to promote this successful program. Rising oil and distillate prices have made this program even more important.

NASEO represents the energy offices in the States, territories and the District of Columbia. The REAP program, and the other critical programs in the energy title of the farm bill, helps create jobs, increases agricultural productivity, saves energy for farmers, ranchers and rural small businesses, generates energy, promotes use of alternative fuels, reduces our dependence on imported petroleum and saves money in rural America. The cost is very low and the payback is very high. REAP is about rural economic development.

We urge your support for the REAP program.

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PREPARED STATEMENT OF THE NATIONAL COMMODITY SUPPLEMENTAL FOOD PROGRAM ASSOCIATION

Mister Chairman and Subcommittee members, thank you for this opportunity to present information regarding the USDA/FNS Commodity Supplemental Food Program (CSFP).

The National Commodity Supplemental Food Program Association (NCSFPA) requests the Senate Agriculture Appropriations Subcommittee fund CSFP for fiscal year 2013 at \$191,935,000; \$186,935,000 as requested by the U.S. Department of Agriculture, an additional \$5 million to begin CSFP operations in six States (Connecticut, Hawaii, Idaho, Maryland, Massachusetts, and Rhode Island) with USDA-approved plans. Additionally, the subcommittee should note that current States requested approximately 116,350 additional slots to meet the rising demand for nutritional assistance among our vulnerable senior population.

CSFP is a unique program because it brings together Federal and State agencies, along with public and private entities. In fiscal year 2011, 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).

In fiscal year 2011, 97 percent of all CSFP recipients were low-income seniors. Our association has proposed as part of the next farm bill fully converting the program into a seniors-only program, allowing sufficient time for those mothers and children to transition off CSFP.

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 for effective access to these supplemental foods as well as 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.

CSFP continues to be a testimony to the power of community partnerships between faith-based organizations, farmers, private industry and Government agencies. The CSFP offers a unique combination of advantages that are unparalleled by any other food assistance program:

- The CSFP specifically targets one of our Nation's most nutritionally vulnerable populations: low-income seniors (but association is suggesting that this becomes senior-only project, so don't mention children?).
- The CSFP provides a monthly selection of food packages tailored to the specific nutritional needs of seniors. 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 or extra light syrup, and low-salt canned vegetables.
- The CSFP purchases foods at wholesale prices, directly supporting American farmers. The average cost of a CSFP food package is estimated at \$19.85 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 the most recent CSFP survey, more than 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 that it is a cost-effective way of providing nutritious supplemental foods. While USDA's budget request will provide adequate resources for our monthly caseload of 599,380 seniors, mothers, and children—a reduction from the 604,931 packages USDA was able to support in fiscal year 2011—we urge the Subcommittee to strongly consider our request for increased funding to allow six additional States to begin providing nutritional assistance to their vulnerable seniors.

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".

According to the 1997 report by the National Policy and Resource Center on Nutrition and Aging at Florida International University, Miami—Elder Insecurities: Poverty, Hunger, and Malnutrition, 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.

CSFP recipients believe this is a very significant and vital program; our belief is supported by agency and recipient testimonials. An Arkansas recipient tells us that they would not be able to eat the balanced meals that CSFP provides each month. Arkansas program operators talk about the importance of interaction between seniors and program staff, saying this interaction is very important for the well-being of recipients, and recipients are able to live more stable, self-sufficient lives as a result. Colorado participants say that they would not be able to have juice and cereal without CSFP, and many appreciate the program because they are homebound, and that there are 100 clients on the waiting list in El Paso County. Seniors in St. Louis, Missouri, say that CSFP foods help them get through to their next checks. Participants in Nebraska say that they don't know what they would do without this food, calling the program a "lifesaver". New Hampshire participants tell us that they use CSFP as a primary source of nutrition each month and would see a dramatic loss in food availability without the program. One Wisconsin recipient said that they would starve without the program, while others said that CSFP on their limited income meant that they could pay their telephone and electric bills.

These anecdotes represent just a small portion of those affected, but it highlights the deep and rising need we are seeing in communities across the country. Whether urban, suburban, or rural—we have seen dramatic rises in the demand from the community—and have become more limited in available resources. With an ever-growing senior population living on fixed incomes, there has never been a more pressing time to fund this vital program.

The CSFP is supported by 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 Department of Agriculture for their continued innovations to strengthen the quality of the food package and streamline administration.

PREPARED STATEMENT OF THE NATIONAL ORGANIC COALITION

Chairman Kohl, Ranking Member Blunt, and Members of the Subcommittee: My name is Steven Etka. I am submitting this testimony on behalf of the National Organic Coalition (NOC) to detail our fiscal year 2013 funding requests for USDA programs of importance to organic agriculture.

The NOC is a national alliance of organizations working to provide a voice for farmers, environmentalists, consumers, cooperative retailers and others involved in organic agriculture. The current members of NOC are the Beyond Pesticides, Center for Food Safety, Equal Exchange, Food and Water Watch, Maine Organic Farmers and Gardeners Association, Midwest Organic and Sustainable Education Service, National Cooperative Grocers Association, Northeast Organic Dairy Producers Alliance, Northeast Organic Farming Association–Interstate Policy Council, Organically Grown Company, Organic Seed Alliance, Rural Advancement Foundation International–USA, and the Union of Concerned Scientists.

USDA/AGRICULTURAL MARKETING SERVICE (AMS)

*National Organic Program*

*Request: 9.896 Million*

Sales of organic food and beverages have experienced a rapid growth over the last decade, averaging nearly 20 percent per year. Despite the recession, organic sales grew at a rate of 5 percent in 2009 and 8 percent in 2010. In 2011, the organic sector experienced a 9.5 percent growth rate. The National Organic Program (NOP) is the agency charged with regulating and enforcing the USDA organic label. For years, the rapid growth of the organic industry has far outpaced the resources provided to the NOP, which has greatly limited the ability of NOP to fulfill its regulatory and enforcement role credibly.

Fortunately, both Congress and the Administration responded with an increase in funding in fiscal years 2009 and 2010 to meet these needs. In the final fiscal year 2011 Continuing Resolution cuts were made to AMS overall, and funding levels for individual AMS programs were left to the discretion of the agency. The resulting NOP funding level for fiscal year 2011 is \$6.919 million.

We are requesting for \$9.896 million for the NOP, which is the same level requested by the Administration's fiscal year 2012 budget, representing an increase of \$2.98 million over current levels. The Administration's fiscal year 2013 level-funding request for NOP does not adequately address the needs of this rapidly growing sector. Increased funding is needed to accelerate the review and amendment of program standards and regulations to reflect industry and consumer expectations through a transparent and participatory process; improve the consistency in certifier application of the standards; and improve timeliness and effectiveness of enforcement actions to protect organic integrity.

USDA (AMS, ERS, NASS)

*Organic Data Initiative*

*Request: \$300,000 for AMS Price Report; Report Language for NASS Organic Production Survey, and ERS Organic Data Analysis*

Authorized by Section 7407 of the 2002 Farm Bill, the Organic Production and Marketing Data Initiative states that the "Secretary shall ensure that segregated data on the production and marketing of organic agricultural products is included in the ongoing baseline of data collection regarding agricultural production and marketing." Section 10302 of the Farm, Conservation, and Energy Act of 2008 amends the provision to provide mandatory funding, and to authorize \$5 million annually in discretionary funding.

As the organic industry matures and grows at a rapid rate, the lack of national data for the production, pricing, and marketing of organic products has been an impediment to further development of the industry and to the effective functioning of many organic programs within USDA. The organic data collection and analysis effort at USDA has made significant strides in recent years, but remains in its in-

fancy. Because of the multi-agency nature of data collection within USDA, organic data collection and analysis must also be undertaken by several different agencies within the Department.

In 2008, NASS conducted the first-ever comprehensive Organic Production Survey as a follow-on survey to the 2007 Census of Agriculture. Published in February 2010, the survey has provided information vital to the organic sector's growth and to the U.S. Department of Agriculture. The Organic Production Survey should be conducted on a regular basis to properly assess the characteristics, trends, and changes in the sector.

The Administration's fiscal year 2013 budget proposes to address organic data collection needs within the overall budget request for the data collection agencies. However, we are requesting that report language be included in the fiscal year 2013 report to clearly specify the organic data collection efforts within AMS, ERS and NASS. Specifically, we are requesting report language identifying \$300,000 for AMS organic price reporting, level with fiscal year 2012 funding. In addition, we are requesting report language urging NASS to undertake the necessary planning to conduct an Organic Production Survey on an on-going 5-year cycle, as a follow-on survey to the Census of Agriculture, starting in 2013; and for ERS to continue its organic data analysis efforts.

USDA/NATIONAL INSTITUTE OF FOOD AND AGRICULTURE (NIFA)

*Organic Transitions Program*

*Request: \$5 Million*

The Organic Transition Program, authorized by Section 406 of the Agricultural Research, Education and Extension Reform Act (AREERA) for Integrated Research Programs, is a research grant program that helps farmers surmount some of the challenges of organic production and marketing. As the organic industry grows, the demand for research on organic agriculture is experiencing significant growth as well. The benefits of this research are far-reaching, with broad applications to all sectors of agriculture, even beyond the organic sector. Yet funding for organic research is minuscule in relation to the relative economic importance of organic agriculture and marketing in this Nation.

The Organic Transition Program was funded at levels ranging between \$2.1 and \$1.8 million during the period of fiscal year 2003 through fiscal year 2009, received an increase to \$5 million in fiscal years 2010, and \$4 million in fiscal years 2011 and 2012. The Administration's fiscal year 2013 budget requested level funding. We are requesting \$5 million to restore the program to its fiscal year 2010 level.

*Agriculture and Food Research Initiative (AFRI)*

*Request: Report language on Conventional/Classical Plant and Animal Breeding*

In recent decades, public resources for classical plant and animal breeding have dwindled, while resources have shifted toward genomics and biotechnology, with a focus on a limited set of major crops and breeds. This problem has been particularly acute for organic and sustainable farmers, who seek access to germplasm well suited to their unique cropping systems and their local environment.

Since fiscal year 2005, the Senate Agriculture Appropriations Subcommittee has included report language raising concerns about this problem, and urging CSREES (now NIFA) to give greater consideration to research needs related to classical plant and animal breeding when setting priorities within the National Research Initiative (now AFRI).

In Section 7406 of the Food, Conservation, and Energy Act of 2008, the National Research Initiative was merged with the Initiative for Future Agriculture and Food Systems to become the Agriculture and Food Research Initiative (AFRI). Congress included language within AFRI to make "conventional" plant and animal breeding a priority for AFRI research grants, consistent with the concerns expressed by the Appropriations Committee in preceding appropriations cycles.

Despite the many years of Senate report language and the 2008 Farm Bill language on this matter, research proposals for classical breeding that have sought AFRI funding in recent years have been consistently denied. Of the 127 AFRI-funded projects in 2009, 2010, and 2011 related to plant breeding and genomics, there was only one project that could truly be classified as classical breeding, which was a 2010 grant to Kansas State University for \$210,000. Of the 59 AFRI-funded projects in animal breeding, fertility and genomics, there appear to be no classical animal breeding projects funded at all.

It is becoming clear that unless a separate AFRI subgrant category dedicated to classical plant and animal breeding and the development of public cultivars is created, the 2008 Farm Bill classical breeding requirement and concerns stated in years of Senate report language will not be adequately addressed.

We are requesting strong report language from the Subcommittee to reiterate that the funding for classical plant and animal breeding and public cultivar development should be a priority area within the AFRI program, and urging that a separate and distinct RFA be created within AFRI to address this critical need. Specifically, we are requesting the following report language in the AFRI section of the Committee report:

The Committee believes that funding for classical plant and animal breeding that results in finished public cultivars and breeds should be a priority area within the AFRI program, and urges the agency to create a separate and distinct RFA within AFRI to address this critical need.

*Sustainable Agriculture Research and Education (SARE)*

*Request: \$30 Million (\$18 Million for Research and Education Grants, \$7 Million for the Federal-State Matching Grant Program, and \$5 Million for Extension and Outreach Grants)*

The SARE program has been very successful in funding on-farm research on environmentally sound and profitable practices and systems, including organic production. The reliable information developed and distributed through SARE grants have been invaluable to organic farmers. The President's budget requests \$22.7 million for SARE program for fiscal year 2013, including \$3.5 million to start the Federal-State Matching Grant program. We are requesting \$18 million for research and education grants, \$7 million for Federal-State Matching Grant program, and \$5 million for extension and outreach.

USDA/RURAL BUSINESS COOPERATIVE SERVICE

*Appropriate Technology Transfer for Rural Areas (ATTRA)*

*Request: \$3 Million*

ATTRA, authorized by Section 6016 on the Food, Conservation, and Energy Act of 2008, is a national sustainable agriculture information service, which provides practical information and technical assistance to farmers, ranchers, Extension agents, educators and others interested and active in sustainable agriculture. ATTRA interacts with the public, not only through its call-in service and website, but also provides numerous excellent publications written to help address some of the most frequently asked questions of farmers and educators. Much of the real-world information provided by ATTRA is extremely helpful to both the conventional and organic communities, and is available nowhere else. As a result, the growth in demand for ATTRA services has increased significantly, both through the website-based information services and through the growing requests for workshops.

Funding for ATTRA was completely eliminated in the fiscal year 2011 Continuing Resolution, greatly jeopardizing information transfer to farmers seeking the most up-to-date scientific and practical information about sustainable farmers systems, but was funded at \$2.25 million in fiscal year 2012. The President's fiscal year 2013 budget requests level funding (\$2.25 million) for ATTRA. We are requesting \$3 million for fiscal year 2013, to help meet the growing demand from farmers for up-to-date, science-based information.

USDA/AGRICULTURE RESEARCH SERVICE (ARS)

*Classical Plant and Animal Breeding Activities*

*Request: \$9.03 Million*

As noted above in the AFRI section of this request, public resources for classical plant and animal breeding have dwindled in recent decades, and as a result, our capacity for public breeding is at a critical point. While USDA's statutory obligation to address this problem through the AFRI competitive grant program remains strong, ARS also has an obligation in this regard. Although ARS has the resources and expertise to help reverse this dangerous trend, the agency has not made a concerted effort in this regard.

We are requesting \$9 million for ARS classical plant and animal breeding efforts, to be utilized in a manner similar to that described in the Administration's fiscal year 2011 budget request (pages 16-19 and 16-29 of USDA's fiscal year 2011 Budget Justification document), which called for an increase of \$4.289 million for "crop breeding to enhance food and production security" and other \$4.75 million for "crop

protection to enhance food and production security,” with a clear focus on classical plant and animal breeding activities. With the change in leadership at USDA, the Administration’s fiscal year 2012 and 2013 requests for ARS have failed to reiterate this request. However, we believe the fiscal year 2011 ARS request for this research was well stated, and urge the Subcommittee to provide funding for this critical ARS activity.

Thank you for your consideration of these fiscal year 2013 funding priorities. We look forward to working with the Subcommittee throughout this year’s appropriations process.

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PREPARED STATEMENT OF THE NATIONAL RURAL HOUSING COALITION

On behalf of the National Rural Housing Coalition (NRHC), I would like to thank the Subcommittee for the opportunity to submit testimony on fiscal year 2013 appropriations for Department of Agriculture (USDA) Rural Housing Programs. I strongly urge this Subcommittee to fund USDA Rural Housing programs at the higher of fiscal year 2012 levels or the President’s fiscal year 2013 budget request: (1) \$900 million for Section 502 Family Direct Homeownership Loans; (2) \$28 million for Section 504 Very-Low Income Rural Housing Repair Loans; (3) \$29.5 million for Section 504 Very-Low Income Rural Housing Repair Grants; (4) \$26 million for Section 514 Farm Labor Housing Program Loans; (5) \$9 million for Section 516 Farm Labor Housing Program Grants; (6) \$64.5 million for Section 515 Rural Rental Housing Program; (7) \$907 million for Section 521 Multi-Family Rental Housing Rental Assistance Program; (8) \$30 million for Section 523 Self-Help Housing Program; (9) \$3.6 million for Section 533 Housing Preservation Grants Program; (10) \$150 million for Section 538 Guaranteed Multi-Family Housing Loans; (11) \$46.9 million for the Multi-Family Housing Preservation and Revitalization Program; and (12) \$13 million for the Rural Community Development Initiative.

NRHC is a national membership organization consisting of housing developers, nonprofit housing organizations, State and local officials, and housing advocates. Since 1969, NRHC has promoted and defended the principle that rural people have the right, regardless of income, to a decent, affordable place to live, clean water, and basic community services.

*Housing Needs in Rural America*

Even in strong economic times, the needs of rural America are too often overlooked. And, although our most recent economic crisis pushed these many of these communities to the brink, their needs continue to be neglected by the mainstream media, traditional sources of capital, and Federal policymakers. For example, although nearly 20 percent of the population lives in rural communities, other Federal agencies consistently overlook their unique housing needs; less than 7 percent of the Federal Housing Administration assistance, 10 percent of Veterans Affairs programs, and 12 percent of Section 8 Rental Assistance serves rural areas.

Rural communities have severe housing and development needs. With some of the Nation’s lowest incomes, rural communities are four times more likely to have at least 20 percent of their population living in poverty. About 98 percent of “consistently poor counties” are rural, as are nearly all communities with inadequate drinking water. As a result, rural families are far more likely to live in substandard housing or be overburden by rent. Housing in rural America is simply too expensive relative to household income, overcrowded, or lacks certain basic facilities.

Despite the overwhelming need for safe, clean, and affordable housing in rural America, Congress has consistently cut funding for the very programs specifically tailored to meet this need. And now, President Obama has proposed significant cuts to the Section 502 Direct Loan and Self-Help Housing programs, and the elimination of the Section 515 Rural Rental Housing program. Because these programs overwhelmingly serve our most vulnerable residents—lower income families, the elderly, and persons with disabilities, these cuts will only make it harder for low-income, rural Americans to access safe, decent, affordable housing. As such, I would like to focus my testimony on how these programs are critical to meeting the needs of rural families.

*Section 502 Single-Family Direct Homeownership Loans*

Over 60 years, the Section 502 Direct Loan Program has helped more than 2.1 million families realize the American Dream and build their wealth by more than \$40 billion. Despite the program’s success, demand for Section 502 loans continues to outpace supply. Over 25,000 loan applications—amounting to more than \$2 billion—are currently on Section 502 waiting lists.

No other Federal home ownership program can match the profile of the families served under Section 502. It is the only Federal homeownership program that is exclusively targeted to very low- and low-income rural families. By law, at least 40 percent of Section 502 funds must be used to assist families earning less than 50 percent of the area median income. Two-thirds borrowers have incomes less than 60 percent of AMI, with an average income less than \$27,000.

Despite serving families with limited economic means, Section 502 is the single, most cost-effective Federal housing program, period. On average, each Section 502 loan costs less than \$7,200 over its entire lifetime. Compare that to the average Section 8 Housing Assistance payment, which costs taxpayers nearly \$7,000 each year.

Although some have suggested that the Section 502 Guarantee Program can serve as an adequate alternative, this is simply untrue. Unlike the Direct Loan program, the Guarantee program overwhelmingly serves higher-income individuals—with an average income of nearly twice that of Direct Loan families—leaving rural communities with the greatest credit needs without any alternative. Even the USDA has held that the guarantee program is the worst-targeted of all its rural development guarantees, with loans going to larger, wealthier communities. Likewise, the guarantee program does not provide interest rate subsidies. This defect will become even more harmful when interest rates return to normal levels.

#### *Section 523 Mutual Self-Help Housing*

The Self-Help Housing program adapts the rural tradition of barn-raising to provide housing opportunities for families with limited economic means. Through this program, more than 3,500 families have been able to realize the American Dream in the past 3 years. This construction has led to over 11,000 jobs, more than \$738 million in local income and \$77 million in taxes and revenue in rural communities across the country. If the President's budget is approved by Congress, Self-Help Housing will be cut to its lowest funding in more than 30 years, decimating the network of over 100 Self-Help organizations over 37 States and deserting 50,000 families currently on their waiting lists.

Self-Help Housing is the only Federal program that combines “sweat equity” homeownership opportunities with technical assistance and affordable loans for America's rural families. Self-Help Housing families work nights and weekends to provide 65 percent of the construction labor on their own and each other's homes. In doing so, families earn equity, decrease construction costs, and make lasting investments in their community. The hallmark of the Self-Help Housing program is its emphasis on hard work, self-reliance, and community.

This program is exclusively targeted to very low- and low-income families who are otherwise unable to access decent housing. Over half of the participants are minorities. Although these families have lower incomes, default rates are significantly lower than other borrowers. Section 515 Rural Rental Housing

Section 515 is the principal source of financing for rental housing in rural communities. Today, more than 500,000 families live in housing financed by Section 515. If approved by Congress, the President's budget will end a 40-year effort to improve the quality of rural housing, leaving seniors, low-income families, and those with disabilities even more vulnerable.

Rental units developed with Section 515 loans are exclusively targeted to very low-, low-, and moderate-income families, the elderly, and persons with disabilities. A vast majority—94 percent—of Section 515 tenants have very-low incomes. The average yearly income is only \$11,000. Some 57 percent these households are elderly or disabled, 26 percent are headed by persons of color, and 73 percent are headed by women.

Demand for affordable, rural rental housing continues to outpace supply. More than 7.8 million rural residents—including 19 percent of all rural children—live in poverty. Almost 1 million rural renters live in substandard housing. Yet, despite its success and increased demand, Section 515 funding has been cut drastically, stalling the production of new units and the preservation of existing ones.

#### *Conclusion*

Providing adequate funding for USDA Rural Housing programs is essential to efforts to improve the quality of life and economic opportunity in rural America. These programs are all part of the toolbox that USDA employs address the shortfall in decent, clean, and affordable housing in these communities. For a very small fraction of the USDA's budget, Congress can provide affordable rental and homeownership opportunities to thousands of rural families with limited means and boost flagging economies in small communities.

Thank you for this opportunity to submit this statement.

## PREPARED STATEMENT OF THE NATIONAL SUSTAINABLE AGRICULTURE COALITION

Thank you for the opportunity to present our fiscal year 2013 funding requests. NSAC is a national alliance of over 90 organizations that advocates for policies that support the economic, social, and environmental sustainability of agriculture, natural resources, and rural communities. Our USDA requests are as follows, in the order they appear in the appropriations bill.

*Departmental Administration*

*Office of Advocacy and Outreach.*—The Office of Advocacy and Outreach coordinates policy and outreach in two vital areas—small and beginning farmers, and socially disadvantaged or minority farmers. It administers the Outreach and Technical Assistance for Socially Disadvantaged Farmers and Ranchers program and the Farm Labor Grants program. We support USDA's request for \$1.4 million for the OA&O.

*National Institute of Food and Agriculture*

*Sustainable Agriculture Research and Education Program (SARE).*—We urge you to fund this innovative competitive grants program at \$30 million, divided among research and education grants (\$18 million), extension and professional development grants (\$5 million), and Federal-State matching grants (\$7 million). SARE has helped turn farmer-driven research, education, and extension initiatives into profitable and environmentally sound practices for over 20 years.

*Organic Transitions Integrated Research Program.*—We request \$5 million to maintain the funding level established in fiscal year 2010 and in USDA's fiscal year 2012 request. Maintaining the fiscal year 2010 funding level will allow cooperation with natural resource programs to provide environmental solutions with strong farmer delivery mechanisms built in. Without full funding, organic research will fall further behind in its fair share of the research budget, a share that continues to lag behind trends in agriculture.

*National Food Safety Training, Education, Extension, Outreach, and Technical Assistance.*—We request \$10 million to help small and mid size farms and small processing facilities comply with new food safety regulations. This food safety training for farmers and small processors, authorized in the Food Safety Modernization Act of 2010, is one of the best, quickest, and least costly ways to improve food safety outcomes without resorting to excessive regulation.

*Agricultural Marketing Service*

*Federal-State Market Improvement Program (FSMIP).*—The FSMIP provides matching funds to State departments of agriculture to help grantees increase marketing efficiency and innovation, reduce costs, stabilize food prices, and support local and regional food marketing opportunities. NSAC supports the USDA request of \$1.3 million.

*Organic Market Reporting.*—NSAC requests level funding at \$0.3 million for AMS for this price data collection and reporting initiative. As the organic industry surpasses \$30 billion a year in sales, this multi-agency initiative is vital to maintaining markets, creating risk management tools, and negotiating equivalency agreements with foreign governments. We also support baseline funding for NASS and ERS to continue coordinated data collection and reporting on organic production, marketing, and pricing, including NASS funding for the Organic Production Survey.

*Farm Service Agency*

*Direct Farm Ownership and Operating Loans—(Program Levels).*—Direct loans provide a crucial source of capital for beginning farmers and others not well served by commercial credit. The final fiscal year 2011 continuing resolution cut direct farm ownership loan funding by \$175 million and the fiscal year 2012 bill retained this lower level. Nearly \$130 million worth of qualified applications were turned away in fiscal year 2011. In light of the increasing age of farmers and the challenges faced by beginning farmers, it is critical that we fund these direct loan programs in the most effective way possible. We ask that Congress appropriate sufficient funds to provide for program levels of \$600 million for Direct Farm Ownership loans and \$1,050 million for Direct Operating Loans.

*Beginning Farmer and Rancher Individual Development Account (IDA) Program.*—We urge you to provide \$5 million for this program, as authorized in the 2008 farm bill. This competitive grants program enables low-income, limited resource beginning farmers and ranchers to open an IDA (matched savings account) to save for asset-building purchases, including farmland, equipment, breeding stock, or similar expenditures. A 50 percent local match is required.

*Natural Resources Conservation Service*

*Conservation Technical Assistance (CTA).*—CTA, a subset of Conservation Operations, supports farmers enrolling in financial assistance programs and helps farmers with conservation planning and implementation. CTA also funds assessment of conservation practices and systems that underpin the conservation programs, as well as NRCS collection, analysis, and dissemination of information on the condition of the Nation's natural resources. NSAC urges you to provide \$740 million for CTA in order to adequately support and maximize the effectiveness of conservation financial assistance. We also support the addition of report language encouraging a modest net increase in the percentage of farm bill mandatory funding that may be used for technical assistance.

*Rural Business and Cooperative Service*

*Value-Added Producer Grants (VAPG).*—VAPG offers grants to farmers and ranchers developing new farm and food-related businesses that boost farm income, create jobs, and increase rural economic opportunity. VAPG grants encourage the kind of entrepreneurship in agriculture that enables farms and communities to survive economically. Moreover, growing interest in local and regional foods is generating greater demand for mid-tier value chains and enterprises that aggregate local production, exactly the kind of rural development strategy VAPG is designed to support. We request VAPG funding of \$30 million.

*Rural Microentrepreneur Assistance Program (RMAP).*—RMAP provides business training, technical assistance, and loans to owner-operated businesses with up to 10 employees. Small businesses make up 90 percent of all rural businesses, and micro-businesses are the fastest growing segment in many areas. RMAP creates jobs and local markets and alleviates poverty. This program was stripped of its mandatory farm bill funding (only \$3 million) in fiscal year 2012. NSAC requests \$5.7 million in discretionary funding in fiscal year 2013 and opposes any limitation to renewed or extended direct Farm Bill spending for RMAP.

*Appropriate Technology Transfer for Rural Areas (ATTRA).*—The ATTRA program, also known as the National Sustainable Agriculture Information Service, provides critical support to farmers and Extension agents throughout the country. The national program was reauthorized by the 2008 farm bill. We urge \$3 million for fiscal year 2013.

*General Provisions*

Repeated annual cuts the Conservation Stewardship Program, Environmental Quality Incentives Program, and other mandatory conservation programs have created enormous backlogs among highly qualified producers and made it more difficult for farmers to maintain healthy, productive soil and to protect water and other natural resources. These programs provide critical public benefits such as clean water, erosion reduction, and carbon sequestration and act as a key piece of the farmer safety net. We strongly oppose the proposed cuts to these critical conservation programs. We also oppose changes in mandatory program spending to any existing, renewed, or extended farm bill direct spending for the Organic Agriculture Research and Extension Initiative, Beginning Farmer and Rancher Development Program, Outreach and Assistance to Socially Disadvantaged Farmers and Ranchers, Farmers' Market Promotion Program, National Organic Certification Cost-Share Program, Community Food Grants, and Rural Energy for America Program.

Finally, we oppose any limitation to full implementation of the Packers & Stockyards rule on fair competition that Congress directed USDA to promulgate in the 2008 farm bill.

SUMMARY OF NSAC'S FISCAL YEAR 2013 REQUESTS  
 [Dollars in millions]

	Fiscal year 2012	USDA 2013 request	NSAC 2013 request
Departmental Administration: Office of Advocacy and Outreach .....	\$1.2 .....	\$1.4 .....	\$1.4 .....
National Institute of Food and Agriculture:			
Sustainable Agriculture Research and Education Program .....	\$14.5 (research & education) + \$4.7 (extension) = \$19.2 .....	\$14.5 + \$4.7 + \$3.5 (Federal-State matching grants) = \$22.7 .....	\$18.0 + \$5.0 + \$7.0 = \$30 total
Organic Transitions Program .....	\$4.0 .....	\$4.0 .....	\$5.0
National Food Safety Training, Education, Outreach and Technical Assistance (Authorized by Congress in the Food Safety Modernization Act of 2010).			\$10.0
Agricultural Marketing Service:			
Federal-State Market Improvement Program .....	\$1.2 .....	\$1.3 .....	\$1.3
Organic Market Reporting .....	\$0.3 .....	Funding for this activity included in top line request.	\$0.3
We also support continued baseline funding for NASS and ERS to continue coordinated data collection and reporting on organic production, marketing, and pricing, including NASS funding for the Organic Production Survey.			
Farm Service Agency:			
Direct Farm Ownership and Operating Loans—(Program Levels) .....	\$475.0 + \$1,050.0 .....	\$475.0 + \$1,050.0 .....	\$600.0 + \$1,050.0
Beginning Farmer Individual Development Account (IDA) Pilot Program .....	\$2.5 .....	\$2.5 .....	\$5.0
Natural Resources Conservation Service: Conservation Technical Assistance .....	\$729.5 .....	\$728.8 .....	\$740.0
Rural Business and Cooperative Service:			
Value-Added Producer Grants .....	\$14.0 .....	\$15.0 .....	\$30.0
Rural Microentrepreneur Assistance Program .....	\$0.0 (\$3.0 CHIMP + \$0 discretionary any).	\$3.7 (discretionary) .....	\$5.7 (\$5.7 discretionary + no CHIMP/limitation on 2012 farm bill direct funding)
National Sustainable Agriculture Information Service (ATTRA) .....	\$2.25 .....	\$2.25 .....	\$3.0

<p>General Provisions: Conservation Stewardship Program .....                  We also oppose changes in mandatory program spending (CHIMPS) for: other                  directly funded farm bill conservation programs; and any existing, renewed                  or extended mandatory farm bill spending for the Organic Agriculture Re-                  search and Extension Initiative, Beginning Farmer and Rancher Development                  Program, Outreach and Assistance to Socially Disadvantaged Farmers and                  Ranchers, Farmers' Market Promotion Program, National Organic Certifi-                  cation Cost-Share Program, Community Food Grants, and Rural Energy for                  America Program.                  We oppose any limitation to full implementation of the Packers &amp; Stockyards                  rule on fair competition that Congress directed USDA to promulgate in the                  2008 farm bill.</p>	<p>\$768.5 (\$75.5 CHIMP) .....</p>	<p>\$972.0 (\$68.0 approx. CHIMP; perma-                  nent cut of 759,632 acres).</p>	<p>No CHIMP/limitation on farm bill direct                  spending</p>
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## PREPARED STATEMENT OF THE NORTHWEST REGIONAL HOUSING AUTHORITY

USDA Rural Development funding for these programs needs to be funded to at least the level of 2012. Section 502 Direct Program should be at \$900 million or more and the Section 523 funding needs to be maintained at \$30 million. The 502 Direct Program is the only Federal homeownership program that is exclusively targeted to very low- and low-income rural families. In the past 60 years this program has helped more than 2.1 million families build wealth and achieve the American dream of homeownership. By law 40 percent of 502 Direct Loan funds must be used to assist families earning less than 50 percent of area median income. 25,000 loan applications are currently on a waiting list for Section 502 loan funding.

The Section 523 program helps organizations to provide training, supervision and technical assistance to families. Families work nights and weekends providing construction labor on their own and each other's homes to decrease construction costs increase equity and build wealth. Every 100 homes built on this program results in 324 jobs, \$21.1 million in local income and \$2.2 million in tax revenue. Even though Self-Help families have lower income, default rates are significantly lower than other borrowers. More than 50,000 families are currently on Self-Help Housing waiting lists. Each family that builds a Self-Help home makes many sacrifices. Throughout the process and after all the hard work they will say, yes, it was worth it. It does not make sense to let these programs deteriorate to the point of extinction.

Thank you for the opportunity to address these issues today.

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 PREPARED STATEMENT OF THE OREGON WATER RESOURCES CONGRESS

The Oregon Water Resources Congress (OWRC) strongly supports the U.S. Department of Agriculture's (USDA) Natural Resources Conservation Service (NRCS) and is deeply concerned about reductions to programs important to our members for fiscal year 2013. OWRC is requesting that funding for several key NRCS programs be increased for fiscal year 2013 and that the "Bridging the Headgates" MOU between NRCS and the Bureau of Reclamation be reactivated and expanded to include other Federal agencies.

OWRC was established in 1912 as a trade association to support district member needs to protect water rights and encourage conservation and water management statewide. OWRC represents non-potable agricultural water suppliers in Oregon, primarily irrigation districts, as well as other special districts and local governments that deliver irrigation water. The association represents the entities that operate water management systems, including water supply reservoirs, canals, pipelines, and hydropower production.

*Need*

OWRC and its members believe conservation of natural resources through collaborative partnerships is crucial to ensuring the viability of irrigation districts and similar organizations that deliver irrigation water for the Nation's agriculture. Federal support of water conservation activities funded through NRCS programs including the Agricultural Watershed Enhancement Program (AWEP) and the Cooperative Conservation Partnership Initiative (CCPI) are essential to the conservation of our natural resources and critical to protecting our food, energy and water supply. Irrigation districts and other agricultural water users in Oregon have used these programs to develop collaborative projects with Federal, State, and other local entities—proving that on-the-ground conservation can be best achieved by leveraging partnerships, pooling available resources, and focusing on each partner's strengths.

We are deeply disappointed that the NRCS budget for fiscal year 2013 is a 13 percent decrease from fiscal year 2012 estimated budget levels. While we recognize that the administration has increased funding for some of the NRCS programs, the need for additional financial assistance with conservation projects still far outweighs the budget. NRCS programs are essential to irrigation districts in developing and implementing conservation projects that benefit not only the individual farmers they serve but also the entire watershed and community as a whole. Furthermore, conservation projects also benefit the economy through job creation and ensuring the future viability of American agriculture. OWRC is requesting that funding for AWEP be increased to at least \$75 million, which is comparable to the enacted fiscal year 2011 levels but is still far less than what could be used in Oregon and nationally.

*AWEP and CCPI Needs*

AWEP and CCPI help fill a funding void for multi-partner conservation projects. Often large conservation projects do not include individual on-farm projects which limits the effectiveness of the project. AWEP and CCPI allow farmers to pool together and leverage the dollars invested in the off-farm project with the addition of EQIP on-farm projects. Because of the large number of successful project applications for AWEP, USDA will have to obligate a large amount of the annual \$60 million appropriation to existing multiyear projects. It is important that the funding for these projects not be interrupted so that they may be completed. However, it is equally important to have funding available for new eligible AWEP and CCPI projects that simultaneously benefit the environment and economy.

*Bridging the Headgates MOU and Watershed Planning Needs*

The need for continued coordination among Federal agencies, including NRCS, the Bureau of Reclamation (BOR), Bureau of Land Management (BLM), Environmental Protection Agency (EPA), NOAA Fisheries, U.S. Fish and Wildlife Service, and Army Corps of Engineers (ACOE), is a significant issue. With the loss of watershed planning funding, reactivating and expanding this program to other Federal agencies would be a very cost-effective alternative.

In the past, Oregon NRCS used a watershed resources planning team to conduct Rapid Watershed Assessments throughout Oregon. This planning program helped prioritize projects to bring about the most benefit in critical watersheds. The use of the Rapid Watershed Assessment has been instrumental in getting on-the-ground conservation projects completed in a timely manner. A number of NRCS funded district projects have been implemented using the data from this program.

Following in the vein of the Rapid Watershed Assessments, Oregon has adopted a Strategic Approach to Conservation. The goal is to invest technical and financial resources to strategically solve natural resource problems and be more effective, efficient, and accountable for staffing, funding and partnerships. The process builds from the ongoing planning process utilizing existing conservation plans, watershed assessments; conservation agencies, organizations, groups and producers to develop consensus on overarching 5–10 years local goals and priorities for conservation; including vision, resource inventories, resource problems, desired outcomes, other Government/NGO partners interests and contributions. This is a method to prioritize and develop detailed strategies to address natural resource problems. This strategy is intended to accelerate the conservation implementation and leverage technical and financial resources required to solve the problem. These types of program activities are effective tools that need a consistent funding source.

*Program Benefits*

OWRC strongly supports AWEP and CCPI, which are both critical tools for districts and other agricultural water suppliers in developing and implementing water and energy conservation projects in Oregon. AWEP has been highly successful in developing cooperative approaches on a basin-wide scale. This program allows districts and other agricultural water suppliers to partner with farmers to address regional water quantity and quality issues in local watersheds.

The CCPI allows partnerships to be formed with Federal, State and local interests to address Endangered Species Act (ESA) and Clean Water Act (CWA) issues in watershed basins and sub basins. We believe that water supply issues in Oregon and elsewhere in the Nation can be resolved best locally in cooperative partnership efforts that promote conservation with a more aggressive Federal funding partnership as defined in AWEP and CCPI. In the spirit of streamlining farm bill programs, OWRC would support combining AWEP and CCPI into one program, but only if the current authorized funding is maintained or increased for the two programs combined. OWRC strongly supports the continuation and increased funding of the AWEP and CCPI programs for fiscal year 2013.

*Examples of Successful AWEP Projects in Oregon*

Oregon has had several successful AWEP applicants over the past several years, three from our member districts (described below). The full list of Oregon projects can be found on the Oregon NRCS website at: <http://www.or.nrcs.usda.gov/programs/awep/index.html>.

—The Whychus Creek/Three Sisters Irrigation District Collaborative Restoration Project focuses on irrigation water efficiency with irrigation improvements in the Upper Division of the Three Sisters Irrigation District, which is the project partner. The effort will improve stream flows and water quality for native fish while providing farmers a reliable supply of water. Fiscal year 2012 funding: \$251,300 (AWEP).

- The Talent Irrigation District Project works with agricultural producers to install conservation practices that will properly utilize limited surface water resources, improve water quality on flood irrigated land by converting to more efficient irrigation systems, and apply irrigation water management to eliminate irrigation runoff. Fiscal year 2012 funding: \$4,470 (AWEP).
- The Willow Creek Project helps landowners in the Lower Willow Creek Watershed portion of Malheur County convert to water-saving irrigation systems, reduce irrigation runoff, and improve water quality in Willow Creek and Malheur River. The project partner is the Vale Oregon Irrigation District. Fiscal year 2012 funding: \$251,300 (AWEP).

In 2012 Oregon requested approximately \$3.1 million for project funding but only received \$2.4 million for existing AWEP approved projects. Oregon also requested approximately \$3.2 million of CCPI funds and received \$3 million. Each year local interest has increased to compete for AWEP and CCPI funding and additional innovative projects like the ones above could be developed and implemented in Oregon if more funding is made available.

The projects above are just a few examples of how NRCS programs have been successfully used in Oregon to develop and implement collaborative multi-benefit conservation projects. In the future, OWRC would also like to see additional funding targeted for projects that conserve both water and energy—which are two key and complimentary resource areas for the agricultural community. In Oregon, NRCS is helping develop the Save Water, Save Energy Initiative, a multi-agency cooperative effort to develop a clearinghouse of information on financial incentives and technical expertise to assist districts and their water users in implementing conservation measures. Supporting projects like the pilot project being implemented in the Deschutes Basin will provide the groundwork for future Save Water, Save Energy projects and help maximize Federal investment in conservation efforts.

#### *Conclusion*

Our member districts, the farms and other water users they serve, and the communities in which they are located benefit greatly from the NRCS programs described in our testimony. Oregon's agricultural community is actively committed to water conservation programs, but those programs require Federal participation if the agricultural community is to be able to continue its efforts to address Oregon's water supply needs through water conservation. These valuable programs are essential tools in not only conserving natural resources but also in leveraging Federal, State, local partnerships and resources to implement important projects that would otherwise be unrealized. Increasing the budget for NRCS programs is a strategic investment that will pay both environmental and economic dividends to Oregonians and America as a whole.

Thank you for the opportunity to provide testimony for the record on the proposed fiscal year 2013 budget for the U.S. Department of Agriculture.

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#### PREPARED STATEMENT OF THE ORGANIC FARMING RESEARCH FOUNDATION

The Organic Farming Research Foundation (OFRF) is a national, farmer-led non-profit organization that fosters the improvement and widespread adoption of organic farming systems. Organic agriculture is one of the fastest growing sectors of American agriculture, creating jobs in rural areas and keeping farmers in business. In 2011, the organic sector grew by 9.5 percent; the sector experienced double-digit growth before the economic recession and has maintained positive growth since. Ensuring the continued growth and job creation ability of the organic sector requires upholding the integrity of the U.S. Department of Agriculture organic label and continuing the modest but important investment in organic agriculture. The following requests are for national programs authorized by Congress in past farm bills. The agencies included in the requests are all at the U.S. Department of Agriculture (USDA): National Institute of Food and Agriculture (NIFA), Agricultural Marketing Service (AMS), Rural Business—Cooperative Service (RBCS). The programs are the Organic Transitions Integrated Research Program (ORG) at \$5 million, the Sustainable Agriculture Research and Education Program (SARE) at \$30 million, the National Organic Program (NOP) at \$10 million, the Organic Production and Market Data Initiatives (ODI) at \$0.3 million, and the Appropriate Technology Transfer for Rural Areas (ATTRA) at \$3 million. We present sensible, modest requests that support a basic investment in a fast-growing, job-creating sector of agriculture. Additionally, we urge no cuts to mandatory program funding. Please read below for further details.

*Organic Transitions Integrated Research Program (ORG)—USDA–NIFA*

*2008 Farm Bill Authorized: Sums as Appropriate; Fiscal Year 2013 OFRF Request: \$5 Million*

An investment in research underpins growth in any sector. One of the barriers to continued growth in organic is lack of research and information that growers need to improve and increase production. ORG is a national, competitive research, education, and extension program that provides research to the fast-growing organic sector. Funding ORG at \$5 million would help bridge the gap between sector growth and research investment.

*Sustainable Agriculture Research and Education Program (SARE)—USDA–NIFA*

*2008 Farm Bill Authorized: \$60 Million; Fiscal Year 2013 OFRF Request: \$30 Million*

SARE is a farmer-driven and regionally led competitive research and extension grants program that provides farmers with business, marketing, and production information to be successful. SARE complements the activities of dedicated organic research programs by funding on-farm research. Funding SARE at \$30 million would allow for the launch of a Federal-State Matching Grants program to build capacity at the State level for research and extension to address regional and local needs. We support splitting the funding between the Research and Education section of SARE (\$25 million) and the Extension (or Professional Development Program) section of SARE (\$5 million).

*National Organic Program (NOP)—USDA–AMS*

*2008 Farm Bill Authorized: \$11 Million; Fiscal Year 2013 OFRF Request: \$10 Million*

NOP enforces the national organic program standards, accredits certifiers, develops equivalency agreements, handles complaints—in essence, NOP ensures the integrity of the organic seal. NOP performs regulatory oversight of the organic label and ensures that consumers are getting what they pay for when they choose foods with the organic label. These are essential functions to the survival and growth of the organic sector.

*Organic Production and Market Data Initiatives (ODI)—USDA–AMS*

*2008 Farm Bill Authorized: \$5 Million; Fiscal Year 2013 OFRF Request: \$0.3 Million*

Every sector needs reliable, current data and statistics to function properly and grow. USDA has historically not collected basic data and statistics on the growing organic sector. In the 2008 farm bill, Congress directed USDA to collect data for organic through ODI. As the industry surpasses \$32 billion, the information collected through this multi-agency initiative is vital to maintaining stable markets, creating proper risk management tools, and negotiating equivalency agreements with foreign governments. The request of \$0.3 million for AMS is specifically to continue the collection of price data and its dissemination through Market News Reports. We also support continued baseline funding for NASS and ERS to continue coordinated data collection and reporting on organic production, marketing, and pricing, including NASS funding for the Organic Production Survey.

*Appropriate Technology Transfer for Rural Areas (ATTRA)—USDA–RBCS*

*2008 Farm Bill Authorized: \$5 Million; Fiscal Year 2013 OFRF Request: \$3 Million*

ATTRA serves farmers and ranchers nationwide by providing cutting-edge production and marketing information through web publications and a toll-free phone line. Authorized originally in the 1985 farm bill, ATTRA has provided technical assistance and educational resources to a broad range of farmers and agricultural professionals for over two decades. Just last year, ATTRA received over 60,000 technical requests, had over 5.8 million publication downloads from its website, and conducted workshops in 45 States that over 177,000 individuals attended. The program was recently zeroed out because of the mistaken assumption that the program is an earmark. ATTRA is a national program that is run according to statute by a national, nonprofit organization through a cooperative agreement with USDA. The classification of the program as an earmark is a mistake.

*No Cuts to Mandatory Program Spending*

OFRF urges the Subcommittee not to cut mandatory program spending. Over half a billion dollars in cuts have already been made to mandatory farm bill programs

(primarily conservation and energy), and we urge the Subcommittee not to make anymore. These cuts have negative impacts on the baseline funding available for the next farm bill and should not unfairly be targeted to certain sectors of agriculture.

Thank you for the opportunity to submit testimony. Organic agriculture is a growth industry. Making the modest investments in the key programs described above will help to ensure that organic sector operations and businesses continue to grow, to hire new employees, and to meet the strong consumer demand for organic food.

PREPARED STATEMENT OF PICKLE PACKERS INTERNATIONAL, INC.

SUMMARY

Sustained and increased funding is desperately needed to maintain the research momentum built over recent years and to defray rising fixed costs at laboratory facilities. Companies in the pickled vegetable industry generously participate in funding and performing short-term research, but the expense for long-term research needed to insure future competitiveness is too great for individual companies to shoulder on their own.

*Additional Budget Requests for Fiscal Year 2013*

Funding needs for four USDA/ARS laboratories are as follows:

REQUESTS FOR PROGRAM ENHANCEMENT—PICKLED VEGETABLES

	Amount
Emerging Disease of Crops .....	\$500,000
Quality and Utilization of Agricultural Products & Food Safety .....	500,000
Applied Crop Genomics .....	500,000
Specialty Crops .....	550,000
Total Program Enhancements Requested—Pickled Vegetables .....	2,050,000

*USDA/ARS Research Provides*

Consumers with over 150 safe and healthful vegetable varieties providing vitamins A, C, folate, magnesium, potassium, calcium, and phytonutrients such as antioxidant carotenoids and anthocyanins.

Genetic resistance for many major vegetable diseases, assuring sustainable crop production with reduced pesticide residues—valued at nearly \$1 billion per year in increased crop production.

Classical plant breeding methods combined with bio-technological tools, such as DNA marker-assisted selection and genome maps.

New vegetable products with economic opportunities amidst increasing foreign competition.

Improved varieties suitable for machine harvesting, assuring post harvest quality and marketability.

Fermentation and acidification processing techniques to improve the efficiency of energy use, reduce environmental pollution, and reduce clean water intake while continuing to assure safety and quality of our products.

Methods for delivering beneficial microorganisms in fermented or acidified vegetables, and produce reduced sodium, healthier products.

New technology and systems for rapid inspection, sorting and grading of pickling vegetable products.

*Health and Economical Benefits*

Health agencies continue to encourage increased consumption of fruits and vegetables, useful in preventing heart disease, cancer, stroke, diabetes and obesity.

Vegetable crops, including cucumbers, peppers, carrots, onions, garlic and cabbage (sauerkraut), are considered “specialty” crops and not part of commodity programs supported by taxpayer subsidies.

Current farm value for just cucumbers, onions and garlic is estimated at \$2.4 billion with a processed value of \$5.8 billion. These vegetables are grown and/or manufactured in all 50 States.

The pickled vegetable industry strongly supports and encourages your committee 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 correlations between high fruit and vegetable consumption and reduced incidence of these debilitating and deadly diseases.

As an association representing processors that produce over 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. This industry can grow by meeting today's lifestyle changes 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 are in any "commodity program" and do not rely on 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 rural America. 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 Economics Mission Area (REE) of the 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 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 over 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., pest resistances and health-enhancing characteristics) 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 over 20 other vegetables used by thousands of vegetable growers. Their innovations meet long-term needs and bring innovations in these crops for the United States and export markets, for which the United States has successfully competed.

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, tolerance to environmental stresses, and higher yield have recently been identified along with molecular tools to expedite delivery of elite cucumber lines to U.S. grow-

ers. A new genetic resistance to nematode attack was found to almost completely protect the carrot crop from one major nematode. 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. The genetic bases of onion flavor, as well as compounds that enhance cardiovascular health and have anti-carcinogenic effects have been determined and are being used to develop onions that are more appealing and healthier 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 should 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 bio-technological 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 United States and export markets.

#### FOOD SCIENCE RESEARCH UNIT, RALEIGH, NORTH CAROLINA

The USDA/ARS Food Science Research Unit (FSRU) 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. The scientists in the FSRU have consistently provided innovative solutions to processing challenges which have helped this industry remain competitive in the current global trade environment. Major accomplishments of the FSRU include: pasteurization treatments currently used for most acidified vegetables; the preservation technology used for manufacturing shelf stable sweet pickles; fermentation technology (purging) used to prevent the formation of air pockets within fermented pickles. These innovations have improved processing and product quality and yielded significant savings industry-wide. Furthermore, the FSRU has determined the microbial safety parameters now used for acidified vegetable process filings, as required by the Food and Drug Administration. The pickling industry in the United States relies on the FSRU for the development of new and improved technologies that will increase the economic value of processed vegetable products, provide consumers with safe, high quality, healthful vegetable products, and reduce the environmental impact of industrial activities. Additional funding is needed to support important new research initiatives.

First, nearly all retail pickled vegetables are pasteurized for safety and shelf stability. Current steam and water bath pasteurizers rely on technology from the 1940s and 1950s. Promising new technologies include continuous flow microwave technology and "hot-fill-and-hold" pasteurization. The objective is to reduce water use and significantly improve energy efficiency with new, scientifically validated thermal processing technology.

Second, additional research that offers significant economic and environmental advantages to the U.S. industry includes the reduction or replacement of salt in commercial vegetable fermentations. Calcium substitution of salt in commercial vegetable fermentations has the potential to eliminate salt disposal problems and create opportunities to manufacture calcium enriched, reduced sodium, healthier vegetable products. Reducing environmental impact and production costs for the manufacture of healthier products is essential to the sustainability of the U.S. industry.

Third, there is a growing body of research indicating that certain beneficial microorganisms (probiotics) improve human health by remaining in the intestinal tract after they are consumed. New processing technology is needed to develop high value probiotic vegetable products, opening new markets in the United States and improving the health benefits derived from consumption of fermented and acidified vegetables.

#### SUGAR BEET AND BEAN RESEARCH UNIT, EAST LANSING, MICHIGAN

Quality inspection and assurance of pickling vegetables is critical to growers and processors and ultimately consumers of pickling vegetables. While automated sys-

tems are currently used in many pickle processing facilities, they are only for inspecting product surface quality characteristics. Opportunities exist for developing more efficient sensors and automated inspection technologies, 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. New and/or improved inspection 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. 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

Research at the USDA/ARS U.S. Vegetable Laboratory in Charleston, South Carolina, addresses national problems confronting the vegetable industry of the southeastern United States. The mission of the laboratory is to develop disease and pest resistant vegetables, and also new, reliable, environmentally sound disease and pest management practices that do not rely on conventional pesticides. The laboratory's program currently addresses 14 crops, including those in the cabbage, cucumber, and pepper families, all of major importance to the pickling industry. Research at this ARS facility is recognized world-wide, and its accomplishments include over 150 new vegetable varieties and many improved management practices.

Expansion of the Charleston program would directly benefit the southeastern vegetable industry. Vegetable growers depend heavily on synthetic pesticides to control diseases and pests. Cancellations of many effective pesticides directly impacts future vegetable crop production. Without the use of certain pesticides, producers will experience crop failures unless other effective, non-pesticide control methods are readily identified. In this context, 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. Research like this can help provide U.S. growers with a competitive edge they must have to sustain and keep their industry vibrant, allowing 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 at the U.S. Vegetable Laboratory could 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 in-

volves 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.

It is important to note that fiscal year 2012 funding for four USDA ARS laboratories (Charleston, South Carolina; East Lansing, Michigan; Madison, Wisconsin; and Raleigh, North Carolina) totaled \$11,004,900. However, funding for all cucurbits equaled just \$3,939,000 with only \$1,718,000 directed toward pickled vegetable research. For fiscal year 2013, PPI is requesting an additional \$2,050,000 in program enhancements that will provide needed research for pickled vegetables.

#### U.S. VEGETABLE LABORATORY, CHARLESTON, SOUTH CAROLINA

There is a critical need to establish and fund a plant pathology position to address cucumber diseases, especially the disease caused by a new strain of the downy mildew pathogen responsible for recent extensive damage to cucumber production in South Atlantic and Midwestern States. The pathologist is needed to characterize pathogen strains and to develop new management approaches, as well as resistant cucumber varieties, to combat the disease. Ultimately, this proposed plant pathologist would accomplish research that results in effective protection of cucumbers from disease without the use of conventional pesticides.

	Amount
Fiscal year:	
2012 (pickled vegetables) .....	\$456,100
2013 (proposed budget) .....	456,100
2013 additional request (plant pathologist and support) .....	500,000

#### FOOD SCIENCE RESEARCH UNIT, RALEIGH, NORTH CAROLINA

The current funding includes research and development for a variety of vegetable products, including fermented and acidified vegetables. To carry out new research initiatives to reduce energy and water use, reduce environmental impact from commercial fermentations, and develop new health-promoting food (probiotic) technology, we request additional support for the Food Science Research Unit of \$500,000 in fiscal year 2013. This will provide support for Post-Doctoral or Pre-Doctoral research associates in food engineering and food microbiology along with necessary equipment and supplies to develop these new areas of research.

	Amount
Fiscal year:	
2012 (pickled vegetables) .....	\$647,800
2013 (proposed budget) .....	647,800
2013 additional request (post-doctoral and pre-doctoral research associate and support) .....	500,000

#### VEGETABLE CROPS RESEARCH LABORATORY UNIT, MADISON, WISCONSIN

Emerging diseases, such as downy mildew of cucumber, threaten production of the crop in all production areas. Therefore, we request an additional \$500,000 to fully fund the scientists and support staff in fiscal year 2013, including graduate students and post-doctorates for researching genetic resistance to emerging diseases.

	Amount
Fiscal year:	
2012 (pickled vegetables) .....	\$456,600
2013 (proposed budget) .....	456,600
2013 additional request (post-doctoral and pre-doctoral research associate and support) .....	500,000

#### SUGAR BEET AND BEAN RESEARCH UNIT, EAST LANSING, MICHIGAN

The current funding is far short of the level needed to carry out research on inspection, sorting and grading of pickling cucumbers and other vegetable crops to as-

sure the processing and quality of pickled products. An increase of \$550,000 in the current base funding level would be needed to fund the research engineer position.

	Amount
Fiscal year:	
2012 (pickled vegetables) .....	\$157,500
2013 (proposed budget) .....	157,500
2013 additional request (research engineer and support) .....	550,000

Thank you for your consideration and expression of support for the USDA/ARS.

LETTER FROM THE RURAL COALITION/COALICIÓN RURAL, ET. AL

MARCH 30, 2012.

Hon. HERB KOHL, Chairman,  
 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.*

DEAR SENATORS: As the Senate considers the Agriculture Appropriation for fiscal year 2013, we respectfully request that the Senate Appropriations Subcommittee on Agriculture, Rural Development and FDA provide adequate funding for a set of critical programs that make a real difference in communities that most need support.

The 2008 Farm Bill made significant improvements in programs designed to address the outreach and technical assistance challenges of historically underserved producers. We urge you to provide long-term protection and continued funding for this critical subset of programs and offices charged with serving the most chronically underserved segments of agriculture. These represent a fraction of the full agriculture budget but are the lifeblood of the sustainable agriculture community, beginning, socially disadvantaged and veteran producers, and farmworkers.

We urge you to consider the following recommendations:

*Farm Credit.*—Farm Service Agency (FSA) Direct Farm Ownership and Operating Loans provide a crucial source of capital for farmers who are ineligible for commercial credit. The final fiscal year 2011 continuing resolution cut direct farm ownership loan funding by \$175 million and the fiscal year 2012 bill retained this lower level. Nearly \$130 million worth of qualified applications were turned away in fiscal year 2011. This is the funding that is essential to create opportunities for individuals to get into the farming business. To meet the challenges faced by many farmers who are confronting increasing input costs and volatile prices, it is critical to fund these direct operating loan programs at the highest level possible. We ask that Congress appropriate sufficient funds to provide for program levels of \$600 million for Direct Farm Ownership loans and \$1.05 billion for Direct Operating Loans.

We further urge you to ensure that farmers and ranchers who are in economic trouble receive fair loan restructuring and servicing of their loans by funding the Federal match for State Mediation Programs at \$5 million. These programs currently operate in 40 States. We urge the Committee to instruct FSA to develop price information to improve eligibility and lending capabilities to farmers growing for local and regional food markets.

*Tribal Communities.*—We urge you to support and expand funding to a level of \$10 million for the Office of Tribal Relations Program to enhance its ability to serve its function as a critical link between the Department of Agriculture and the Nation’s Tribes.

In addition, in order to provide critically needed services to tribal producers, we urge you to expand funding for the Federally Recognized Tribal Extension Program (FRTEP) to \$10 million for fiscal year 2013 to reach at least 100 of the 566 tribes. Congress mandates research and extension services in every county in the Nation—over 3,100 offices nationwide, funded cooperatively by county, State, and Federal levels of government. Extension services are not extended to Indian Reservations, except through the limited Federal funds provided through USDA to the FRTEP, the only vehicle by which extension programs are currently delivered to Indian Country. Tribes contribute in-kind cost share for office space and a small portion of operating expenses.

Only 36 extension agents are supported on Indian reservations with current funding of \$3 million. These programs have significantly affected not only agriculture, but natural resources, 4-H/youth development, human nutrition, community re-

source development and family and consumer sciences program areas—much like the impacts seen in non-reservation, county-based extension programs. The inadequate funding of FRTEP has, without question, a profound negative impact on the long-term viability of tribal agriculture, which remains a critical basis for the economic security, health and nutrition of Native Americans.

Fewer than 4 percent of American Indians living on America's Indian reservations have access to these programs, yet more than 97 percent of America's counties have had robust programs since 1914. Increased funding would allow FRTEP to serve better the many tribes who have repeatedly requested full access to these programs. It is time that Native American producers, families, youth and reservation residents receive the same level of service as U.S. citizens who are not reservation-bound. In order to correct this grave inequity, we urge you to appropriate \$10 million for this program in the fiscal year 2013 Agriculture Appropriation.

*Farmworker Communities.*—Farmworkers are a critical component of our food and agriculture system. We urge you to maintain the Farmworker Coordinator in the Office of Advocacy and Outreach (see below), restore funding of at least \$4 million annually for the Grants to Improve the Agricultural Labor Workforce Program, and provide at least \$2 million to the Emergency Disaster Grants for Farmworkers program to provide funding for services to farmworkers affected by natural disasters and keep this critically needed workforce in place in disaster affected areas.

*Coordination Activities.*—For many years, beginning and socially disadvantaged producers have lacked an office at USDA to better understand and utilize the wide array of USDA services. The Office of Advocacy and Outreach, established in the 2008 Farm Bill, is now in full operation and working effectively with communities across the Nation to provide equitable access to its programs and enhance the viability and profitability of small farms, beginning farmers and ranchers, and socially disadvantaged farmers and ranchers, and farmworkers. An increase to \$5 million would fund the staffing and operational needs of this office to allow OAO to adequately conduct its activities related to overseeing the Advisory Committees on Minority Farmers and Beginning Farmers and Ranchers, overseeing the activities of the Office of Small Farms Coordination and the Farm Worker coordinator; managing the 1890, 1994 and Hispanic-serving institutions programs; managing outreach programs and performing any other outreach functions that improve coordination among USDA agencies to improve their ability to enhance access to USDA programs for underserved constituencies. We urge Congress to provide at least \$5 million to this office to allow it to continue to provide the important coordination services it is designed to deliver.

*Rural Housing.*—These Federal rural housing programs provide loans, grants and related assistance that create jobs and ensure that low-income families live in safe, decent housing. Of particular importance is maintaining adequate funding levels for the Section 502 Direct Loan program, the Mutual Self Housing program, and programs to finance Rural Rental Housing construction and preservation.

Under the Section 502 Direct Loan program, nearly 66 percent of the families receiving loans have incomes at or below 60 percent of area median income and 40 percent of the loans go to households with incomes at or below 50 percent of area median income. In fiscal year 2011, the average total cost to the government for a Section 502 loan was less than \$7,200 per unit

We support funding levels for Rural Housing programs administered by the Rural Housing Service (RHS) at USDA at the following levels:

- \$900 million for the Section 502 Single Family Direct Homeownership Loans;
- \$28 million for the Section 504 Very Low-Income Rural Housing Repair Loans;
- \$29.5 million for the Section 504 Very Low-Income Rural Housing Repair Grants;
- \$26 million for the Section 514 Farm Labor Housing Program Loans;
- \$9 million for the Section 516 Farm Labor Housing Program Grants;
- \$64.5 million for the Section 515 Rural Rental Housing Program;
- \$907 million for the Section 521 Multi-Family Rental Housing Rental Assistance Program;
- \$30 million for the Section 523 Self-Help Housing Program;
- \$3.6 million for the Section 533 Housing Preservation Grants Program;
- \$150 million for the Section 538 Guaranteed Multi-Family Housing Loans; and
- \$46.9 million for the Multi-Family Housing Preservation and Revitalization Program; and \$13 million for the Rural Community Development Initiative.

*Farmers Market Nutrition Programs.*—We strongly urge the Committee to fund the WIC Farmers Market Nutrition Program at its fiscal year 2011 funded level of \$20 million. The fiscal year 2012 cut will translate into a loss of 25 percent in the benefits available to eligible consumers this year who shop at our Nation's farmers' markets and roadside stands. In fiscal year 2010, 2.15 million WIC participants re-

ceived FMNP benefits and over 18,000 farmers were authorized to receive them at 3,647 farmers' markets and 2,772 roadside stands. According to USDA's data, this translated into over \$15.7 million in revenue to farmers.

*Conservation Programs.*—We further urge you to protect and maintain funding agricultural conservation programs including maintaining support for the Environmental Quality Incentive Program and the Conservation Stewardship Program, and other programs which are helping producers across the Nation protect their land. The diverse producers many of the undersigned groups represent are returning to USDA through these programs, and building up small operations that care for the land and contribute to the economic viability of small rural communities in some of the poorest areas of the Nation.

*Beginning Farmer and Rancher Individual Development Account (IDA) Program.*—We urge you to provide \$5 million for this program, as authorized in the 2008 Farm Bill. This pilot program would enable low-income, limited resource beginning farmers and ranchers to open an IDA (matched savings account) to save for asset-building purchases, including farmland, equipment, breeding stock, or similar expenditures.

In addition to the programs outlined in this letter, we urge you to oppose changes in mandatory program spending to any existing, renewed, or extended farm bill direct spending. These programs include the Outreach and Assistance to Socially Disadvantaged Farmers and Ranchers, Beginning Farmer and Rancher Development Program, Farmers Market Promotion Program, Community Food Project Competitive Grants, National Organic Cost-Share Program, Organic Agriculture Research and Extension Initiative, and the Rural Energy for America Program.

As you proceed with funding for these important programs for fiscal year 2013, we urge you to consider the impacts of your funding decisions on the future, a concern for the next generation of American farmers and ranchers, and great care to being inclusive of beginning, minority, tribal women, and limited resource farmers who are often in most need of these important programs.

Sincerely,

Alliance of Forest Workers and Harvesters, Oakland, CA	Live Real, Oakland, CA
American Federation of Government Employees Local 3354, St. Louis, MO	National Family Farm Coalition, Washington, DC
American Federation of Government Employees (AFL–CIO), Washington, DC	National Hmong American Farmers, Inc., Fresno, CA
BioRegional Strategies, Albuquerque, NM	National Latino Farmers and Ranchers Trade Association, Washington, DC
Birthing Project USA, Albuquerque, NM	National Wildlife Federation, Washington, DC
California Food & Justice Coalition, Oakland, CA	National Women in Agriculture Association, Oklahoma City, OK
Casa de Cultura, Las Vegas, NM	National Young Farmers' Coalition, Tivoli, NY
CASA del Llano, Inc., Hereford, TX	New Orleans Food & Farm Network, New Orleans, LA
Church Women United in New York State, Rochester, NY	Northern New Mexico Stockman's Association, Albuquerque, NM
Community Food Security Coalition, Portland, OR	Oklahoma Black Historical Research Project, Inc., Oklahoma City, OK
D.C. Farm to School Network, Washington, DC	Rural Advancement Fund, Orangeburg, SC
Family Farm Defenders, Madison, WI	Rural Coalition/Coalición Rural, Washington, DC
Farmworker Association of Florida, Apopka, FL	Southern Regional Asset Building Coalition, Tuskegee, AL
Federation of Southern Cooperatives, Atlanta, GA	Taos County Economic Development Corporation, Taos, NM
Food & Water Watch, Washington, DC	The Cornucopia Institute, Cornucopia, WI
Idaho Rural Council, Filer, ID	The Presbyterian Church (U.S.A.) Office of Public Witness, Washington, DC
Intertribal Agriculture Council, Billings, MT	United Farmers USA, Manning, SC
Just Food, New York, NY	World Farmers, Inc., Lancaster, MA
Kentucky Resources Council, Inc., Frankfort, KY	
Lideres Campesinas, Oxnard, CA	

## PREPARED STATEMENT OF THE RURAL HOUSING DEVELOPMENT CORPORATION

On behalf of Rural Housing Development Corporation (RHDC), I would like to thank the Subcommittee for the opportunity to submit testimony on fiscal year 2013 Appropriations for two of Department of Agriculture (USDA) Rural Housing Programs. I strongly urge this Subcommittee to fund USDA Rural Housing programs at the higher of fiscal year 2012 levels or the President's fiscal year 2013 budget request: (1) \$900 million for Section 502 Family Direct Homeownership Loans; and (2) \$30 million for Section 523 Self-Help Housing Program.

RHDC is a nonprofit affordable housing organization in Utah. Since 1998, RHDC has promoted affordable housing opportunities to low-income families living in Central Utah. Over 300 single family homes have been built through USDA's Mutual Self-Help Housing program using the 502 loan in Central Utah and over 1,000 homes have been built across the State of Utah.

*About the Mutual Self-Help Housing Program*

The Mutual Self Help Housing program takes the rural tradition of barn-raising and puts it to use for families who, after working all day and all week, spend their nights and weekends building their own home. It is a model of how low-income families help themselves through sweat equity. Without the opportunity, many of these families would never own their own home. Consider the West family in Utah, a low-income family of 5 (children ages 5, 3 and 1), who have lived in two-room log cabin built in the 1880's. The cabin measures 21 by 26 feet, which is very similar to a modes two-car garage.

In their own words:

"While we enjoy the 'coziness' of our home, it does present some challenges. The cabin is not well-insulated. We can feel the wind through the single-paned windows and cracks throughout the house. Big rainstorms cause leaks. Other than weather problems, we are not sure which we have the most of living in the walls of our home: bees, spiders or mice. Our home is on a cinderblock basement built into a dike constructed to control the flooding of the river in the 1980's. Because of our close proximity to the river and lake, we have had to face additional challenges. This year the ground water is so high it fills the septic tank, causing the sewer to back up. The high water flow in the river also caused the water to seep through the cracks in our basement floor. At the highest point, we had almost 2 feet of standing water. Even though the water level has recently dropped, we are left with the challenge of the profuse growth of mold. Every summer, we have a mold problem in the basement. However, this year, with the flooding, the mold is 100 percent worse. This makes us concerned for our family's health.

"Unfortunately for us, moving is not an option at this time. For these reasons, we are telling you our story—not to complain, but to ask you for the much needed financial assistance in purchasing a new, healthy home for our family through the Mutual Self Help Housing Program. We cannot better our situation without your help."

Families like the West family have found refuge in building their own home and for that reason take great care in the homes they have a major stake in. Of the 1,000+ homes built in Utah, there is a foreclosure rate of less than 1 percent. This means that the 502 loans borrowed are paid back with interest and perpetuated for future families.

*Economic Impact*

The economic impact in Utah has been substantial; it is anticipated that during 2011 and 2012, the Self Help Housing program would bring Utah's economy approximately \$58,210,788. The program also creates employment opportunities in rural areas; each year in Utah, over 500 jobs are created for subcontracts, suppliers, realtors, and land developers.

The Section 502 program provides loans to low- and very-low income families at a low cost the Government, and as mentioned, has a very low foreclosure rate. Sixty percent of the families borrowing direct loans from USDA have incomes at or below 60 percent of the area median income. The proposed budget contends that the 502 guarantee loan program can assist families who are now receiving direct loans. There is ample evidence to the contrary; including an Economic Research Service report indicating that the guarantee loan program is not working well in smaller, more isolated communities. Nor does the guarantee loan product have a track record of serving households with incomes at 60 percent AMI or less, while the direct loan program does. The proposed change will not provide homeownership opportunities for many of the current workforce in rural areas, who struggle to find affordable

rental housing that is both safe and adequate for their family size. The loss of this program will also destabilize rural workers, negatively impacting rural employers.

I would ask that the Subcommittee reconsider the proposed budget and look at ways to reallocate the reduced spending level in a manner that still supports the 502 and 523 programs as indicated above. I appreciate your consideration of this request.

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PREPARED STATEMENT OF THE SELF-HELP ENTERPRISES

Self-Help Enterprises is a regional nonprofit housing and community development organization serving eight expansive counties in California's agricultural San Joaquin Valley. Founded in 1965, Self-Help Enterprises has developed nearly 6,000 self-help homes and 1,200 units of multifamily rental housing for farmworkers and other low wage earners. In partnership with local governments, SHE has rehabilitated or replaced 6,000 homes, assisted 1,500 first-time homebuyers, and provided planning and technical assistance to dozens of small, unincorporated communities meeting needs for safe drinking water and wastewater treatment.

The Rural Housing Service's housing programs continue to be the most effective, and in many cases, the only, resources which address the critical housing needs of rural America. Self-Help Enterprises strongly supports an appropriation to maintain USDA's Rural Housing programs at the following levels.

- Section 502 Family Direct Homeownership Loans: \$900 million
- Section 504 Very-Low Income Rural Housing Repair Loans: \$28 million
- Section 504 Very-Low Income Rural Housing Repair Grants: \$29.5 million
- Section 514 Farm Labor Housing Program Loans: \$26 million
- Section 516 Farm Labor Housing Program Grants: \$9 million
- Section 515 Rural Rental Housing Program: \$64.5 million
- Section 521 Multi-Family Rental Housing Rental Assistance Program: \$907 million
- Section 523 Self-Help Housing Program: \$30 million
- Section 533 Housing Preservation Grants Program: \$3.6 million
- Section 538 Guaranteed Multi-Family Housing Loans: \$150 million
- Multi-Family Housing Preservation and Revitalization Program: \$46.9 million
- Rural Community Development Initiative: \$13 million

*Section 523 Mutual Self-Help Housing Program*

No other program combines the unique features which make the Self-Help program a success. The Section 523 grants provide support to Self-Help sponsors who provide technical assistance, recruiting, training, and supervising to families to earn "sweat equity." This unique construction method also promotes strong communities by building close bonds among future neighbors. (PART review, [www.expectmore.gov](http://www.expectmore.gov))

Created by the Housing and Community Development Act of 1968, the USDA Rural Development Section 523 Mutual Self-Help Housing Program is one of the best and most successful avenues to sustainable homeownership for low-income rural Americans.

With its roots in the tradition of barn raising, mutual self-help housing gives hardworking rural families the opportunity to work together to achieve the dream of homeownership which individually could not be attained. Mutual self-help housing programs, which still retain a style reminiscent of pioneer barn raisings, provide the organizational structure that allows low-income families to build the homes they so desperately want and need. This includes the capital, training and supervision, coordination, accounting, and myriad of other technical skills necessary to any successful housing development effort.

The concept is straightforward: groups of 6–12 low-income families join together to pool their labor to build each other's homes, in the process building a neighborhood for their community, for their children, and for themselves. The future homeowners commit to completing 65 percent of the work necessary to build the homes. At Self-Help Enterprises, these families pour the concrete, frame the walls, and install electrical wiring, heating ducts, roof framing, as well as all finish, tile, paint, and trim. Reducing the labor cost of the home reduces the total cost of the home, enabling lower-income households to become homeowners and earn equity at the same time.

The economic benefits extend far beyond the individual homeowners. As contractors are hired to turn raw land into subdivisions, local vendors provide building materials and subcontractors complete technical work such as plumbing. Local governments receive building permit fees, and in the long term, property taxes from proud

homeowners. Rural communities, often plagued with an abundance of substandard housing, gain an expanding stock of good housing and the stability that comes to a community of homeowners.

In the San Joaquin Valley each year, as many as 120 hardworking families each commit 1,400 hours, 40 hours per week, week after week, through the heat of summer and the cold of winter, sharing the labor necessary to build homes for their neighbors, their children and themselves.

It is popular today to talk about the importance for homebuyers to have “skin in the game” as protection against failed mortgages. Mutual self-help families have more than skin in the game. They have skin, sweat, and occasionally a bit of blood as they invest themselves in the home of their dreams. And does it work? With 47 years of experience behind us, those of us at Self-Help Enterprises say “YES” unequivocally. Self-help homebuilders achieve remarkable stability. Despite being the lowest income of the Section 502 borrowers, our self-help homebuilders have lower delinquency rates and very low foreclosure rates.

No other path to homeownership for low-income families has proven to be as successful.

#### *Section 502 Direct Lending Program*

The Section 502 Direct Loan program is an equally important element of self-help housing, affording well-underwritten construction-to-permanent mortgages that finance the home from the start of construction to the final mortgage payment. But the reach of this model mortgage program goes far beyond self-help households.

Since the Housing Act of 1961, the USDA 502 Direct Loan Program has been a cornerstone of homeownership opportunity in rural America, with over 2 million homeowners seizing the opportunity for an affordable mortgage which would enable them to be homeowners in the town where they live and work. For a surprisingly low Federal budget cost, the 502 Direct mortgage is a well underwritten, affordable, no gimmicks financing for rural families who want to invest in homes and in their communities.

No other Federal home ownership program can match the profile of the families served by the section 502 direct loan program. The average income for families receiving direct loans is \$27,000. By law, 40 percent of families participating in the program have incomes that do not exceed 50 percent of the median income. For the past 2 years at Self-Help Enterprises, fully 60 percent of the borrowers have incomes below 50 percent of median.

Despite serving families with limited economic means, the section 502 direct loan program is the most cost effective affordable housing program in the Federal Government. In fiscal year 2011, the total per unit cost for a homeownership loan to a low income family was less than \$7,200. There are a number of reasons for this overall low cost to the Government. First, a low interest rate environment reduces the cost of borrowing. Less well known is a longstanding requirement to recapture subsidy when a house financed under section 502 is sold. Essentially a family and the Government share in the appreciation on a home, taking into account how long a family has lived in the house. Recapture provides a substantial return to the Government.

Although the Section 502 Direct Loan Program lends to families with limited incomes, the program has a record of success not only in creating affordable homeownership opportunity, but also protecting the Federal investment. For example, in 2010, USDA Rural Development in California foreclosed on a mere 57 mortgages out of a loan portfolio of nearly 10,000 loans. This is a foreclosure rate of just over 0.5 percent and stands in stark contrast to what is happening in the conventional market in California.

It has been stated that the Section 502 guarantee program is an alternative for families eligible for direct loans. It is not. The average annual income for families receiving the guarantee is \$48,000. The majority of the loan guarantees go to households with incomes at or above 100 percent of the median, and only about 5 percent of families receiving guarantees make between 60–70 percent of the median. With the inevitable end of the current low interest rate environment, interest rates on 502 Guarantee loans will once again rise, and the number of qualifying low income borrowers will drop, if not disappear altogether.

#### *Summary*

USDA's Rural Housing Service and the resources it delivers represent vital resources to the people and the economies of rural American communities so desperate for jobs. As the recession seems finally to be fading in some areas of the country, its grip on rural America is still devastatingly strong. This is no time to reduce the investment so important to the recovery of Rural America.

## PREPARED STATEMENT OF THE SELF-HELP HOUSING CORPORATION OF HAWAII

The Self-Help Housing Corporation of Hawaii is requesting the same allocations from fiscal year 2012 for the USDA Rural Development 502 Direct Loan Program, and the RD 523 Technical Assistance Mutual Self-Help Housing Program. With the average sales price for a single family house in Hawaii at \$550,000, there would be no affordable housing for homeownership in Hawaii without the USDA Rural Housing Programs. Because of the extreme gap of income levels for low income families in Hawaii and the average housing prices, even the "workforce" of Hawaii cannot afford homeownership without the subsidies offered by these programs.

Through the recent development of its 72 lot subdivision in a rural low income neighborhood, SHHCH is able to offer homeownership opportunities to 72 very low and low income families who will build their own houses through the mutual self-help housing program. SHHCH is providing more than 200 jobs with just this self-help housing project with the construction of the infrastructure, materials and equipment from building supply houses, and services from title companies, appraisers, insurance companies, lenders, etc. With the Federal funding of these programs acting as a catalyst, SHHCH has been able to leverage another \$11 million in private financing to undertake this development. Additionally, very low and low income families, who presently live in sub-standard, and severely crowded situations, not only improve their housing situations, but also gain equity; thereby, continuing to improve their lives.

The Self-Help Housing Corporation has built 591 self-help units throughout the State of Hawaii with firemen, policemen, teacher's aides, hospital workers, hotel workers, laborers, and those considered the "workforce" of Hawaii. Currently, in a remote rural area of Maui, SHHCH is assisting native Hawaiian low income families to build three and four bedroom houses through the RD 523 and RD 502 Direct Loan Programs. This is the first affordable housing program in Hana in 35 years. Some of these self-help builders have no electricity or potable water in their existing houses. Without these Rural Housing Programs, these families, and thousands of rural low income families across the country would continue to live in severely sub-standard conditions, some without electricity and potable water; conditions I saw as a Peace Corps volunteer in third world countries!

In the past 3 years more than 3,500 low income families in more than 37 States have built their own houses through the RD 523 Technical Assistance Program in tandem with the RD 502 Direct Loan Program. With a cost of approximately \$5,000 to subsidize the program over the entire 33 year amortization period, these programs are less expensive than rental subsidy programs. Through these programs not only does the family improve their living situation, gain equity, and learn invaluable skills in leadership, team work, and building skills, but the community benefits with a broadening of the tax base, an enhancement of property values, and an establishment of stable neighborhoods with well maintained houses. Every 100 homes built in this program results in 324 jobs, \$21.1 million infused in the local economy, and \$2.2 million paid in for tax revenues. These significant housing programs are assisting to rebuild the economy in rural areas.

I urge you, as at the leaders of our country, to consider funding such valuable community development programs at the fiscal year 2012 funding levels.

## PREPARED STATEMENT OF THE SCHOOL NUTRITION ASSOCIATION

The School Nutrition Association (SNA) strongly supports approval of the \$35 million requested by the Food and Nutrition Service for School Meal Equipment Grants. Many School Food Authorities (SFAs) throughout the Nation have a significant need to replace and upgrade their equipment, particularly as we all work to implement the final rule revising school lunch and school breakfast meal standards. Most importantly, new equipment will directly benefit the millions of children that school food service professionals serve each and every school day by enabling SFAs to provide more fruits and vegetables, and enabling SFAs to maintain, expand, and establish school breakfast programs throughout the Nation.

Mr. Chairman and Members of the Committee, SNA represents more than 55,000 members who provide high-quality, low-cost meals to students across the country. We appreciate your continuing support for all school meal programs. These programs are needed more than ever before and we want to work with you to improve the efficiency and integrity of school meals.

Our members are charged with several simultaneous tasks. First, they must provide the best meal possible. Second, they must provide the safest meal possible. Third, they must do so within extremely tight budget limits that often do not leave any resources for replacing and upgrading equipment on a regular basis.

School meals must be nutritious and varied in order to qualify for Federal reimbursement, and to maintain student interest. As a result of both the new meal pattern standards and requirements of the Healthy, Hunger-Free Kids Act of 2010, SFAs are required to serve both a greater volume and a wider array of fruits and vegetables. We are prepared to meet that challenge, but many SNA members will need additional refrigeration equipment, storage equipment, and food preparation equipment in order to meet these requirements. Equipment assistance is vitally needed to fully achieve the requirement for nutritious and varied meals.

Food safety is a tremendous responsibility. SNA members take great care to provide safe food for the benefit of each child, and for the integrity of school meal programs. Old equipment that is in need of constant repair or is scheduled to be replaced jeopardizes food safety. Equipment assistance is vitally needed to help ensure the continued provision of safe food.

And while we certainly recognize and respect the financial challenges facing the Federal budget, one school food service professional after another is prepared to tell you about the difficult budget situations they face in their States, their school districts, and their individual schools. Many areas that have traditionally been well off financially are facing significant budget difficulties. We see this in our schools every day as more and more students move from paid meals to reduced price meals to free meals as families face economic difficulties. As a consequence, school food service professionals are managing tighter and tighter budgets, and are forced to put off replacing and upgrading equipment more than they should. Equipment assistance is vitally needed to help SFAs deal with little or no local resources for replacing and upgrading equipment.

It is well known that the \$100 million provided by the American Recovery and Reinvestment Act, and the \$25 million provided as part of the fiscal year 2010 Agriculture Appropriations Act made a positive difference for the 6,500 successful applicants. Yet many more SFAs need to upgrade their equipment. There were 25,000 applications submitted for the prior program, with priority having been given to school districts where 50 percent or more students are eligible for free or reduced price meals.

As an example of what this prior funding accomplished, Burlington, Vermont, schools received several ARRA fund grants. Most went into walk-in coolers and one went into a Blodgett oven. The new walk-in coolers have given the Burlington schools the ability to provide more fresh fruits and vegetables to their students daily. Between the use of salad bars, the Fresh Fruit and Vegetable Program, breakfast, and after-school suppers and snacks they are now providing at least 8+ fruit and vegetable choices daily, to all students K-12. In addition, the increased refrigeration space has improved their food safety and storage capacity as well as reducing energy costs, noise and heat in their kitchens. The addition of the oven, which replaced a 25+ year old electric model, was not only more cost effective, but also reduced cooking times and improved food quality.

The amount requested as part of the fiscal year 2013 FNS budget is projected to assist up to 10,000 schools in 15 to 25 States make similar improvements.

We also would like to respectfully point out that many schools serving fewer than 50 percent free and reduced price meals need equipment assistance. While SNA understands the desire to prioritize who may be eligible for this assistance, schools serving fewer than 50 percent free and reduced price meals face the same budgetary problems and equipment needs. The prior program established an assistance scale for SFAs with less than 50 percent free and reduced price participation. If a school applying had less than 30 percent F&R, they would only have been reimbursed for 25 percent of the cost of the equipment. This discouraged SFAs from applying at all last time. The situation is further complicated by the Paid Equity requirement included in the Healthy, Hunger-Free Kids Act. This provision requires SFAs with meal prices below the Federal reimbursement rate to increase their prices, even if they are already covering all of their costs. SFAs are relying on paying students for most of their income, and find that any price increase usually means a drop in participation. This drop in participation makes it even harder for SFAs to derive sufficient revenue to replace equipment absent a full grant. We hope that FNS will have the flexibility to consider additional methods for prioritization of grant applications in addition to just meal participation rates.

We thank you for this opportunity to share our support for the requested \$35 million for School Meal Equipment Grants, and look forward to continue to work with you in the future.

## 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 Committee to increase the fiscal year 2013 budget authority (BA) appropriations (non-user fees) for the U.S. Food and Drug Administration (FDA) to \$2.656 billion, resulting in a 6 percent increase over 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.

SWHR, a national nonprofit organization based in Washington, DC, is widely recognized as the thought leader in research on sex differences and is dedicated to improving women's health through advocacy, education, and research. SWHR was founded in 1990 by a group of physicians, medical researchers and health advocates who wanted to bring attention to the myriad of diseases and conditions that affect women uniquely.

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 increase of \$150 million to FDA reflects the Agency's increased responsibilities and workload. Appropriate funding of the FDA by 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 dollar 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, over 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 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 post-market surveillance reporting for these differences is placed in the hands of physicians and ultimately the patient.

*FDA Must Improve Its IT 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 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 5 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 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 Office of Women's Health (OWH), like the Agency that houses it, requires 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. The OWH continues to provide women with invaluable tools for their health and ensure that the agency is examining sex and gender differences during its review of new drugs, devices, and biologics.

To address OWH's growing list of priorities, SWHR recommends that Congress support an additional \$1 million budget for OWH for fiscal year 2013 within the budget for the FDA. Each year, OWH exhausts its budget as OWH's pamphlets are the most requested of any documents at the Government printing 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's intramural research program funded over 23 new and 8 continuing research studies conducted by FDA scientists. To date, over 50 concept papers were submitted. OWH has also collaborated with CDRH to award a contract to Duke Research Institutes for prospective assessment of clinical and patient-reported outcomes for female patients undergoing percutaneous coronary intervention (PCI) procedures via femoral and radial access. Further, FDA OWH has worked closely with CDRH on its publication of the Draft Guidance on the Evaluation of Sex Differences in Medical Device Clinical Studies.

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 website is a vital tool for consumers and physicians. It is regularly updated to include new and important health information. The website provides free, downloadable fact sheets on over 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 provides imperative information to the medical communities in the form of web trainings to keep medical professionals up to date with emerging science. OWH developed Sex and Gender Differences in Health and Behavior, with assistance from the Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH) to develop the second in a web series of free courses on the "Science of Sex and Gender in Human Health". Developed in partnership with the Health Resources and Services Administration (HRSA), OWH developed online courses in health literacy to help promote best practices for improving patient/provider communication and addressing factors such as low health literacy that limit a patient's ability to safely use their medications.

#### *OWH 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 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 Committee for its strong record of support for the FDA and women's health. SWHR recommends for fiscal year 2013 BA appropriations (non-user fees) of \$2.656 billion 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 the Office of Women's Health for fiscal year 2013, and to ensure that future budget appropriations for the OWH never fall below fiscal year 2012 funding levels of \$6 million.

We look forward to continuing to work with the Committee 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 2013 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 USDA accounts:

- APHIS/Animal Welfare Act Enforcement—\$27,087,000;
- APHIS/Horse Protection Act Enforcement—\$891,000;
- APHIS/Investigative and Enforcement Services—\$16,275,000;
- FSIS/Horse Slaughter—language mirroring fiscal year 2012 House bill provision;
- FSIS/Humane Methods of Slaughter Act Enforcement—language directing FSIS to ensure that inspectors hired with funding previously specified for Humane Methods of Slaughter Act enforcement focus their attention on overseeing com-

pliance with humane handling rules for live animals as they arrive and are offloaded and handled in pens, chutes, and stunning areas;  
 —OIG/including Animal Fighting Enforcement—\$85,621,000;  
 —NIFA/Veterinary Medical Services Act—\$4,790,000;  
 —APHIS/Emergency Management Systems/Disaster Planning for Animals—\$1,017,000;  
 —APHIS/Wildlife Services Damage Management—reduce by \$10 million; and  
 —APHIS/Class B Dealers—language barring expenditures of funds for licensing or renewal of licenses of any Class B Dealers who sell dogs or cats for use in research, teaching, or testing.

At this time of intense budget pressure, we thank you for your outstanding past support for enforcement of key animal welfare laws by the U.S. Department of Agriculture and we urge you to sustain this effort in fiscal year 2013. 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 difference, helping to protect the welfare of millions of animals across the country and upholding the values of the American public. As you know, better enforcement also directly benefits American citizens by: (1) preventing the sale of unhealthy pets from unlawful commercial breeders, commonly referred to as “puppy mills”; (2) improving laboratory conditions that may otherwise impair the scientific integrity of animal-based research; (3) reducing risks of disease transmission from, and dangerous encounters with, wild animals in or during public exhibition; (4) minimizing injury, loss, and death of pets on commercial airline flights due to mishandling and exposure to adverse environmental conditions; (5) decreasing food safety risks to consumers from sick animals who can transmit illness, and injuries to slaughterhouse workers from suffering animals; and (6) dismantling orchestrated dogfights and cockfights that often involve illegal gambling, drug trafficking, human violence, and can contribute to the spread of costly illnesses such as bird flu. In order to continue the important work made possible by the Committee’s prior support, we request the following for fiscal year 2013.

*Animal and Plant Health Inspection Service (APHIS)/Animal Welfare Act (AWA) Enforcement*

We request that you support level funding of \$27,087,000 for AWA enforcement under APHIS. We commend the Committee for responding in recent years to the urgent need for increased funding for the Animal Care division. The funding has helped improve inspections by Animal Care of approximately 12,870 sites, including commercial breeding facilities, laboratories, zoos, circuses, and airlines, to ensure compliance with AWA standards. In May 2010, USDA’s Office of Inspector General 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. While Agriculture Secretary Vilsack called for more inspections and a tougher stance on repeat offenders, the agency must have the resources to follow through on that commitment. USDA is also implementing a new responsibility created by 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. Animal Care currently has 122 inspectors (with 14 vacancies that are in the process of being filled), compared to 64 inspectors at the end of the 1990s. An appropriation at the requested level would help the agency 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.

*APHIS/Horse Protection Act (HPA) Enforcement*

We request that you support \$891,000, the amount provided in last year’s Senate bill, for strengthened enforcement of the Horse Protection Act. 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. 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 Office of Inspector General 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 the USDA to do a better job enforcing this law. To meet the goal of the HPA, Animal Care inspectors must be present at more shows. Exhibitors who sore their horses go to great lengths to avoid detection—even fleeing shows when USDA inspectors arrive. With current funding Animal Care is able to attend only about 10 percent of the more than 500 Tennessee Walking Horse shows held annually. We greatly appreciate the enactment of a modest increase for Horse Protection Act enforcement last year (bringing the budget for this to \$696,000), the first time in decades that the program received more than \$500,000. An appropriation at the requested level will help ensure that this program doesn't lose ground but instead builds on last year's crucial first step in addressing the need for additional inspectors, training, security—for threats of violence against inspectors—and advanced detection equipment.

*APHIS/Investigative and Enforcement Services*

We request that you support level funding of \$16,275,000 for APHIS Investigative and Enforcement Services (IES). We appreciate the Committee's consistent support for this division. IES 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. An appropriation at the requested level would enable the agency to keep pace with the additional enforcement workload.

*Horse Slaughter*

We request inclusion of the same language barring USDA from the expenditure of funds for horse slaughter inspection as was included in the Committee's fiscal year 2012 Agriculture Appropriations bill. This provision is vital to prevent renewed horse slaughter activity in this country.

*Food Safety and Inspection Service (FSIS)/Humane Methods of Slaughter Act (HMSA) Enforcement*

We request language to ensure strengthened HMSA enforcement. We appreciate the Committee's inclusion of language in the fiscal year 2012 Committee report regarding humane slaughter. USDA oversight of humane handling rules for animals at slaughter facilities is vitally important not only for animal welfare but also for food safety. Effective day-to-day enforcement can prevent abuses like those previously documented in undercover investigations, and reduce the chance of associated food safety risks and costly recalls of meat and egg products. We therefore urge inclusion of language directing FSIS to ensure that inspectors hired with funding previously provided specifically for Humane Methods of Slaughter Act enforcement 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.

*Office of Inspector General/Animal Fighting Enforcement*

We request that you support level funding of \$85,621,000 for the Office of Inspector General (OIG) to maintain staff, ensure effectiveness, and allow investigations in various areas, including enforcement of animal fighting laws. We appreciate the Committee's inclusion of funding and language in recent years for USDA's OIG to focus on animal fighting cases. 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. Its work with State and local agencies to 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, is commendable. Dogs bred and trained to fight endanger public safety, and some dogfighters steal pets to use as bait for training their dogs. Also, in 2002–2003 cockfighting was linked to an outbreak of Exotic Newcastle Disease that cost taxpayers more than \$200 million to contain. Cockfighting has further been linked to the death of a number of people in Asia reportedly exposed 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 the Animal Welfare Act, the Horse Protection Act, and the Humane Methods of Slaughter Act and downed animal rules.

*National Institute of Food and Agriculture/Veterinary Medical Services Act*

We request that you support level funding of \$4,790,000 to continue the implementation of the National Veterinary Medical Service Act (Public Law 108-161). We appreciate that Congress is working to address the critical maldistribution 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. 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 support our Nation's defense against bioterrorism. The Centers for Disease Control estimates that 75 percent of potential bioterrorism agents are zoonotic—transmitted from animals to humans. Veterinarians 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 \$142,613 on average, with an average starting salary of \$66,469. 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 repay student debt. It also authorizes financial assistance for those who provide services during Federal emergency situations such as disease outbreaks.

*APHIS/Emergency Management Systems/Disaster Planning for Animals*

We request that you support level funding of \$1,017,000 for Animal Care 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 Animal Care division develops infrastructure to help prepare for and respond to animal issues in a disaster and incorporate lessons learned from previous disasters. Funds are used for staff time and resources to support the efforts of State, county and local governments and humane organizations to plan for protection of people with animals. They also enable the agency to participate, in partnership with FEMA, in the National Response Plan without jeopardizing other Animal Care programs.

*APHIS/Wildlife Services Damage Management*

We request that funding be reduced for Wildlife Services Damage Management by \$10 million. This is the amount that the USDA estimates it spends annually on lethal predator control to protect livestock. In light of record deficits, this is a wasteful subsidy that needs to be terminated. Under its "livestock protection" program, Wildlife Services provides taxpayer-subsidized wildlife extermination services to private agribusiness. USDA data show that less than 1 percent of livestock are killed by predators. Livestock producers and property owners—not U.S. taxpayers—should be financially responsible for protecting their property from damage attributed to wildlife. Expensive lethal control methods used by Wildlife Services such as aerial gunning, poisoning, and trapping are indiscriminate and ineffective, often killing non-target species including endangered species protected by Federal law and companion animals. Common sense non-lethal methods like the use of guard animals (e.g., llamas, dogs), lighting, penning, and good animal husbandry practices like shepherding are cheaper and proven more effective in reducing predation to livestock. Ranchers have no incentive to use these methods if the Federal Government continues to pay for unlimited lethal control. By cutting this wasteful and unnecessary program, we will ensure that U.S. taxpayers stop subsidizing lethal wildlife control for the benefit of private livestock producers and property owners.

*APHIS/Class B Dealers*

We also ask that you include a funding limitation as suggested below regarding Class B Dealers. A September 2010 Government Accountability Office report to Congress found that numerous Animal Welfare Act violations have been documented during inspections of Class B dealer facilities, seven of the nine licensed Class B dealers of live, random-source dogs and cats at that time had one or more violations, and several Class B dealers were under further investigation by the USDA because of repeated violations. The USDA is spending an inordinate amount of its limited resources in an attempt to regulate these Class B dealers, especially considering that a 2009 study by the National Academies—"Scientific and Humane Issues in the

Use of Random Source Dogs and Cats in Research”—found that Class B dealers are not necessary to supply random-source dogs and cats for NIH-funded research.

Requested bill language: “*Provided*, That appropriations herein made shall not be available for any activities or expense related to the licensing of new Class B dealers who sell dogs or cats for use in research, teaching, or testing, or to the renewal of licenses of existing Class B dealers who sell dogs or cats for use in research, teaching, or testing”.

Again, we appreciate the opportunity to share our views and priorities for the Agriculture, Rural Development, FDA, and Related Agencies Appropriation Act for Fiscal Year 2013. We are so grateful for the Committee’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.

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PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES—EQUINE PROTECTION

On behalf of the undersigned animal welfare and horse industry organizations, with combined supporters exceeding 12 million, and former Senator Joseph Tydings, we submit the following testimony seeking funding for the USDA/APHIS Horse Protection Program of \$891,000 for fiscal year 2013. We recognize that 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 \$891,000 is urgently needed to begin to fulfill the intent of the Horse Protection Act—to eliminate the cruel practice of soring—by allowing the USDA to strengthen its enforcement capabilities for this law.

In 1970, Congress passed the Horse Protection Act 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.

The Horse Protection Act 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 10 percent of Tennessee Walking Horse shows. So the agency set up an industry-run system of certified Horse Industry Organization (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, and has begun to work with the Department of Justice in prosecuting criminal cases as provided for under the act. In 2011, a Federal prosecutor sought the first-ever criminal indictments under the act and as a result, a well-known, winning trainer in the Spotted Saddle Horse industry is serving a prison sentence of over

1 year. A former Walking Horse Trainers' Association Trainer of the Year and winner of the Tennessee Walking Horse World Grand Championship was recently indicted on 52 counts (18 of them felony) of violating the act and is awaiting trial.

While these are significant actions which should have a deterrent effect, there are many other violators who go undetected, and many cases which go unprosecuted—all due to a lack of resources. USDA needs enhanced resources to carry out its responsibilities under this act, as Congress, and the public, expects.

In years past, inspections were limited to physical observation and palpation by the inspector. Protocols for the use of new technologies, such as thermography and “sniffer” devices (gas chromatography/mass spectrometry—or GC/MS—machines), have been implemented, which can help inspectors identify soring more effectively and objectively. The results of USDA’s recent GC/MS testing for prohibited foreign substances used by violators on the legs of horses (either to sore them, or to mask underlying soring and evade detection by inspectors) are staggering: 97.6 percent of the samples taken at various Tennessee Walking Horse competitions in 2011 tested positive for illegal foreign substances, and 86 percent tested positive in 2010.

Effective though this inspection protocol may be, due to budget constraints, USDA has been unable to purchase and put enough of this testing into use in the field, allowing for industry players to continually evade detection. In 2011, USDA was able to afford to collect and test samples at only three of the industry’s largest shows; in 2010, only five. With increased funding, the USDA could purchase more equipment and hire and train more inspectors to use it properly, greatly increasing its ability to enforce the HPA.

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. Armed security is frequently 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.

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.

The egregious cruelty of soring is not only a concern for animal protection and horse industry organizations, 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 . . . allocated to the USDA to enforce these rules and regulations.”

The USDA Office of Inspector General conducted an audit of the Horse Protection Program, and issued its final report in September 2010. The report recommends the abolition of the DQP program, and an increase in funding for APHIS enforcement of the Horse Protection Act. 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 would 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 the Horse Protection Act, the USDA still lacks the resources needed to end this extreme form of abuse. It is time for 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.

## UNDERSIGNED ORGANIZATIONS

Friends of Sound Horses, Inc.; former U.S. Senator Joseph Tydings; Animal Welfare Institute; American Society for the Prevention of Cruelty to Animals (ASPCA); American Horse Protection Association; American Horse Defense Fund; Plantation Walking Horses of Maryland; Red Rover; National Plantation Walking Horse Association; Plantation Walking Horse Association of California; United Pleasure Walking Horse Association; Gaitway Walking Horse Association; International Pleasure Walking Horse Registry; Sound Horse Outreach (SHO); One Horse At a Time, Inc. Horse Rescue; Northern California Walking Horse Association; Tennessee Walking Horse Association of Oklahoma; Pure Pleasure Gaited Horse Association; Northwest Gaited Horse Club; New York State Plantation Walking Horse Club; Northwest Pleasure Tennessee Walking Horse Association.

## PREPARED STATEMENT OF THE WILDLIFE SOCIETY

The Wildlife Society appreciates the opportunity to submit testimony concerning the fiscal year 2013 budgets for the Animal and Plant Health Inspection Service, National Institute of Food and Agriculture, Natural Resources Conservation Service, and Farm Service Agency. The Wildlife Society represents over 11,000 professional wildlife biologists and managers dedicated to sound wildlife stewardship through science and education. The Wildlife Society 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 President's request is a \$7 million decrease from fiscal year 2012 and a \$10 million decrease from fiscal year 2011. In recognition of the important work that Wildlife Services performs regarding methods development and wildlife damage management, we request that Congress appropriate \$94 million to Wildlife Services in fiscal year 2013.

A 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. We recommend funding Methods Development at \$18 million in fiscal year 2013.

*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 four to one, with a focus on private landowners. The need for RREA educational programs is greater than ever because of continuing fragmentation of land ownership, urbanization, diversity of landowners needing assistance, and increasing societal concerns about land use and increasing human impacts on natural resources. The Wildlife Society recommends that the Renewable Resources Extension Act be funded at \$10 million.

The McIntire-Stennis Cooperative Forestry Program is essential to the future of resource management on non-industrial private forestlands while conserving natural resources, including fish and wildlife. As the demand for forest products grows, 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-term 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 \$33 million in funding allocated in the fiscal year 2012 appropriations process and urge that amount to be continued in fiscal year 2013.

*Natural Resources Conservation Service*

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. The Natural Resources Conservation Service (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 2013 request for Conservation Operations is \$828 million, level with fiscal year 2012 but down from \$871 million in fiscal year 2011. Conservation Operation's Technical Assistance (TA) subactivity provides funding for NRCS to support implementation of the various farm bill programs. The fiscal year 2013 budget recommends level funding for TA, which is a decrease of \$26 million from the fiscal year 2011 level of \$755 million. The Wildlife Society encourages you to return funding for TA to the fiscal year 2011 level of \$755 million.

Overall, The Wildlife Society 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, 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 OMB that are more than what was historically allocated if NRCS is to fulfill congressional intent as expressed in the 2008 farm bill. Recently, Congress allowed the use of mandatory funds for TA and, under current economic conditions, The Wildlife Society believes that such funds must continue to be utilized for effective delivery to occur. The Wildlife Society urges 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 Congress to explore new ways of funding technical assistance in fiscal year 2013 and beyond.

The Wildlife Society also supports the continuation of funding 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.

The Wildlife Society recommends farm bill conservation programs be funded at levels mandated in the 2008 farm bill. 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 like to specifically highlight the Wildlife Habitat Incentive Program (WHIP), a voluntary program for landowners who want to improve wildlife habitat on agricultural, non-industrial, 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 appreciate the proposed increase in WHIP funding, to \$73 million in fiscal year 2013 from \$50 million in fiscal year 2012, but would urge Congress to fully fund WHIP at \$85 million.

The Voluntary Public Access and Habitat Incentives Program was first authorized in the Food, Conservation, and Energy Act of 2008 (2008 farm bill) for \$50 million for fiscal year 2008–2012, and was administered by the Farm Service Agency. This funding has expired, and the fiscal year 2013 budget includes \$5 million for the program within the NRCS budget. The Wildlife Society commends the administration for continuing to fund this program in fiscal year 2013. 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.

#### *Farm Service Administration*

The administration's request would increase funding for the Conservation Reserve Program (CRP) to \$2.2 billion in fiscal year 2013, up from \$2.07 billion in fiscal year 2012. This increase assumes a CRP enrollment of 6 million acres in 2012. The Wildlife Society applauds FSA efforts to have a 6 million acre general sign-up in 2012, and to more fully utilize CRP enrollment authority to address conservation needs. Lands enrolled in CRP are important for the conservation of 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 periodic compatible use in times when other livestock forage is limited due to drought or other

natural disasters. We strongly encourage Congress to fund CRP at a level that fully utilizes program enrollment authority through CRP general sign-up. We are pleased with and support the general sign-up and target enrollment of 6 million acres FSA included in the fiscal year 2012 budget. However, we are concerned about the proposed reduction in the acreage cap from 32 million to 30 million.

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. Please feel free to contact Laura Bies, Director of Government Affairs, at [laura@wildlife.org](mailto:laura@wildlife.org) if you need further information or have any questions.

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LETTER FROM THE USA RICE FEDERATION

MARCH 30, 2012.

Hon. HERB KOHL, Chairman,  
 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 2013 Agriculture Appropriations Requests

DEAR CHAIRMAN KOHL AND RANKING MEMBER BLUNT: This is to convey the rice industry's requests for fiscal year 2013 funding and related policy issues 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, Illinois, Kentucky, Louisiana, Mississippi, Missouri, Tennessee, 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. The rice industry annually supports about 128,000 jobs and more than \$34 billion of economic output nationally.

USA Rice understands the budget constraints the subcommittee faces when developing the fiscal year 2013 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 this year, is paid for, and represents a five-year contract with America's producers. USA Rice also strongly opposes reducing the farm-safety net to appropriate funds for other Federal programs. We urge that the President's fiscal year 2013 legislative proposals be rejected that would eliminate farm-bill commodity programs, change crop-insurance provisions, and reduce conservation-program funding. We also urge that the Natural Resources Conservation Service technical-assistance user-fee proposal be rejected.

A list of the programs the USA Rice Federation supports for appropriations in fiscal year 2013 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 \$4 in matching funds for each \$1 of FAS funds received. The USA Rice Federation uses MAP and FMD funding in over 20 markets to conduct successful export-market-development initiatives.

The Foreign Market Development Program allows USA Rice to focus on importer, foodservice, and other non-retail promotion activities around the world. This program should be fully funded for fiscal year 2013 at the authorized level of \$34.5 million.

The Market Access Program (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 2013 at the authorized level of \$200 million.

In addition, the Foreign Agricultural Service 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

Food-aid sales historically account for an important portion of U.S. rice exports. 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 2013 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.

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 U.S. 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 2013 budget estimate of \$170 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 strongly 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.*

#### PREPARED STATEMENT OF THE WISCONSIN WALNUT COUNCIL

Mister Chairman, Ranking Member and Members of the subcommittee, thank you for the opportunity to submit testimony for the record. I am writing to share my concerns regarding a recently recognized Thousand Cankers Disease (TCD) that poses an enormous economic and ecological risk to our Nation's black walnut resources. Over the past decade, TCD has caused the death of millions of black walnut trees in nine western States (Arizona, California, Colorado, Idaho, Oregon, New Mexico, Nevada, Utah, and Washington) and recently has been discovered in the native walnut range (Tennessee, Virginia and Pennsylvania). The USDA-APHIS has estimated the standing value of walnut timber as being \$539 Billion. This does not

include potential loss of: Jobs related to logging, transportation, and domestic milling; derivatives of the domestic milling industry to make veneer and lumber for furniture, cabinetry, paneling, flooring, and gun stocks; export market accounts for about 60 percent of the harvested logs; and nuts are shelled into nutmeats and the shells are processed for many industrial uses.

The negative economic impacts of TCD will be felt by private landowners with immature walnut timber and by home owners with millions of walnut trees in residential areas of the Midwest and Eastern States. It will be any ugly site and very expensive to safely remove all the walnut trees as they succumb to TCD over the next couple of decades if this disease is not contained, suppressed, and locally eradicated. Research efforts to date have been limited to monitoring, ecological studies of the walnut twig beetle, epidemiology of the fungal pathogen, and development of phytosanitation treatment of walnut logs harvested in quarantined areas. Insecticide and fungicide application is not feasible or practical as a means of controlling the spread of TCD. Development of biological insect control of the walnut twig beetle is expected to be the most effective and feasible technique in stopping the advancement of TCD through the native range of black walnut.

While States are attempting to stop the spread of TCD through surveys and quarantines, greater Federal assistance and funding are needed. I request dedicated funding be allocated to the USDA-ARS for leadership in the development of biological insect control techniques of the walnut twig beetle and to the USDA-FS for continued efforts in monitoring for TCD for fiscal year 2013.

*What Is TCD?*

TCD is a recently recognized disease in which a tiny walnut twig beetle (*Pityophthorus juglandis*) spreads a fungal organism (*Geosmithia morbida*) that causes cankers under the bark which prevents nutrient flow to the foliage leading to dieback of branches and ultimately death to the tree. While the walnut twig beetle advances only a mile or two per year, humans are the vector that spread TCD great distances within days by hauling walnut slabs with fresh bark attached that harbor the tiny beetles and fungal spores. Such shipments are believed to be the reason TCD moved into the native walnut range from the western States. Movement of firewood, logs, stumps, and burls with fresh bark attached can spread the disease great distances.

*Need for Greater Federal Funding and Specific Directives*

The USDA-APHIS considers both the walnut twig beetle and the fungal pathogen to be indigenous to the USA (historical evidence shows them to reside on a different walnut species in Arizona and New Mexico). Since neither is considered exotic to the USA, APHIS is not productively serving any role in combating TCD.

Federal funding needs to be directed to the USDA-ARS to lead research and development of techniques that will contain, suppress, or potentially locally eradicate the walnut twig beetle. Additional funding needs to be directed to the USDA-FS for continued effort in monitoring and development of phyto-sanitization treatment of walnut logs harvested in quarantined areas.

I thank the committee for this opportunity to provide testimony on this important subject. Please do not hesitate to contact me if you should require additional information.

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LETTER FROM THE WYOMING STATE ENGINEER'S OFFICE

HERSCHLER BUILDING, 4-E,  
Cheyenne, Wyoming, March 29, 2012.

Hon. HERB KOHL, Chairman,  
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: Support for Designation to the Colorado River Basin Salinity Control Program of Not Less Than \$18 Million of the Total Environmental Quality Incentives Program (EQIP) Funding Recommended in the President's Fiscal Year 2013 Budget

DEAR CHAIRMAN KOHL AND RANKING MEMBER BLUNT: This letter is sent in support of the designation of \$18 million of the fiscal year 2013 Environmental Quality Incentive Program (EQIP) funding for the Department of Agriculture's (USDA's) Colorado River Salinity Control (CRSC) Program. Realizing that agricultural on-

farm strategies<sup>1</sup> provided some of the most cost-effective strategies to control salinity, the Congress in 1984 directed the USDA to implement its CRSC Program. Since enactment of the Federal Agriculture Improvement and Reform Act of 1996 (FAIRA; Public Law 104-127), the USDA's CRSC Program is a component program within EQIP. Wyoming views the inclusion of the CRSC Program in EQIP as a congressional recognition of the Federal obligation and commitment to maintaining the EPA-adopted, basin-wide water quality standards for salinity in the Colorado River. The USDA has played a vital role in meeting that commitment over the past 25 years we have observed and encouraged Agriculture's efforts effectively reducing salt loading into the Colorado River system through proven and cost-effective irrigation water application and management practices. Each of the seven Colorado River Basin States, acting collectively through the Colorado River Basin Salinity Control Forum, have actively assisted the U.S. Department of Agriculture in implementing its unique, collaborative and important program.

Established in 1973, the seven State Colorado River Basin Salinity Control Forum coordinates with the Federal Government on the maintenance of the basin-wide Water Quality Standards for Salinity in the Colorado River System. The Forum is composed of gubernatorial representatives and serves as a liaison between the seven States and the Secretaries of the Interior and Agriculture and the Administrator of the Environmental Protection Agency. The Forum advises the Federal agencies on the progress of efforts to control the salinity of the Colorado River. Its annual recommendation process includes suggesting to the Department of Agriculture the funding amount the Forum believes USDA should expend in the subsequent 2 years for its CRSC Program. The combined efforts of the Basin States, the Bureau of Reclamation and the USDA have resulted in one of the Nation's most successful nonpoint source control programs.

The Colorado River provides municipal and industrial water for nearly 33 million people and irrigation water to approximately 4 million acres of land in the United States. The River is also the water source for some 3 million people and 500,000 acres in Mexico. The high concentration of total dissolved solids (e.g., the water's salinity concentration) in the water limits users' abilities to make the greatest use of this water supply. This remains a major issue and continuing concern in both the United States and Mexico. The water's salinity concentration especially affects agricultural, municipal, and industrial water users. The Bureau of Reclamation presently estimates direct and computable salinity-related damages in the United States amount to more than \$300 million per year.

At its recent October 2012 meeting, the Forum recommended that the USDA CRSC Program expend not less than \$18 million of the Environmental Quality Incentive Program's funding. In the Forum's judgment, this funding is necessary to implement one of the most successful Federal/State cooperative nonpoint source pollution control programs in the United States.

The State of Wyoming greatly appreciates the Subcommittee's support of the Colorado River Salinity Control Program in past years. We continue to believe this important basin-wide water quality improvement program merits support by your Subcommittee. We request that your Subcommittee direct the allocation of \$18 million of the Environmental Quality Incentives Program funding for the USDA's CRSC Program during fiscal year 2013. Thank you in advance for your consideration and this statement's inclusion in the record for 2013 appropriations.

Respectfully submitted,

PATRICK T. TYRRELL,  
*Wyoming State Engineer,  
Member, Colorado River Basin,  
Salinity Control Forum.*

DAN S. BUDD,  
*Interstate Stream Commissioner,  
Member, Colorado River Basin,  
Salinity Control Forum.*

<sup>1</sup> These strategies include reducing deep percolation of irrigation water through salt-bearing shale formations below farmlands across the Upper Colorado River Basin through improving irrigation water application efficiency by changing from flood and furrow irrigation methods to gated pipe, side-roll sprinkler and center-pivot sprinkler and low-energy, precision application (LEPA) irrigation practices.

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