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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2014

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

ROBERT B. ADERHOLT, Alabama, *Chairman*

TOM LATHAM, Iowa
ALAN NUNNELEE, Mississippi
KEVIN YODER, Kansas
JEFF FORTENBERRY, Nebraska
THOMAS J. ROONEY, Florida
DAVID G. VALADAO, California

SAM FARR, California
ROSA L. DELAURO, Connecticut
SANFORD D. BISHOP, JR., Georgia
CHELLIE PINGREE, Maine

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

MARTIN DELGADO, TOM O'BRIEN, BETSY BINA,
PAM MILLER, and ANDREW COOPER,
Staff Assistants

PART 5

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Food and Drug Administration	**177**

Printed for the use of the Committee on Appropriations

PART 5—AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2014

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AGRICULTURAL, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2014

THURSDAY, APRIL 25, 2013.

U.S. DEPARTMENT OF AGRICULTURE FARM AND FOREIGN AGRICULTURAL SERVICES

WITNESSES

MICHAEL SCUSE, UNDER SECRETARY, FARM AND FOREIGN AGRICULTURAL SERVICES
JUAN GARCIA, ADMINISTRATOR, FARM SERVICE AGENCY
SUZANNE HEINEN, ADMINISTRATOR, FOREIGN AGRICULTURAL SERVICE
BRANDON WILLIS, ADMINISTRATOR, RISK MANAGEMENT AGENCY
MICHAEL YOUNG, BUDGET OFFICER, DEPARTMENT OF AGRICULTURE

INTRODUCTION OF WITNESSES

Mr. ADERHOLT. Good morning. Our subcommittee will come to order. We appreciate everyone being here this morning for your testimony before the Subcommittee.

We will begin our review of the fiscal year 2014 budget request from the agencies of USDA's Farm and Foreign Agricultural mission area.

While the FDA appropriation hearing is tomorrow and it will be our last regularly scheduled appropriation hearing, today is our last of nine USDA budget hearings for fiscal year 2014.

I want to welcome Mr. Michael Scuse, USDA Under Secretary for Farm and Foreign Agricultural Services; Mr. Juan Garcia, Administrator, Farm Service Agency; Ms. Suzanne Heinen, Administrator, Foreign Agricultural Service; Mr. Brandon Willis, Administrator, Risk Management Agency; and last but not least, Mr. Mike Young, USDA's Budget Director.

OPENING STATEMENT

Many of our fellow Americans do not see the behind the scenes of this mission area, though the vital programs managed by these agencies help farmers, ranchers and growers produce an abundant supply of diverse foods for the United States and people around the globe.

From the farm operating loans for beginning farmers to crop insurance needed to manage financial risk to the agricultural attache in foreign countries fighting for the U.S. market share, we expect

this mission area to provide many services that are critical to the backbone of our agricultural economy.

The ongoing challenge for this Subcommittee is to provide limited resources to the highest priority needs of agriculture and often times the priority with the greatest return on investment.

As your testimony points out, this mission area has made a number of positive steps to control costs, one being the closing of 125 field offices and two overseas offices, condensing the number of reporting dates for reporting acreage and crop data, and reducing staffing levels by using existing authorities.

You also have a positive story to tell on trade. That being said, there is always room for improvement in the way USDA manages the American taxpayer dollar.

The fiscal year 2014 President's budget for Farm and Foreign Agricultural Services mission area seeks total discretionary funding of $2.032 billion, of which approximately $1.59 billion is for the Farm Service Agency programs, and $373.3 million is for the Foreign Agricultural Service programs.

While there are smaller increases and decreases, the one major change is on the discretionary side, a proposal to fundamentally change the nearly 60 year old Food for Peace program in this appropriation by transferring nearly $1.4 billion to USAID.

Additionally, with just a two percent increase in loan support, the request estimates a 22 percent increase in loan authorizations for farm ownership and operating loans. This backing will help an additional 34,000 farmers and ranchers.

We look forward to getting answers to a number of questions that we have on the President's request.

Before I recognize you, Mr. Scuse, for your opening statement, I would like to ask the Ranking Member of the Subcommittee, the gentleman from California, for any opening comments he may have.

Mr. FARR. Mr. Chairman, I always look forward to these hearings. We have essentially people who administer the ground level in America, the most basic production of the lands that produce our agriculture and carrying that agriculture all the way to its furthest point on earth, in all the countries we have international relations and offices with, so we really can market our products abroad.

A lot of my questions are going to be about how you use your authorities. I have been on this Committee a long time. Every year we go through this.

What I think the Federal Government and Secretary Vilsack is keen on is trying to build the capacities by building sort of local capacity.

I want to focus on some of those issues, about how to use your authorities as a carrot stick to kind of encourage local capacity building, whether it be the local level or the foreign level.

I appreciate you coming today and I appreciate your testimony. Thank you, Mr. Chairman.

Mr. ADERHOLT. Thank you, Mr. Farr.

If anybody has any electronic devices, if they could put those on mute during the hearing.

Also, let me just say not only to you, Under Secretary Scuse, but also to all our panel, members are going to be coming and going

because we have 12 appropriation bills that we are working on simultaneously.

Inevitably, there are going to be hearings that take place at the same time, so if members come in and out, it is nothing you said. It is just part of the process. Please understand that.

Without objection, your entire written testimony will be included in the record. I will now recognize you, Mr. Under Secretary, for your opening comments, and then we will proceed with the questioning.

OPENING STATEMENT

Mr. SCUSE. Mr. Chairman, Ranking Member, I would like to thank both of you for your opening comments this morning. It is refreshing that we have those that understand what the Farm and Foreign Agricultural Service does and the importance that it plays in the lives of Americans.

I would like to thank all the members of the Subcommittee for being here today, and I am pleased to be with you today to present the 2014 budget and program proposals for the Farm and Foreign Agricultural Services.

As you pointed out, Mr. Chairman, accompanying me today is Brandon Willis, Administrator of the Risk Management Agency; Suzanne Heinen, Administrator of the Foreign Agricultural Service; Juan Garcia, Administrator of the Farm Service Agency.

Also with me today is Michael Young, Director of the Department's Office of Budget and Program Analysis.

Mr. Chairman, we appreciate the difficulties of today's budget environment and the need to reduce the Federal deficit.

We have reviewed our programs and developed proposals that will streamline our operations, improve efficiency, and reduce our administrative costs.

Turning to the Farm Service Agency, the budget request for salaries and expenses of FSA is $1.6 billion, which is a decrease of $179 million since 2012. The request reflects our focus on streamlining processes, investing in more efficient systems, and evaluating our internal costs to maximize efficiency.

FSA provides a broad range of services for American agriculture, disaster assistance, income support payments, marketing assistance loans, and certain conservation programs.

FSA also plays a critical role in our nation's agricultural production by providing a variety of direct loans and loan guarantees to farm families who are temporarily unable to obtain the credit they need.

For the Farm Credit Program, the budget proposes a program level of about $5.6 billion, an increase of about $1 billion from 2012, at a subsidy cost that is about $16 million less.

The request reflects the ongoing credit needs of beginning and minority farmers.

For the 2012 crop year, the Risk Management Agency through the Federal Crop Insurance Program provided a record $117 billion in protection, which is on a record 282 million acres of farm land.

Due to the widespread drought and other natural disasters that impacted agricultural producers during the crop year, the program

has paid out more than $16 billion in indemnities to producers, which is also a record.

Our current projections for the 2013 crop year are liabilities will decline to about $82 billion, largely the result of lower commodity price projections.

For the salaries and expenses of RMA, the budget requests $71 million to support 455 employees, compared to 2010's $80 million appropriation that supported 528 employees. It is a reduction of about 11 percent and 14 percent, respectively.

The Foreign Agricultural Service leads the Department's efforts to expand and preserve overseas markets and foster global food security.

The budget is designed to ensure that FAS has the resources needed to represent American agriculture and create new market opportunities overseas.

The budget provides $179 million for FAS salaries and expenses, about $7 million below 2011.

For trade expansion and promotion activities, the budget does include $200 million for the market access program. Other trade promotion activities such as foreign market development are subject to re-authorization and their appropriation levels will be set in the next Farm Bill.

For International Food Aid, the budget includes $185 million for McGovern-Dole and $255 million for Food for Progress.

For P.L. 480, Title II, the budget provides $1.47 billion in the accounts of USAID rather than USDA, consistent with the Administration's food aid reform proposals.

I would like this morning to make two announcements, two very important announcements, working with OMB, we have received our Section 714 funding, and we will not be furloughing any of the staff for the Farm Service Agency.

The second announcement is that we have been working for several years on our modernization project for our Farm Service Agency County Offices. I would like to announce before this Committee today that program is live nationwide.

We now have this morning 3,300 users using the MIDAS Program. By the end of the day, there will be another 2,200 added for a total of 5,500 users nationwide using our modernization program, and within the next 30 days, we fully expect to have everyone across the United States fully trained and tested to use that program.

I want to thank this body and Members of Congress for their support, financial and otherwise, in helping us reach this major milestone on a project that was desperately needed to help our County Office staff, and get rid of a system that was antiquated, to say the very least.

Again, thank you.

[The information follows:]

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House Committee on
Appropriations

Statement by Michael T. Scuse
Under Secretary for
Farm and Foreign Agricultural Services
Before the House Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies

Mr. Chairman and Members of the Sub Committee, I am pleased to appear before you today in order to present the 2014 budget and program proposals for the Farm and Foreign Agricultural Services (FFAS) mission area of the Department of Agriculture (USDA). I am accompanied by the Administrators of the three agencies that comprise our mission area: Brandon Willis, Administrator of the Risk Management Agency; Suzanne Heinen, Administrator of the Foreign Agricultural Service; and Juan Garcia, Administrator of the Farm Service Agency. We also are accompanied by Michael Young, Director of the Office of Budget and Program Analysis.

Statements by each of the Administrators providing details on the agencies' budget and program proposals for 2014 already have been submitted to the Committee. My statement will summarize those proposals, after which we will be pleased to respond to your questions.

Mr. Chairman, the FFAS mission area carries out a diverse array of programs and services that support a competitive agricultural system and provide the foundation for prosperity throughout rural America. Price and income support, farm credit assistance, conservation and environmental incentives, risk management tools, and trade expansion and export promotion–provide a critical safety net for our producers and have spurred record exports. The importance of this safety net has been apparent particularly during the 2012 drought, the worst since the 1930s.

The 2014 budget reflects a number of legislative proposals that would reduce the deficit by $38 billion over ten years compared to current baseline spending. Several of these proposals

affect the programs of this mission area. These proposals lower the deficit while maintaining a strong safety net for American agriculture. The savings would result, in part, from eliminating direct farm payments, decreasing payments to crop insurance companies and premium subsidies to producers, and capping the Conservation Reserve Program at 25 million acres. The budget also proposes to extend some disaster assistance programs for the 2014 through 2018 crops and provides additional assistance to dairy farmers through expansion of the dairy gross margin insurance program.

Also reflected in the budget is the Department's *Blueprint for Stronger Service*. Since 2009, USDA has undertaken historic measures to save more than $700 million in taxpayer funds through the streamlining and modernization of management and operations. These improvements have allowed the Department to strengthen its mission of building a stronger middle class and economy in rural America and to continue the success of American agriculture. The *Blueprint for Stronger Service* takes a realistic view of the needs of American agriculture in a challenging budget climate, and outlines USDA's plans to renew and accelerate the delivery of services and enhance the customer experience through the use of up-to-date technologies and business solutions. Ultimately, these improvements will help producers and rural businesses drive America's economy and respond to 21st century challenges.

Today, American agriculture is strong, with record income and exports over the past four years. During that period, our mission area has worked hard to do more with less, to manage current and future budget challenges, and to ensure that critical investments in rural America continue. Specifically, FFAS has taken a variety of steps to cut costs and improve services, including:

- Saved $4 billion over 10 years with the negotiation by RMA of a new standard reinsurance agreement for the Federal Crop Insurance Program;
- Cut travel, printing and supplies budgets;
- Cut burdensome paperwork for farmers and administrative costs for RMA and FSA condensing 70 common dates down to 15 for reporting acreage and crop data;
- Consolidated 125 Service Centers in compliance with the 2008 Farm Bill while improving high quality service from the remaining 2,100 plus offices;

- Closed two overseas locations while strengthening trade policy, trade promotion, and capacity building efforts in 96 international locations; and
- Implemented employee buy-out and early-out authorities. All three agencies are operating with fewer staff. Staffing levels in FSA have declined 32 percent since 2003; and, during the past decade RMA staff years declined by nearly eight percent, while the value of insurance protection has more than tripled.

Farm Service Agency

FSA provides producers with a broad range of helpful services, such as farm ownership and operating loans, disaster assistance, income support payments, commodity marketing assistance loans, and certain conservation programs, such as the Conservation Reserve Program (CRP). FSA administers discretionary programs as well as mandatory programs that are funded through the Commodity Credit Corporation (CCC).

Salaries and Expenses

The 2014 budget requests $1.49 billion for salaries and expenses from appropriated sources, including credit reform transfers. This level is adequate to maintain a staffing level of 4,436 Federal staff years and 7,980 non-Federal staff years.

We are grateful for the Committee's support for FSA's efforts to upgrade its aging information technology. FSA continues to implement paperless, web-based services and more streamlined business applications for more timely, more accurate, and more reliable service to farmers and ranchers. This year, FSA expects to reach its target of 76 percent of FSA programs with web-enabled applications and plans to boost this to 88 percent in 2014.

The 2014 budget also recommends $65.5 million in funding for the continued development and operation of MIDAS (Modernize and Innovate the Delivery of Agricultural Systems). In 2012, FSA developed the first version of MIDAS and began testing the system

to prepare for implementation. After user training is complete, the first versions of the MIDAS system will begin to operate in FY 2013 and will provide farm records, customer data, and acreage reporting with GIS mapping capability. For the first time, FSA staff will have access to this data through a single operating system, eliminating the need for staff to re-enter data because the systems were not interlinked. This change alone will speed the application process, reduce input errors, and improve program compliance and integrity.

Commodity Credit Corporation

The farm commodity price and income support programs are financed through the CCC, a Government corporation for which FSA provides operating personnel. CCC also provides funding for conservation programs, including CRP and certain programs administered by the Natural Resourees Conservation Service. CCC also funds some export promotion and foreign food aid activities administered by FAS. The commodity programs were mandated by provisions of the 2008 Farm Bill. The American Taxpayer Relief Act of 2012 (ATRA) extended the authority to operate some Farm Bill programs through 2013.

Under provisions of current law, CCC outlays are projected to be $10.1 billion in 2013 and $9.1 billion in 2014, down from the record high of $32.3 billion in 2000. The reductions since 2000 are due primarily to reduced commodity program outlays, reflecting higher prices for most commodities. Commodity prices are expected to remain relatively robust into 2014 resulting from strong exports and demand for production of bio-based products and bio-energy. The increase in CCC outlays from 2012 to 2013 reflects 2008 Farm Bill changes which eliminated the option for producers to receive advance direct payments. This shifted some direct payments that would have been paid in 2012 into 2013.

Conservation Reserve Program

CRP is a voluntary program that provides annual rental payments and cost-share assistance to agricultural producers in return for establishing long-term plant cover on

highly erodible and other environmentally sensitive farmland. CRP assists farm owners and operators to conserve and improve soil, water, air, and wildlife resources. Since CRP began in 1985, over eight billion tons of soil has been prevented from eroding, with an estimated 308 million tons in 2012 alone. Approximately 200,000 stream miles are protected with CRP riparian and grass buffers.

Twenty seven million acres were enrolled in CRP as of March 2013. In 2012, FSA held a general sign-up, accepting 3.9 million acres while contracts expired on 6.5 million acres. ATRA provided USDA the authority to enroll new acres in CRP through 2013. Contracts on 3.3 million acres will expire at the end of 2013; however, USDA will hold a general sign-up from May 20 to June 14, 2013. FSA also offers "continuous" signup, which now makes up about 20 percent of total CRP acreage. The budget baseline projects CRP enrollment will end at about 27.6 million acres for 2014.

Farm Loan Programs

FSA plays a critical role for our Nation's agricultural producers by providing a variety of direct loans and loan guarantees to farm families who would otherwise be unable to obtain the credit they need to continue their farming operations. By law, a substantial portion of the direct and guaranteed loan funds are reserved each year to assist beginning, limited resource, and socially disadvantaged farmers and ranchers. In 2012, 66 percent of direct loan funds went to beginning farmers. To further assist small and socially disadvantaged farmers, FSA recently implemented a streamlined microloan program, under the authorities of the direct operating loan program.

The 2014 budget proposes a total program level of about $5.6 billion. Of this total, over $1.9 billion is requested for direct loans and about $3.7 billion for guaranteed loans offered in cooperation with private lenders. These levels reflect credit usage forecasts at the time the budget was developed. Due to the excellent performance of the farm loans portfolio,

we will be able to provide this level of assistance with just $92 million in budget authority. With this funding, we will be able to serve about 34,000 farmers and ranchers.

Risk Management Agency

The Federal crop insurance program represents the primary risk-mitigation tool available to our Nation's agricultural producers. It provides risk management tools that are market driven and reflect the diversity of the agricultural sector; including, specialty crops, organic agriculture, forage and rangeland, as well as traditional row crops.

Over its 75 year history, the value of the Federal crop insurance program to American agriculture has grown. In 2012, the crop insurance program provided coverage on more than 282 million acres of farm and ranch land and protected nearly $117 billion of agricultural production. This represents a 10-fold increase from the $11 billion in crop insurance protection provided just two decades ago. We currently project that indemnity payments to producers on their 2012 crops will be about $16 billion on a premium volume of about $11 billion. Our current projection for the 2013 crop year shows the value of protection will decline, to about $82 billion. The decline is based on the Department's November 2012 estimates of planted acreage and expected changes in market prices for the major agricultural crops.

The 2014 budget requests an appropriation of "such sums as are necessary" as mandatory spending for all costs associated with the program, except for Federal salaries and expenses. This level of funding will provide the necessary resources to meet program expenses at whatever level of coverage producers choose to purchase. For salaries and expenses of the RMA, $71 million in discretionary spending is proposed to support 455 employees. Compared to 2010's $80 million appropriation that supported 528 employees, it is a reduction of nearly 11 percent and about 14 percent, respectively.

Foreign Agricultural Service

Agricultural trade significantly contributes to the prosperity of local and regional economies across rural America through increased sales and higher commodity prices. USDA estimates that every $1 billion of agricultural exports generates $1.3 billion in economic activity and supports 6,800 American jobs throughout the economy. The Department, with the FFAS mission area in the lead, plays an important role to remove agricultural trade barriers, develop new markets, and enhance the competitive position of U.S. agriculture in the world marketplace.

U.S. farm exports reached $135.8 billion in fiscal year 2012, the second highest total on record, and the agricultural trade surplus reached $32.4 billion. The fiscal year 2013 forecast for U.S. agricultural exports was recently revised to $142 billion – the highest total on record. In 2013, agricultural exports are expected to contribute a positive trade balance of $29.5 billion to the Nation's economy. For U.S. agriculture to continue to thrive, we must continue to open, expand, and maintain access to foreign markets, where 95 percent of the world's consumers live.

Fiscal years 2009 through 2012 represent the strongest four years in history for agricultural trade. To achieve this, USDA worked with the Office of the U.S. Trade Representative, the Department of Commerce, the White House, Congress and industry stakeholders to gain approval for new trade agreements with Panama, Columbia, and South Korea. These agreements will result in an estimated $2.3 billion in additional agricultural trade each year and support nearly 20,000 domestic jobs. Since 2009, the United States has also entered into free trade agreements with Jordan, Oman and Peru; and an organic equivalency agreement with the European Union. This progress will be continued under President Obama's National Export Initiative, which has set a goal to double U.S. exports by the end of 2014.

Today, FAS trade negotiators are involved in two major negotiations: the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP). The TPP is an opportunity to shape a high-standard trade agreement in a region that represents more than 40 percent of global trade. Key objectives in the TTIP negotiations are to eliminate duties on agricultural goods and eliminate or reduce trade distorting non-tariff barriers between the United

States and the EU, currently our fifth largest agricultural export market. Expanding markets abroad creates more jobs and boosts the bottom line for companies all along the supply chain.

As we work to open new and maintain existing markets overseas, we face many challenges and barriers that must be addressed. In the past year, FAS and has been instrumental in resolving numerous sanitary, phytosanitary and technical barriers to trade. USDA efforts to remove trade barriers led to billions of dollars in additional U.S. exports around the world in FY 2012. We've expanded beef market access with Japan, Mexico, and Hong Kong. We've removed barriers in the Korean market to U.S. cherries - U.S. cherry exports to Korea for the 2012 season totaled nearly $74 million, compared to $39 million in the previous year. We have also participated in negotiations with the European Union that resulted in the elimination of its ban on the use of lactic acid as a pathogen reduction treatment on beef and discussions that led authorities in Taiwan to adopt and implement a maximum residue limit for ractopamine in beef. Monthly shipments of U.S. beef to Taiwan more than doubled from $2 million to $5 million per month and remain at record levels.

The FFAS mission area also makes a significant contribution to the Department's strategic goal of enhancing global food security. Through foreign food assistance, technical assistance, training, and capacity building activities, we are working closely with other U.S. departments and agencies to address global food insecurity. USDA is well positioned to encourage the adoption of new technologies and production practices that can help increase the availability of food and improve its marketing and distribution.

Salaries and Expenses

FAS is the lead agency for the Department's international activities and is in the forefront of our efforts to expand and preserve overseas markets and foster global food security. FAS carries out its activities through a network of 96 overseas offices and its headquarters staff here in Washington. FAS overseas staff represents American agricultural interests world-wide.

The 2014 budget is designed to ensure that FAS has the resources needed to continue to represent and advocate on behalf of American agriculture on a global basis and to create new market opportunities overseas. The budget provides a program level of $185 million. This level of funding is expected to be sufficient to maintain the agency's overseas presence at current levels. The budget reflects ongoing cost avoidance in headquarters through the continuation of a hiring freeze and further reductions to travel and training.

In 2012, under the *Blueprint for Stronger Service*, FAS closed two overseas offices. The 2014 budget provides an increase of $1.5 million for higher operating costs at the agency's overseas posts, including increased payments to the State Department for administrative and security services provided at overseas posts. FAS has no administrative staff overseas and, therefore, relies on the State Department for those services.

International Food Assistance

For the McGovern-Dole International Food for Education and Child Nutrition Program, the 2014 budget provides funding of $185 million. The requested level is expected to assist as many as 4.3 million women and children during 2014. About 34 million children throughout the world have now received benefits from the McGovern-Dole program and its predecessor, the Global Food for Education Initiative.

The 2014 budget proposes to replace $1.47 billion in funding for P.L. 480 Title II food assistance with an equivalent amount in U.S. Agency for International Development accounts, including International Disaster Assistance (IDA). The proposed reform replaces Title II funding with robust levels of flexible emergency food aid and related development funding, with the goal of making food aid more timely and cost-effective. The reform will improve program efficiencies and performance by shifting resources to programs that will allow greater ability to use the right tool at the right time for responding to emergencies and chronic food insecurity. The tools include interventions such as local and regional purchase, cash vouchers and transfers, and cash for work programs. As part of the reform proposal, appropriations language is included

requiring that at least fifty-five percent of the requested FY 2014 IDA emergency food aid funding be used for the purchase and transport of U.S. agricultural commodities.

Food assistance will also be provided through the Food for Progress program that FAS administers. The 2014 budget includes an estimated program level of $255 million for this CCC-funded program, which supports the adoption of free enterprise reforms in the agricultural economies of developing countries.

Export Promotion and Market Development Activities

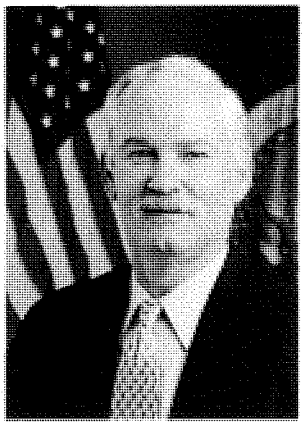
The CCC export credit guarantee programs (GSM-102 and Facilities Guarantee) provide payment guarantees for the commercial financing of U.S. agricultural exports. The guarantees facilitate sales to buyers in countries where credit is necessary to maintain or increase U.S. sales. For 2014, the budget includes a program level of $5.5 billion for the CCC export credit guarantee programs.

For the foreign market development programs, the budget includes a program level of $200 million for the Market Access Program. The remaining programs, including the Emerging Markets Program, Foreign Market Development Program, and Technical Assistance for Specialty Crops Program are subject to reauthorization and funding levels are expected to be established in the next Farm Bill.

Mr. Chairman, this concludes my statement. Thank you for the opportunity to present our 2014 budget and program proposals. The Administrators and I would be pleased to answer any questions you and other Members of the Committee may have.

Under Secretary of Agriculture

Farm and Foreign Agricultural Services



Michael Scuse

Michael Scuse was named USDA Under Secretary for Farm and Foreign Agricultural Services on May 14, 2012. In this position, Scuse has responsibility for overseeing the Farm Service Agency which administers farm commodity disasters, and conservation programs for farmers and ranchers, and makes and guarantees farm emergency, ownership, and operating loans through a network of State and Country offices; the Risk Management Agency which oversees and administers the crop insurance program under the Federal Crop Insurance Act; and the Foreign Agricultural Service which administers the USDA's export credit guarantee and food aid programs and is responsible for USDA's activities in the areas of international marketing, trade agreements and negotiations, and the collection and analysis of international statistics and market information.

Prior to this position, Scuse served as Deputy Under Secretary for the FFAS mission area from 2009 to 2011 with primary responsibility over our domestic programs.

Before joining USDA, Scuse was Secretary of Agriculture for Delaware from May 2001 until September 2008, when Governor Ruth Ann Minner (D) named him as her chief of staff. From 1996 to 2001, Scuse served as both chairman of the Kent County (Delaware) Regional Planning Commission and chairman of USDA's FSA State Committee. Before that, he was Kent County Recorder of Deeds. In addition to serving as NASDA vice president while agriculture secretary, Scuse was also president of the Northeast Association of State Departments of Agriculture.

He lives in Smyrna, Delaware, with his wife Patrice.

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House Committee on
Appropriations

FARM SERVICE AGENCY

Statement of Juan Garcia, Administrator

Before the Subcommittee on Agriculture, Rural Development,

Food and Drug Administration, and Related Agencies

Mr. Chairman and Members of the Subcommittee, I appreciate this opportunity to provide information on Farm Service Agency (FSA) programs and funding. Our Fiscal Year (FY) 2014 budget emphasizes our commitment to customer service, efficiency and continued investments in modernizing our operations to the benefit of farmers and ranchers.

AGENCY OPERATIONS

FSA delivers its programs through 2,119 county level USDA Service Centers, 50 State offices, and an office in Puerto Rico. FSA has headquarters offices in Washington, DC, Kansas City, Salt Lake City, and St. Louis. At the end of FY 2012, FSA's permanent, full-time, end-of-year Federal employment was 4,322. FSA non-Federal permanent employment in USDA Service Centers was 7,716. FSA employees totaled 12,038, of which 10,896 were in State and county level offices. This represents an 8 percent reduction in FSA's staff levels from 2011.

Since 2003, staffing levels at FSA have declined over 32 percent, a reduction of 5,857 employees. In 2013, further staff reductions will continue to be achieved through Voluntary Early Retirement Authority and Voluntary Separation Incentive Payments, if approved, to meet FSA's FY 2014 budget allocation.

Business Processes and IT

FSA continues to make progress toward replacing outdated technology with more modern functionality and re-engineering old business processes. Both of these will provide timelier and more reliable delivery of benefits to producers. This fiscal year, we will reach our target of 76 percent of programs with web-enabled applications, with the addition of Noninsured Crop Disaster Assistance Program (NAP) and Conservation Program processes. FSA plans further efforts in FY 2014 to reach its next target of 88 percent, including modernization of the Farm Storage Facility Loan Program (FSFL) and Farm Loan Program (FLP) systems, streamlining direct and guaranteed loan reporting capabilities and reducing the high cost of

reporting from mainframe systems. Our efforts to replace outdated program delivery information technology should be completed by FY 2015.

Additionally, the Modernize and Innovate the Delivery of Agricultural Systems (MIDAS) project is expected to provide business improvements in 2013 and 2014. The first phase of MIDAS has been released this spring, and includes deployment of customer data, farm records with GIS mapping capability and crop table data. Additional planned deployments will provide acreage reporting with GIS mapping capability and will establish common processes that can be leveraged for FSA farm programs. For the first time, FSA staff will have access to this data through a single operating system, eliminating the need for staff to re-enter data because the systems were not interlinked. This change alone will speed the application process, reduce input errors, and improve program compliance and integrity.

FSA has also completed the consolidation of geospatial data into a centralized database, eliminating dependency on outmoded servers and extending the GIS functionality for FSA's service center personnel. Together, GIS modernization and MIDAS enable FSA to enhance program delivery and support, allow for timelier implementation of programs, and enable the integration of geospatial data with business operations.

We are also upgrading and replacing outdated components of our IT infrastructure, an effort known as the Common Computing Environment (CCE). Network optimization that began in FY 2012 and FY 2013 continues to streamline network traffic so that it can handle the increased activities of our new program applications. These will help centralize county office data, support the modernized systems and ensure the integrity of information.

PROGRAM UPDATE

The American Taxpayer Relief Act of 2012 (ATRA) extends authority under the Food, Conservation, and Energy Act of 2008 (the 2008 Farm Bill) for select programs, including the Direct Payment program. Eliminating that program, as proposed in the FY 2014 President's Budget, would save $3.3 billion annually.

Among other FSA programs extended by ATRA are Marketing Assistance Loans (MALs) and Counter-Cyclical Payments (CCPs) for crop producers, and the Milk Income Loss Contract (MILC) program for dairy producers. Given the high crop prices of recent years, MAL net outlays have been, and are expected to remain, minimal. Continued high prices mean that no

CCPs are expected for the 2012 and 2013 crop years. MILC payments are expected to decrease in FY 2013 to $370 million.

The Average Crop Revenue Election (ACRE) program, an alternative to the traditional CCP program, also was extended by ATRA through 2013. ACRE was first authorized by the 2008 Farm Bill and is based on revenue risk rather than just price risk. ACRE participation is low relative to traditional Direct and CCP payments (DCP). In 2012, 1.56 million farms were enrolled in DCP as compared to 142,000 farms in ACRE.

Also extended by ATRA is the Conservation Reserve Program (CRP), which now has 27 million acres enrolled, nearly 10 million acres below the peak enrollment level of 36.8 million acres in 2007. With contracts on 3.3 million acres scheduled to expire at the end of FY 2013, Secretary Vilsack recently announced that a new CRP general sign-up will begin on May 20 and end on June 14, 2013. In addition to CRP general signup, FSA offers year-round "continuous" signup, which has become a larger portion of overall enrollment and now constitutes about 20 percent of total enrolled acreage. We are working to promote continuous programs and target acreage that optimizes environmental benefits.

Revenue growth from high commodity prices has contributed to rising land values and rental rates, making CRP increasingly costly. In light of current economic realities and the need to reduce the federal deficit, the President's Budget proposes capping maximum allowable CRP acreage at 25 million acres, saving about $2.2 billion over 10 years compared to the FY 2014 budget's baseline.

USDA strongly supports disaster assistance programs that protect farmers in their time of greatest need. The 2008 Farm Bill authorized the following programs, which cover losses having occurred on or before September 30, 2011: Livestock Indemnity Program (LIP); Livestock Forage Disaster Assistance Program (LFP); Emergency Assistance for Livestock, Honeybees, and Farm- Raised Fish Program (ELAP); Tree Assistance Program (TAP); and the Supplemental Revenue Assistance Payments Program (SURE). These programs provided financial assistance to producers when they suffered a loss of livestock or the ability to graze their livestock, loss of orchard trees, and other losses due to diseases or adverse weather. While ATRA extended the authority for these programs, with the exception of SURE, funds have not been appropriated for their delivery, leaving the Noninsured Crop Disaster Assistance Program (NAP) as the only FSA disaster program currently available to producers. To strengthen the

safety net, The President's Budget proposal extends LIP, LFP, ELAP, and TAP for 2014 to 2018 through the Commodity Credit Corporation, at an estimated cost of approximately $3 billion over 10 years.

Because of the absence of livestock disaster program funding, and due to the extreme drought of this past summer, the Department assisted affected producers by using other authorities. For example, USDA expanded lands in the CRP that would be eligible for emergency haying or grazing, opening 2.8 million acres to provide up to $200 million in forage value. In addition, USDA simplified the process for Secretarial disaster designations, reducing processing time for counties affected by disasters almost by half. Other actions included a reduced interest rate for emergency loans and a change to the payment reduction from 25 to 10 percent on CRP lands qualified for emergency haying and grazing in 2012.

Other FSA programs help producers in times of need. The Emergency Conservation Program (ECP) provides emergency funding and technical assistance for rehabilitation of farmland damaged by natural disasters. During FY 2012, ECP allocated $148.9 million in "regular" (non-Stafford Act) ECP funding to 43 States and Puerto Rico. FSA currently has $8 million in requests on the waiting list for ECP that will be funded by the recently enacted Appropriations Act, and has about $22 million available in Stafford Act funds that can be distributed to States for additional requests that qualify. In addition, FSA is allocating $15 million in ECP funds that were provided for Hurricane Sandy relief.

The Emergency Forest Restoration Program (EFRP) helps owners of non-industrial private forest land carry out emergency measures to restore land damaged by a natural disaster. FSA has a growing backlog of unfunded requests totaling over $16 million from States for regular (non-Stafford Act) EFRP funding. Some of these requests will be addressed with the $14 million in funds appropriated in the recent Appropriations Act. We currently have over $23 million in a growing backlog of unfunded requests for Stafford Act counties. In addition, FSA is allocating $23 million in EFRP funds that were provided for Hurricane Sandy relief.

Through the Agricultural Credit Insurance Fund, demand for direct USDA loans in FY 2011 and FY 2012 continued at record levels. FSA's direct farm loan programs are some of USDA's largest investments in beginning farmers. In FY 2012, 66 percent of FSA direct lending – just over $1.1 billion – went to beginning farmers. That year, FSA also assisted beginning farmers with an additional $638 million in credit through loan guarantees. FSA now lends 63

percent more dollars to beginning farmers than in FY 2006.

The FSA loan portfolio continues to perform well. As of December 31, 2012, the direct loan delinquency rate stood at 5.50 percent and the guaranteed farm loan delinquency rate stood at 1.15 percent.

Sequestration

FSA is approaching sequestration in a manner that provides the least disruption to producers, particularly those who have already received or are seeking disaster assistance through SURE and NAP. Specifically, USDA has proposed to use the Secretary's interchange authority to transfer funds from the Direct Payment program to SURE (2011 payments are in process), the Tobacco Transition Payment Program, Marketing Assistance Loans, Loan Deficiency Payments, storage and handling, NAP, and MILC to backfill the amount sequestered. This will avoid the costly and disruptive process of FSA having to collect back portions of payments already made to producers on these programs to comply with sequestration. For appropriated programs, funds will be reduced to achieve the required sequestration savings.

BUDGET REQUESTS

Commodity Credit Corporation (CCC)

CCC FY 2014 baseline expenditures are projected to be $9.1 billion, a decrease from approximately $10.1 billion forecast for FY 2013, which is primarily due to lower milk payments and lower net lending. In FY 2012, $7.9 billion was expended as compared to a record high of $32.3 billion in FY 2000. Commodity prices are expected to remain relatively robust into FY 2014, resulting from increased demand for bio-energy production and strong exports.

CCC is authorized to replenish its borrowing authority, as needed, through annual appropriations up to the amount of net realized losses recorded in CCC's financial statements at the end of the preceding Fiscal Year. In FY 2013, the CCC received $9.1 billion for reimbursement of 2012 losses.

Appropriated Programs

For FY 2014, the Budget proposes a total Farm Loan Program level of about $5.5 billion – over $1.9 billion for direct loans and nearly $3.65 billion for guaranteed loans. Only $91.6 million in budget authority will be necessary to garner this level of assistance. For Direct Farm Ownership Loans the Budget proposes an increased loan level of $575 million to help

beginning farmers achieve a base level of operation. For Direct Farm Operating Loans the Budget proposes a loan level of $1.22 billion to assist family farmers in maintaining productive farming operations. At least 75 percent of the amount appropriated for Direct Farm Ownership Loans and at least 50 percent of the amounts appropriated for Direct Farm Operating Loans will be reserved for qualified beginning farmers and ranchers during the first 11 months of the fiscal year.

For Guaranteed Farm Ownership Loans in FY 2014, the Budget proposes a loan level of $2 billion. The requested loan level is expected to meet the increased demand for this program. For Guaranteed Farm Operating Loans we propose an FY 2014 program level of approximately $1.5 billion.

A portion of both direct and guaranteed farm operating and ownership loan funds is targeted to socially disadvantaged borrowers, based on county level demographic data. The statutory targets vary by loan program.

For Emergency Disaster Loans FSA is requesting $1.7 million to support a $35 million program level. Funding has historically been provided through supplemental appropriations. However, prior supplemental appropriations were drawn down by 2013 and funding is requested to ensure available support in the event of a natural disaster. In addition, the Budget proposes program levels of $2 million for Indian Tribal Land Acquisition Loans and $60 million for Boll Weevil Eradication Loans.

FSA also requests funding for two farm loan programs authorized under the 2008 Farm Bill – Guaranteed Conservation Loans and the Indian Highly Fractured Land Program. The FY 2014 budget requests $150 million for Guaranteed Conservation Loans and $10 million for the Indian Highly Fractured Land Program, which is a direct loan program that provides authority to make and insure loans to eligible purchasers of highly fractionated land under the Indian Land Consolidation Act.

For State Mediation Grants, the FY 2014 budget requests $3.782 million for 40 States to assist in continuing cost-effective alternative dispute resolution programs that deal with disputes involving a variety of agricultural issues.

FSA Salaries and Expenses

The FY 2014 Salaries and Expenses Budget requests $1.486 billion from appropriated sources, including credit reform transfers.

This request for administrative support within FSA reflects our continuing focus on administrative cost savings in light of reductions to FSA's Salaries and Expenses appropriation. In the past year, FSA has taken several notable steps to reduce costs, including an initial staff ceiling reduction and subsequent hiring freeze, reduction of certain IT contracts, and continued reduction of other administrative expenses. The consolidation of 125 offices nationwide in the past year will concentrate our resources in the remaining service locations, ensuring our customers receive quality service while reducing infrastructure and related expenses.

The IT request includes funding to continue contract services that support modernization, development and maintenance of applications systems, and deployment support (e.g. data and database administration, testing and certification, and security). These funds will enable FSA to maintain essential program delivery and operations in the field, as well as provide support for improvements.

The IT request also includes a decrease of $21.1 million to the base funding of $86.6 million for the MIDAS initiative. The remaining balance of $65.5 million provides funding for the continued implementation, support and operations of the MIDAS solution. MIDAS is expected to have positive business impacts for producers and FSA employees beginning in FY 2013, and FSA will continue to closely align future development with other Agency and Department-wide modernization efforts.

Mr. Chairman, this concludes my statement. I will be happy to answer your questions and those of the other Subcommittee Members.

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USDA FSA

BIOGRAPHY

UNITED STATES DEPARTMENT OF AGRICULTURE
FARM SERVICE AGENCY

July 2012

Juan M. Garcia
Administrator
Farm Service Agency
U.S. Department of Agriculture
Washington, D.C.

Juan M. Garcia was selected to serve as Administrator for the Farm Service Agency in July 2012. Garcia previously served as Deputy Administrator for Farm Programs where he managed all FSA programs under the Production Emergencies and Compliance Division, Conservation and Environmental Programs Division, and Price Support Division.

Garcia served as State Executive Director for Texas and as the Agricultural Program Manager (APM) for the Farm Service Agency in Texas. Prior to his selection as the APM, Garcia worked as a District Director and served earlier in his career as County Executive Director. During his 35-year career with USDA, Garcia has received numerous honors and is a three-time recipient of the prestigious FSA Administrator's Award for Service to Agriculture.

A native of Lyford, Texas, Garcia was raised on his family's 500-acre farm. Garcia received a Bachelor of Science Degree in Animal Science from Texas A&I in Kingsville (now Texas A&M University-Kingsville) and was recognized as the College of Agriculture's 2010 Hall of Honors Alumnus. Garcia and his wife, Belinda, have three grown children.

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FOREIGN AGRICULTURAL SERVICE

Statement of Suzanne E. Heinen, Administrator
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies

Mr. Chairman and Members of the Subcommittee, I appreciate the opportunity to report on the accomplishments of the Foreign Agricultural Service (FAS) and to present the President's Budget request for FAS programs in fiscal year (FY) 2014.

INTRODUCTION

In early February, an FAS Agricultural Attaché in Mexico City phoned a contact in the Mexican government to inquire if a poultry exporter from Gadsden, Alabama could be expeditiously listed as eligible to ship poultry. The plant was listed the next day. In under two months, over half a million dollars of poultry products from the plant were served in restaurants and further processed for grocery store shelves in Mexico. The diligence of FAS agricultural officers and the relationships they have with their foreign counterparts is one of the reasons the United States exported $1 billion in poultry products to Mexico last year.

Worldwide, U.S. farm exports reached $135.8 billion in fiscal year 2012. FAS' global network of agricultural economists, marketing experts, negotiators, and trade specialists in Washington, D.C. and 96 international offices that cover 163 countries are proud that their efforts helped facilitate this achievement. FY 2013 estimates are for a record $142 billion in U.S. farm exports, supporting nearly one million American jobs.

THE ROLE OF THE FOREIGN AGRICULTURAL SERVICE

FAS is the lead agency within USDA for developing international markets, providing export financing, negotiating trade agreements, and for food aid and technical capacity building efforts that enhance U.S. agricultural exports. FAS attachés and counselors serving at U.S.

Embassies and Agricultural Trade Offices are American agriculture's envoys around the world, providing real-time information on emerging trade and marketing issues, resolving issues that interrupt the normal course of trade, averting problems before they impede exports, and building the capacity of potential trading partners. FAS' targeted trade missions and support for trade shows match U.S. agricultural exporters with buyers around the world.

FAS plays a critical role in USDA's efforts to collect, analyze, and evaluate global market intelligence and data for all major agricultural commodities. Policymakers' ability to make sound decisions is dependent on the quality of the underlying analysis conducted by FAS agricultural economists. U.S. exporters also rely on this information to develop and implement domestic and international programs and make key business decisions.

At FAS, our success is a direct result of our people forging relationships across political and cultural boundaries, negotiating in challenging and complex situations, assessing market opportunities, and promoting pro-trade institutions and policies among developing countries. Working with our agricultural cooperator partners, our Market Access Program (MAP) and Foreign Market Development (FMD) program have been shown to be highly effective, increasing exports by $35 for every dollar of funds invested. Our Cochran and Borlaug Fellowship programs build agricultural capacity abroad and enhance our ability to export to countries by increasing their ability to participate in global trade. The Cochran program has been particularly effective in training foreign officials on the implementation of market access commitments in trade agreements. Our Scientific Cooperative Exchange Program with the People's Republic of China promotes agricultural development, science-based decisions, economic growth; and supports our efforts to mitigate animal and plant health issues that impede trade.

OPENING MARKETS THROUGH TRADE AGREEMENTS

Today, FAS trade negotiators hold seats at the table for U.S. agriculture in two major negotiations, the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP). In the TPP negotiations, FAS experts are an integral part of the negotiating team led by the Office of the U.S. Trade Representative (USTR) and USDA's economic analysis underpins the negotiating strategy on agriculture. The TPP is an opportunity to address not only market access commitments, but also non-tariff, sanitary and phytosanitary (SPS) and technical barriers to trade (TBT) that impede our agricultural exports.

The TPP, which we aim to complete this year, will increase American agricultural exports to a region with some of the world's most robust economies, representing more than 40 percent of global trade. Northwest horticultural exporters identified Vietnam as a priority market that provides excellent growth opportunities. Achieving tariff concessions on apples, pears, and sweet cherries will increase U.S. producers' competitiveness with suppliers from New Zealand and Australia that have duty-free access. Recognizing the potential for growth in TPP markets, the American soybean industry voices strong support for a 21st century TPP agreement. The addition of Canada to the TPP negotiations presents an opportunity to negotiate increased access for U.S. exports of dairy and poultry products. The trade ministers of the 11 TPP countries have agreed by consensus to finalize with Japan the process for entry with Japan's recognition that all agricultural goods will be on the table.

On March 30, 2013, the Administration notified the U.S. Congress of its intent to enter negotiations on the TTIP, a comprehensive trade and investment agreement with the European Union (EU). The EU is currently our fifth largest agricultural export market with U.S. exports valued at nearly $9 billion last year. FAS agricultural trade experts are participating in pre-negotiation preparations with our colleagues at USTR and consultations with stakeholders and Congress to develop the Administration's negotiating positions on agriculture.

TTIP negotiations will address tariff and non-tariff barriers on agricultural goods. Examples of current high tariffs on U.S. agriculture include: dried cranberries (17.6%); strawberries (17.6%); and high-value, processed foods (25% average). Competitor countries, like Chile, enjoy duty-free access, due to existing trade agreements. Through the TTIP we are seeking meaningful market access that includes commitments from the EU to base SPS measures on international standards and scientific risk assessments and to eliminate unjustified technical obstacles to trade.

ENSURING FULL AND FAIR IMPLEMENTATION OF TRADE AGREEMENTS

The Korea-U.S Free Trade Agreement (KORUS), and the U.S.-Colombia and U.S.-Panama Trade Promotion Agreements became effective in 2012. FAS staff have ensured implementation by each country of new tariff schedules, tariff-rate quotas (TRQs), and SPS commitments.

In the first year under KORUS, there were dramatic increases in U.S. exports of key agricultural products benefitting from the reduced tariffs under the agreement. Exports of soybeans went up 48 percent to $395 million and exports of wheat were up 38 percent to $645 million. U.S. orange juice exports to Korea have jumped 130 percent and grape juice exports were up 128 percent in that same time period. Exports of wine to Korea were up 57 percent and exports of fresh fruits were up 46 percent to $370 million.

U.S. agricultural exports to Colombia topped $1 billion in calendar year 2012; 46 percent higher in May-December than the same time period for 2011. In 2012, utilizing our Emerging Markets Program, FAS provided customs and TRQ administration training to 80 Colombian officials. Additionally, we employed our Cochran Fellowship program to demonstrate TRQ administration in the United States to Colombian participants. The capacity-building trainings were instrumental in Colombia announcing all 19 TRQs covered in our trade agreement on schedule, ensuring U.S. exporters could take full advantage of new import opportunities. U.S. rice, soybean oil, pet food, white corn, milk powder, and cheese all benefitted. In 2012, FAS awarded Emerging Markets Program (EMP) funds to the USA Rice Federation and the U.S. Rice Producers Association to assist in the establishment of an export trading company (ETC). The ETC made it possible to launch an auction of rice export certificates last October that resulted in 79,000 metric tons of U.S. rice exports.

For Panama, nearly half of current U.S. agricultural exports (which reached $489 million in calendar year 2012) received immediate duty-free treatment. Utilizing our Cochran Fellowship program, FAS trained officials from Panama's TRQ Licensing Commission and Panama's Customs Authority. This capacity building training was critical to Panama's implementing 22 TRQs on schedule, operating a web-based TRQ information system that can be accessed by U.S. exporters, and processing documents accompanying U.S. exports. With assistance and monitoring by FAS, the TRQ implementation process went smoothly and U.S. exporters of corn, rice, chicken leg quarters, and frozen French fries are now benefitting from these newly-opened TRQs.

RESOLVING SPS and TBT BARRIERS

In the past year, FAS personnel have been instrumental in resolving numerous sanitary, phytosanitary and technical barriers to trade. We've negotiated a new dairy certificate with China

that brings certainty to U.S. exporters and the prospect of expanding a $400 million per year market. We stood firm and the EU dropped their unscientific restrictions on live swine. The FAS office in New Delhi prevented the disruption of the $85 million annual market for U.S. apples and pears, by avoiding the implementation of new technical requirements. In Jakarta, the FAS office spearheaded negotiations that gained the United States an exemption from port restrictions protecting over $150 million in agricultural exports. The exemption gives U.S. exporters an advantage over competitors including China, Thailand, Australia, Canada, and New Zealand.

A major success in the market access arena is U.S. beef exports. Last year, exports of beef and beef products reached an all-time high of $5.5 billion. On February 1, Japan expanded access to U.S. beef and beef products from cattle less than 30 months of age. This is expected to generate hundreds of millions of dollars of additional beef sales. Also in February, Hong Kong expanded access to all deboned beef products and bone-in beef products from U.S. cattle less than 30 months of age. Last November, Mexico expanded trade to allow all beef products from cattle less than 30 months of age, and we project $55 million in additional sales this year. More work is ahead fort USDA to press for full access in all markets based on the demonstrated safety of U.S. beef.

Scientific training for scientists and policymakers from developing and middle-income countries under the Norman E. Borlaug International Agricultural Science and Technology Fellowship Program transfers knowledge that strengthens agricultural practices, including in the SPS arena. For example, in 2012 a Borlaug Fellow from the Republic of Georgia reported that he continues to utilize food safety training he received in the United States in his work on his country's adoption of similar science-based standards. Adoption of such standards reduces obstacles for U.S. agricultural exporters.

IMPORTANCE OF FAS LOCAL PRESENCE IN OVERSEAS MARKETS

The FAS global network of agricultural economists and marketing experts identifies problems, provides practical solutions, averts trade issues, and advances export opportunities on a daily basis.

One example is the first direct deliveries of U.S. peanuts to Poland in eight years. In 2012, FAS Warsaw identified and arranged contact with U.S. suppliers for one of Poland's

leading nut importers. Orders for approximately $3 million were placed with peanut exporters in Alabama, Georgia, and Virginia.

In 2012, the painstaking efforts of FAS Taiwan secured the release of 27 shipments of U.S. meat and poultry valued at $1.79 million. Taiwanese port authorities detained shipments for a variety of documentation issues; but due to their relationships with foreign officials, FAS personnel in Taiwan and around the world kept U.S. exports flowing.

BUDGET REQUEST - Salaries, Operating Costs, and Programs with Examples

The 2014 Budget provides a funding level of $185 million for salaries and expenses to maintain the agency's overseas presence near current levels and continue our core activities: trade promotion, trade policy, and capacity-building/food security. The budget reflects ongoing cost avoidance in headquarters costs, through a continued hiring freeze, reductions to travel and training, and an increased focus in identifying efficiencies in operations. Consistent with the Department's "*Blueprint for Stronger Service*", FAS closed two overseas offices locations and reduced staffing at five additional overseas locations in FY 2012.

FAS implemented significant measures to increase organizational discipline, efficiency, and accountability. This focus has already rendered cost savings in organization-wide services such as contracting, IT support, and human resources. It has revolutionized agency financial management with scores of improved operating procedures, clarified our domestic and overseas financial operations; and provided management with more timely, accurate statements of FAS' overall financial condition. With improved operations, FAS can be more responsive to its workforce; build improved relationships with key agency stakeholders, such as industry cooperators and trade associations, and direct resources to better exploit opportunities for improved access to international markets for U.S. farmers, ranchers, and producers.

The Budget recognizes $19.1 million in operational costs related to the agency's international offices under the International Cooperative Administrative Support Services System (ICASS).

Market Development Programs

For 2014, the Budget assumes MAP will be extended in the next farm bill and includes a $200 million program level for MAP. The budget baseline does not assume funding for FAS' other CCC-funded market development programs: FMD, Technical Assistance for Specialty

Crops (TASC), and EMP. These programs expire at the end of 2013 and are subject to renewal in a new Farm Bill.

Under the MAP program, participants are reimbursed for a portion of the cost of carrying out overseas marketing. Last year, FAS personnel in Sofia, Bulgaria worked with representatives of the U.S. Cranberry Marketing Committee to implement a promotional effort using MAP funds that resulted in a 40 percent increase in U.S. cranberry sales. The promotional effort included outreach to both consumers and importers on the versatility of dried cranberries as a snack food and on the health benefits of the "Power Berry from the USA." FAS Sophia predicts a 45-50 percent increase in the Bulgarian market for U.S. cranberries this year.

With assistance from FAS, the convenience store sector in Japan is a growing outlet for U.S. pork. Using MAP funds, the U.S. Meat Export Federation worked with FAS Tokyo to target convenience store chains to promote processed products using U.S. pork. An initial campaign sold an impressive 800,000 U.S. pork "to go" bento boxes. Due to these efforts, a Japanese chain decided to feature the U.S. pork bento in its stores.

Export Credit Guarantee Programs

The 2014 Budget includes the statutory program level of $5.5 billion for CCC's export credit guarantees; $5.4 billion will be made available for the GSM-102 program and $100 million for the Facility Guarantee Program. The 2012 GSM program increased agricultural exports to Vietnam by facilitating over $87 million in sales of U.S. cotton, distillers dry grain, soybeans and meal, lumber, and other commodities. Skillfully targeting developing markets with the greatest potential for increased U.S. sales, managing risk, and aggressively recovering losses, FAS employees operated a 2012 program that supported $4.13 billion in exports.

Food Assistance and Capacity Building

The 2014 Budget proposes $185 million for the McGovern-Dole International Food for Education and Child Nutrition Program (McGovern-Dole). With this funding, the program is expected to assist 4.3 million women and children worldwide in 2014. The program provides agricultural commodities and technical assistance for school feeding and maternal and child nutrition projects in low-income, food-deficit countries that are committed to universal education. Programs are designed to "graduate" from relying on USDA assistance and continue

with support from other sources, such as the host government or local communities. For example, in Bolivia, twelve municipalities, comprising 21,000 children graduated from the program in 2012.

The 2014 Budget assumes $255 million in CCC funding for the Food for Progress (FFPr) program, which is expected to support approximately 312,500 metric tons of commodity assistance. The FFPr program provides for the donation of U.S. agricultural commodities to developing countries committed to free enterprise in the agricultural sector. In FY 2012, USDA completed a four-year, $5.7-million FFPr investment in micro lending capital and small business loans in Tanzania that allowed small holder producers and small businesses to expand food processing operations, buy new equipment, buy supplies in bulk, improve transportation to markets, and install greenhouses and irrigation infrastructure. The initial capital provided by USDA supported 46,000 borrowers and the success of the program encouraged other lenders, such as the World Bank and Credit Suisse Bank, to invest an additional $18.8 million in the project. This investment from other lenders permitted an additional 382,000 loans valued at more than $206 million, essentially converting the initial loan fund into a sustainable operation.

The Budget proposes to replace $1.47 billion in funding for P.L. 480 Title II international food assistance in FY 2014 with an equivalent amount in the U.S. Agency for International Development assistance accounts, including International Disaster Assistance (IDA). The proposed reform gives the United States greater ability to provide aid effectively. At least fifty-five percent of the requested IDA emergency food aid funding will be used for the purchase and transport of U.S. agricultural commodities.

CONCLUSION

With USDA's Foreign Agricultural Service FY 2014 budget request, I guarantee that the Agency's employees will faithfully execute our mission, maximizing opportunities for U.S. agricultural exporters, and deliver food aid and build agricultural capacity in developing countries. The funding you provide increases prosperity in America and around the world.

Thank you.

Suzanne Heinen, Administrator
General Sales Manager

Suzanne Heinen was appointed Administrator of the Foreign Agricultural Service (FAS) in April 2012, after having served 11 months as the agency's Acting Administrator. She also continues to serve as the General Sales Manager. Prior to that, she worked on food security issues in the Office of the Secretary and as Minister-Counselor for Agriculture at the U.S. Mission to the United Nations Agencies for Food and Agriculture in Rome, Italy.

In her 25 years as a Foreign Service officer, Heinen has served at FAS posts around the world, including Mexico, the People's Republic of China, Russia and Guatemala. In Washington, she served as FAS Deputy Administrator for International Cooperation and Development and as Assistant Deputy Administrator for Foreign Agricultural Affairs. Heinen also held various positions in international trade policy, working on multilateral and bilateral issues, particularly sanitary and phytosanitary agreements.

Heinen, a native of Michigan, received her Bachelor of Science degree from the University of Michigan and her Master of Science from Michigan State University.

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RISK MANAGEMENT AGENCY
FEDERAL CROP INSURANCE CORPORATION

Statement of Brandon Willis, Administrator
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies

Chairman Aderholt, Ranking Member Farr and members of the Subcommittee, I am pleased to discuss the 2014 Budget for the Risk Management Agency (RMA). The Federal crop insurance program is an integral part of our Nation's farm safety net. Our program is especially important during years in which there are natural disasters. By design, the program uses more resources where there are conditions that contribute to crop losses. Last year, spring brought frosts that decimated the fruit industry in the Northeast, and a prolonged and widespread drought across the country left many farmers with significantly reduced yields, contributing to one of the worst disaster years in a generation. I commend our private partners for their success in working with RMA to pay claims quickly. We strive to maintain and improve current insurance products to ensure all of America's farmers and ranchers have the best protection possible.

Budget restraints require government agencies ensure limited resources are used prudently, and I assure you that RMA will deliver our program with the efficiency that America's farmers and ranchers expect. It is in years like 2012 that we can clearly see the success of modern crop insurance as a safety net. The Federal crop insurance program was able to provide quick and effective assistance to struggling producers, without making them wait for supplemental disaster appropriations. We cannot control the weather, but we can control the availability of strong risk management tools to ensure that producers have the support they need to stay in business when catastrophic disaster strikes.

RMA has worked hard to set in place preventive measures to avoid furloughs. However, as we seek to expand crop insurance participation to cover current gaps and to maintain our current

coverage, reductions to discretionary resources threaten to delay new program development and compliance efforts. I look forward to working with you to find funding solutions that will improve program performance and protect taxpayer resources.

RMA has three priorities to ensure that producers can rely on crop insurance as their safety net for years to come in a way that is financially sound. First, we will continue and intensify our focus on program integrity. Our data mining program has been credited with preempting millions of dollars in improper payments, and we are looking at new ways to use data mining to protect taxpayer resources. Second, RMA will work to expand crop insurance where low participation puts producers at financial risk. RMA has made great strides in coverage over the last two decades. Closing coverage gaps even further will help make sure that one unpredictable weather crisis will not undo the work of generations. And thirdly, we will work to educate the public about crop insurance. All Americans, urban and rural alike, benefit from a strong and stable domestic agricultural economy.

In addition, RMA continues to evaluate the crop insurance program for efficiencies to help support funding for these priorities. The ultimate goal is to use the taxpayers' dollars to provide what we need to sustain protection within the farm safety net. Crop insurance is one of the foundations of our farm safety net, but due to increased commodity prices, costs have increased significantly in recent years. RMA strives to continuously offer ways to reduce unnecessary spending, even as we enhance our program within our priorities.

STATUS OF THE FEDERAL CROP INSURANCE PROGRAM

The Federal crop insurance program helps the men and women who produce America's agricultural products to manage risk in a business that is exposed to extreme fluctuations in weather and markets. For 2012, with approximately 1.1 million policies on 282 million acres, the program provided nearly $117 billion in risk protection. Of the $11.1 billion in total premiums, USDA provided $7.0 billion for farmers, and farmers themselves paid $4.1 billion. To date, USDA and our private partners have paid out $16.1 billion in claims for lost revenue or damaged crops. In addition, RMA awarded $12.6 million in risk management education

partnership agreements during 2012, which directly supported women, veterans, small and limited resource farmers and ranchers, and minority producers.

Producers generally have a choice of crop policies with coverage they can tailor to best fit their risk management needs. In many cases, producers can buy insurance coverage for a yield loss, or revenue protection to provide coverage for a decline in yield or price. Today, most producers "buy up" higher levels of coverage ranging up to 85 percent, and catastrophic coverage, which provides a very low level of coverage, is still available for a nominal fee with the premium fully subsidized. Indemnity payments are usually made within 30 days after the producer signs the claim form.

The Federal crop insurance program has seen an increasing proportion of acres insured at buy up levels over the last decade. Purchases of this type of coverage are also shifting to the more comprehensive revenue coverage. In 2012, revenue coverage accounted for 67 percent of the insured acres, compared to just 33 percent in 2000. In addition, the average coverage level (percent of the total crop covered) for buy up insurance has increased to approximately 74 percent for 2012, compared to 68 percent in 2000. Producers also have their choice of livestock programs, which are designed to insure against declining market prices of livestock. Coverage in these programs is determined using futures and options prices from the Chicago Mercantile Exchange Group.

In 2012, Federal crop insurance was available for approximately 130 crops and types of livestock, in over 3,141 counties covering all 50 States and Puerto Rico. RMA maintained a participation rate of nearly 84 percent for the ten principal crops in 2012. Many banks now require crop insurance coverage in order to approve operating loans to producers. Federal crop insurance has become integral to financial planning for many farmers and is especially important in these times of economic uncertainty coupled with severe weather conditions. We have been working to administer the Federal crop insurance program in a manner that provides effective risk management opportunities to farmers and ranchers in all geographic areas regardless of the size of their operation.

RMA has worked with private entities under the authority provided in section 508(h) of the Federal Crop Insurance Act to expand the availability of crop insurance coverage to a more agriculturally diverse population. Over the past two years, the Federal Crop Insurance Corporation (FCIC) Board of Directors (Board) has approved the following 508(h) product submissions:

- Specialty-Trait Soybeans to allow producers of food grade soybeans to insure their production;
- Texas Citrus Tree policy enhancements to provide for more comprehensive coverage;
- Annual Forage to cover a lack of rainfall during a specific period of time;
- Trend Actual Production History (Trend-APH) is an option for growers to adjust their APH to account for long-term yield trends to better reflect their true productive potential;
- Dry Bean Revenue and Dry Pea Revenue Endorsements to the APH polices;
- High Risk Alternate Coverage Endorsement allows producers to insure their high risk land at a buy-up coverage level which is less than the coverage level on their non-high risk land for corn, soybean, wheat, and grain sorghum;
- Downed Rice Endorsement provides an extra indemnity to cover additional harvest costs incurred when rice falls over (is downed) due to wind or rain;
- APH-Olive for California olives;
- Specialty Canola to reflect higher contract pricing for the Spring High Oleic Canola type;
- Specialty Corn to reflect higher contract pricing for the Blue Corn and High Amylase Corn types;
- Significant revisions to Livestock Risk Protection for Lamb; and
- Camelina, which is used to make biofuels.

In addition to the new products, RMA has contracted to provide new insurance programs for Navel Oranges and Strawberries, as well as Pistachios, Grass Seed, and Sesame. At the request of growers, RMA expanded silage sorghum insurance, and made changes to the Florida Citrus Fruit, Pecan Revenue and Peach policy provisions to better serve producers.

RMA is also working to better incorporate precision agriculture into Federal crop insurance procedures by allowing producers to use their acreage and yield monitor records to report production history and assist in loss adjustment determinations.

OVERVIEW OF THE 2014 RMA BUDGET PROPOSAL

The 2014 RMA budget proposal for the discretionary Salaries and Expenses Account is $71.5 million and supports approximately 455 employees, the lowest level ever. Over the last two years RMA has pursued efficiencies and reductions in personnel, travel and other administrative expenses. We will continue to rigorously manage our discretionary resources.

The mandatory FCIC Fund appropriation request reflects a modest decrease of $716 million. For the Federal crop insurance program to support risk protection coverage of $94 billion in 2014, a funding level of $9.5 billion is required.

The 2014 Budget reflects the Administration's deficit reduction proposals, which includes five crop insurance proposals that will save an estimated $11.7 billion over 10 years, while making the program stronger for the future.

The proposal focuses on five elements:

The Budget proposes to save about $1.2 billion over 10 years by establishing a reasonable rate of return to crop insurance companies. A study commissioned by USDA revealed that the reasonable rate of return should be around 12 percent. Yet the actual rate of return has exceeded 12 percent, from a ten-year low of 14 percent in 2008 to a high of 34 percent in 2009. Even with a projected negative rate of return in 2012 of 15 percent due to high commodity prices and poor growing conditions, the 10-year average is 21 percent, a total of over $10 billion in underwriting gains. Setting a 12 percent rate of return target will provide a reasonable profit incentive for crop insurance companies to continue their quality of service and save significant amounts of taxpayer supported funding.

The 2014 Budget further proposes to lower the cap on payments to insurance companies for administrative expenses from about $1.3 billion annually to $0.9 billion, saving $2.8 billion over 10 years. Though a cap on these expenses was introduced in 2011, the capped amount is still much greater than the amount paid to companies prior to the increase in commodity prices. The proposed amounts with the reduced cap will still provide adequate rates to insurance companies and agents to assure effective delivery of the program to producers.

The Budget also proposes to reduce the premium for catastrophic policies to better reflect historical performance, saving about $292 million over 10 years. This change will result in a premium rate that more accurately reflects actual program performance. Farmers are not impacted by the change.

The Budget proposes to lower the producer premium assistance by three percentage points for policies where the Government assists with more than 50 percent of the premium, saving $4.2 billion over 10 years. Producers with policies that have premium assistance at 50 percent or less would not be affected by the change, and even with the reduction, the Government will still assist with around 60 percent of the premium, on average. Premium assistance levels have been steadily increased to encourage greater participation, and today can reach as high as 80 percent.

Lastly, the 2014 Budget will reduce the premium assistance by two percentage points for revenue coverage that provides protection for upward price movements at harvest time. Even with this reduction, the Government will still assist with at least half of the premium cost for the majority of producers purchasing this coverage, and it will not have a significant impact on producers' out of pocket cost for this type of coverage. For example, for a producer purchasing the 85 percent coverage level with basic units, premium assistance will be reduced from 38 percent to 36 percent, or 2 cents per dollar of the premium. This proposal saves about $3.2 billion over a ten-year period.

RECENT KEY ACCOMPLISHMENTS

Drought Response. I would like to take a moment to praise the work of the RMA staff and crop insurance companies across the United States for their tremendous efforts in responding to our customers by providing over $16 billion in indemnity payments for crop and livestock losses resulting from the drought. Through their combined efforts, appraisals and claims adjustments were made in a timely manner, indemnities were promptly paid, and farmers were able to get through the process smoothly despite a record number of claims. The manner in which these difficult circumstances were handled is a testament to the public-private partnership that delivers the Federal crop insurance program.

Clean Audit Opinion. A Clean Audit Opinion was received by RMA and the FCIC for fiscal years 2011 and 2012 and reported to the Office of the Inspector General from independent auditors. This report contains an unqualified opinion on the financial statement as well as an assessment of RMA's internal controls over financial reporting and compliance with laws and regulations.

Premium Rating. As part of its statutory responsibilities for maintaining an actuarially sound program, RMA continues to routinely review and make determinations for fair, equitable, and actuarially sound premium rates. The practice of periodically updating premium rates is consistent with sound actuarial principles to assure the best estimate of premium dollars needed to pay future anticipated losses is achieved, but also to ensure equity for producers and that premium rates are not excessive. Premium rate revisions have been made for many program crops in 2012 and 2013, and will continue as a normal course of business for other similar crops into the future.

The Acreage Crop Reporting and Streamlining Initiative (ACRSI). Representatives from RMA, Farm Service Agency, Natural Resources Conservation Service, and the National Agricultural Statistics Service continue to work towards simplifying and standardizing the crop data, definitions, farm location, producer entity types, acreage reporting process and dates, along with other often used participation information across various USDA programs. These efforts

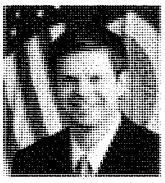
have included development of a common framework for producers to report eligibility and participation information, thereby reducing the reporting burden on producers as well as the administrative and operating costs of USDA.

ACRSI has already demonstrated results. Before the ACRSI initiative, FSA had 17 acreage reporting dates for 273 crops and RMA had 54 acreage reporting dates for 122 crops. With ACRSI, there are now 15 acreage reporting dates common to both RMA and FSA programs with only a few exceptions. As the agencies continue to make strides in this initiative, the long term benefits for USDA and outside parties lead to greater efficiencies, transparency and overall program integrity and savings.

CONCLUSION

I am pleased to report that in 2012 crop insurance functioned as intended by providing timely assistance to producers following a major natural disaster. This assistance did not make them whole nor did it provide these producers with the income they would have earned had their crops not been destroyed, but it helped producers stay in business another year. It also benefited those outside of agriculture by adding stability to lenders and businesses. It will benefit all consumers in the long run by providing the stability that allows America's producers to continue to invest in their farms and ranches so that they can continue to be the most efficient producers in the world. Again, thank you for inviting us here today and I look forward to working with you.

Mr. Chairman, I would be pleased to answer any questions that you and other Members of the Subcommittee may have. Thank you.



Brandon Willis
Administrator, Risk Management Agency
United States Department of Agriculture

Brandon Willis was appointed Administrator of the United States Department of Agriculture (USDA) Risk Management Agency on February 28, 2013. Before this appointment, Brandon served as Senior Advisor to Agriculture Secretary Tom Vilsack on Title I Commodity programs, farm legislation matters, and disaster assistance. In August 2009, he was appointed as Deputy Administrator of Farm Programs for USDA's Farm Service Agency (FSA). In that position, he oversaw all FSA programs under the Production Emergencies and Compliance Division (PECD), Conservation and Environmental Programs Division (CEPD), and Price Support Division (PSD).

Before his appointment as Deputy Administrator, he was a confidential assistant in USDA's Office of the Under Secretary for Farm and Foreign Agricultural Services. Before joining USDA, Willis served as the Agriculture Legislative Assistant for U.S. Senator Max Baucus (2006-2009). During this time, he worked on the Food, Conservation, and Energy Act of 2008.

In 2005, he worked as a graduate assistant at the National Agricultural Law Center. Willis earned his bachelor's degree in crop and soil science from Utah State University in Logan, UT, and his law degree from the University of Wyoming in Laramie, WY. In 2009, he completed his master's degree in agricultural law from the University of Arkansas. He grew up on a third generation sheep ranch in northern Utah and managed his family's raspberry farm, Bursting Berries.

INTERNATIONAL FOOD AID REFORM

Mr. ADERHOLT. Thank you, Mr. Under Secretary, and for those announcements, we appreciate your testimony here this morning and for your work at your agency and what you do.

Let me go ahead and start with the questioning aspect for the hearing today.

One thing that most people with agriculture have noted is the Obama Administration is proposing to transfer funding for the Public Law 480, Title II, Food for Peace Program in the agricultural appropriations and move it into the state and foreign operations appropriations under three separate accounts at USAID.

We are still looking at these changes here at the Subcommittee level and at the full Committee level of what it would mean.

We do need to keep in mind that the unemployment rate is 7.6 percent, and 11.7 million people are without jobs.

The President's proposal would reduce the amount of food provided and shipped by American farmers and ranchers to those in need around the globe, from the current level of approximately 80 percent of $1.12 billion to roughly 55 percent or $605 million.

As noted in your testimony, USDA's Economic Research Service estimates that for every billion of agricultural exports, an estimated 6,800 jobs are supported, and an additional $1.29 billion in economic activity is generated.

The way the program is currently structured almost doubles the return on the American taxpayers' investment by supporting jobs and farmers here at home, while still accomplishing the goal of contributing to food security abroad.

With budget reductions in all sectors and millions of Americans struggling to find work, is it a wise use of the taxpayer money to maximize our investment at home while also contributing to the needs of those overseas?

Mr. SCUSE. Thank you, Mr. Chairman, for the question. If you look at just the trade aspect, which you pointed out, we have had the last four years record amounts of trade, and this year, for another record year of $142 billion in agricultural trade.

We are doing everything that we can to promote American agricultural products throughout the world.

We support the Administration's position on this transfer. If you look at what this will ultimately do, we are still going to be sending 55 percent of the U.S. products overseas for food assistance, we believe through the efficiencies and being able to buy locally products, two things will be accomplished.

First, we are going to get aid to an additional two million people a year by making this change. The second thing that comes to mind is we are going to be able to get this emergency food assistance to those that are in need much quicker.

If you look at how long it takes us today to get emergency food assistance through our current program to those countries that are truly in need, it is over 70 days. We can decrease that time line substantially by taking some of the funding and buying regionally the products needed in a very short period of time.

Mr. ADERHOLT. How does USDA foresee its role changing in providing the international food assistance given this reform proposal?

Mr. SCUSE. We are still going to be involved in the procurement of that 55 percent of those products and the shipping from the United States to those countries in need. We are still going to have involvement in this program.

FOOD FOR PROGRESS PROGRAM

Mr. ADERHOLT. According to your testimony, USDA would still obligate roughly $255 million out of the Commodity Credit Corporation for the Food for Progress Program.

Do you think your Department can continue to effectively and efficiently invest $255 million in the Food for Progress Program on development projects?

Mr. SCUSE. I believe so. Again, we are still going to be doing the procurement for AID for the 55 percent, and then the procurement for the $255 million for the other program. I think we are going to be able to continue to provide the work at a reasonable rate and still do it efficiently as well.

Mr. ADERHOLT. Why would you not recommend that the Administration simply expand its ongoing program at USDA instead of sending an additional $250 million over to USAID for the same purpose under a new program?

Mr. SCUSE. I do not know that we can. It may take legislation to make the change. That would be something we would have to look at with AID as well as the General Counsel's Office from AID and USDA.

Mr. ADERHOLT. Mr. Farr.

Mr. FARR. Thank you, Mr. Chairman. I think the food we send abroad is probably the most expensive food in the world, giving to people who are the poorest in the world. It seems like there is a better way to do it.

The problem is there is a lot of corruption at the local level with distribution of food because you are in a country where we do not control the distribution politics.

Even some good organizations, non-profit organizations, have been known to be selling the food. We do not buy it for people to sell it.

What I would hope is that USAID could design a better model of implementation of aid to empower these countries—you are not going to just be able to feed Sub-Saharan Africa with the amount of poverty and the amount of migration, displaced folks, just with U.S. food aid.

You are going to have to start empowering the rural areas to grow their own agriculture and have their own markets and things like that.

It does not seem like that is at all part of this formula. I do not think we ought to just change it for change sake. We ought to get a better bang for our buck.

I share your concerns about it.

FURLOUGHS

I want to ask, you indicated, and it is good news, that you are not going to have to lay off anybody from FSA, but what about RMA and FAS from sequestration? Are there layoff's there?

Mr. SCUSE. No, sir. We had never planned to have any furloughs with the Foreign Agricultural Service or RMA.

CONSERVATION RESERVE PROGRAM

Mr. FARR. Let me ask you a question. I was interested in your resume and the fact that you served as Chairman of the Kent County, Delaware Regional Planning Commission.

My question goes to the Conservation Reserve Program, which we began in 1985. I come from a state that is very heavily zoned. Every city and county has to have a master plan. The master plan has to address certain elements, housing elements, conservation, hazardous areas and things like that, and then your zoning has to meet your master plan, as you know.

Why have we been sort of bailing out these states with CRP when they do not take any initiative to essentially ban farming on areas you should not farm?

If we have a riparian area or habitat that needs protecting, regardless of if it is on private land, you cannot go out and destroy it.

It seems what we have been doing is paying farmers not to destroy it. Why do we not require—why do we not provide some leadership, as you did when you were a regional planner, of making communities kind of come up to the standards that were set?

It does not seem like we have done that in this program. I just wanted your reflection on it.

What it seems to me we are doing, and correct me if I am wrong, but CRP assists farm owners to not do bad things. You are essentially saying we will pay you not to do bad things, where best management practice is do not do those anyway. You cannot do them. In some states, you cannot do them.

If you had to pay for all the CRP assets that California counties have protected, ag counties, you would take the entire program.

We have just done it through our local zoning and enforcement of our zoning practices. We do not pay people to do it correctly. We tell them that is how you are going to have to do it so you will not have soil erosion.

Mr. SCUSE. Congressman, I appreciate your point. As you are well aware, there are differences among the states. We have some states that have very weak if any zoning regulations at all. It would be very difficult for them to take the appropriate action within their states.

Mr. FARR. How much money do those states get?

Mr. SCUSE. It will vary from state to state, depending on how much CRP is in the states. This money does not go to the state, it actually goes to the land owner who is taking their land out of production.

If I may point out, there is a tremendous environmental benefit to what we are——

Mr. FARR. But it is a huge cost that I think is not essentially best management practices. It is like sort of paying people not to have child labor. We do not have child labor because there are laws against it.

Mr. SCUSE. In some instances, in most instances, in fact, we are protecting environmentally sensitive land, land we have been pro-

tecting since the inception of CRP, over eight billion tons of top soil.

Mr. FARR. What about the EPA's regulations? What about on the coastal areas, Marine Fisheries or Fish and Wildlife? They have regulations that say you cannot disturb this.

Mr. SCUSE. In some of those areas, we use the Conservation Reserve Enhancement Program, which is part of CRP, in coordination and cooperation with the states, with state funding, to protect some of those areas that you have just pointed out.

Mr. FARR. Could you for the record, in writing, just point out what states or counties you have weaned off the program because they have taken responsibilities to enforce what I call "best management practices?"

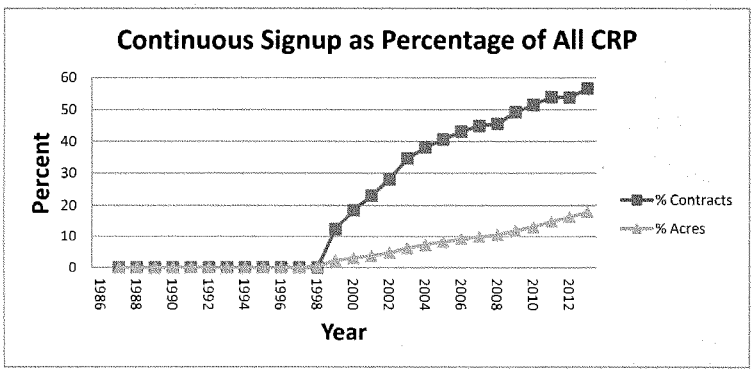
Mr. SCUSE. Sure.

[The information follows:]

Conservation Reserve Program

CRP is a voluntary land retirement program that helps agricultural producers protect environmentally sensitive land, decrease erosion, restore wildlife habitat, and safeguard ground and surface water for 10 to 15 years. Several major changes to CRP policy have occurred since 1985, reflecting CRP's change from being supply control driven to being environmental outcome driven. CRP's enrollment cap has been reduced from 40 to 45 million acres (in the late 1980's) to 32 million acres since 2008, and is likely to be further reduced in the near future. In some sense, all three of these factors have served to help reduce county enrollments.

One of the biggest changes as a result has been the advent of continuous signup, in which a more targeted approach to enrollment is conducted. Continuous signup targets specific practices such as riparian and grass buffer strips along streams and wetland restorations, as well as to specific habitat types for wildlife. As the graphic below shows, continuous signup has increased to account for nearly 60 percent of CRP contracts, and for nearly 20 percent of acreage.



Another way to view CRP changes over time is to follow the change in the average size of CRPs general signup contracts over time. General sign-up contracts are mostly whole-field or whole tract enrollments. The average size of general signup contracts have declined from 95

acres in 1990 to 74 acres in 2012, indicating that farmers and FSA have been more discriminating in selecting acreage for enrollment. For example, farmers are offering the more highly erodible fields or portions of fields for enrollment, and perhaps farming the rest.

One of the most successful programs under Continuous CRP is the Conservation Reserve Enhancement Program (CREP). The program is a partnership among producers; tribal, state, and federal governments; and, in some cases, private groups. CREP is an offshoot of the country's largest private-lands environmental improvement program - the Conservation Reserve Program (CRP).

Like CRP, CREP is administered by USDA's Farm Service Agency (FSA). By combining CRP resources with state, tribal, and private programs, CREP provides farmers and ranchers with a sound financial package for conserving and enhancing the natural resources of farms.

CREP addresses high-priority conservation issues of both local and national significance, such as impacts to water supplies, loss of critical habitat for threatened and endangered wildlife species, soil erosion, and reduced habitat for fish populations such as salmon. CREP is a community-based, results-oriented effort centered around local participation and leadership.

CONSERVATION RESERVE PROGRAM
CUMULATIVE ENROLLMENT BY FISCAL YEAR (ACRES) 1/

STATE	2002	2012	Change
ALABAMA	483,654	360,285	-123,370
ALASKA	29,476	18,983	-10,494
ARIZONA	33	0	-33
ARKANSAS	161,363	251,166	89,803
CALIFORNIA	138,997	101,228	-37,770
COLORADO	2,209,395	2,175,942	-33,453
CONNECTICUT	318	126	-192
DELAWARE	6,572	6,541	-30
FLORIDA	88,286	51,445	-36,841
GEORGIA	313,664	317,305	3,641
HAWAII	21	498	477
IDAHO	792,042	648,800	-143,242
ILLINOIS	964,289	1,030,450	66,161
INDIANA	301,669	280,366	-21,304
IOWA	1,865,730	1,644,429	-221,301
KANSAS	2,658,808	2,522,888	-135,920
KENTUCKY	312,878	332,253	19,375
LOUISIANA	205,781	325,424	119,644
MAINE	24,273	13,554	-10,720
MARYLAND	60,926	78,764	17,838

CONSERVATION RESERVE PROGRAM (Continued)
CUMULATIVE ENROLLMENT BY FISCAL YEAR (ACRES) 1/

STATE	2002	2012	Change
MASSACHUSETTS	121	10	-111
MICHIGAN	310,138	221,691	-88,448
MINNESOTA	1,669,379	1,555,675	-113,703
MISSISSIPPI	864,882	827,811	-37,071
MISSOURI	1,551,755	1,282,784	-268,971
MONTANA	3,411,536	2,492,461	-919,074
NEBRASKA	1,140,851	993,925	-146,927
NEVADA	151	146	-5
NEW HAMPSHIRE	195	13	-182
NEW JERSEY	2,294	2,445	151
NEW MEXICO	593,971	414,320	-179,651
NEW YORK	60,266	50,658	-9,608
NORTH CAROLINA	113,535	111,088	-2,447
NORTH DAKOTA	3,326,883	2,387,324	-939,560
OHIO	304,836	336,198	31,362
OKLAHOMA	1,025,294	818,970	-206,324
OREGON	455,504	546,432	90,928
PENNSYLVANIA	118,052	205,551	87,499
PUERTO RICO	671	1,199	528
RHODE ISLAND	0	28	28
SOUTH CAROLINA	218,828	143,241	-75,587
SOUTH DAKOTA	1,432,131	1,110,292	-321,839
TENNESSEE	248,777	190,174	-58,603
TEXAS	4,043,602	3,354,171	-689,430
UTAH	200,489	178,440	-22,049
VERMONT	1,006	2,827	1,821
VIRGINIA	55,819	61,172	5,353
WASHINGTON	1,281,331	1,488,621	207,290
WEST VIRGINIA	1,077	6,232	5,155
WISCONSIN	634,875	368,230	-266,645
WYOMING	277,959	213,021	-64,938
Total U.S.	33,964,386	29,527,611	-4,436,774

1/ Fiscal year ends September 30.

Mr. FARR. Thank you.

Mr. ADERHOLT. Mr. Valadao.

MIDAS

Mr. VALADAO. Thank you, Mr. Chair. Mr. Under Secretary, congratulations on the release of MIDAS. I am pretty excited to follow it myself.

My question specifically is can you please expand a little bit on how and when farmers will actually have access to it and how they will be able to benefit from it?

Mr. SCUSE. The farmers will have access to it immediately. We are looking at being able—I say "immediately." We need to get our staff. That is one of the reasons why we started it in phases, to get the staff fully comfortable with the use of it. It will be in the next few weeks. We are going to be using this product with our farms.

There are different phases for MIDAS. This is the first phase for our farm records. We will be able to update our producer records when they come into the office.

I think the biggest change that farmers and ranchers are going to see is now we do not use two different systems when they come in to do a crop report.

We are going to be able now to combine everything into a single system, which will save not just staff time but save reporting time by our farmers and ranchers.

We are still using a great deal of paper when a producer comes in to do a crop report. This system will allow us to not have to go actually do paper maps and draw lines on paper, fields or portions of fields. That will all be able to be done on the screen itself.

We are excited about this. I think where your question is going is when will farmers actually be able to do this at home, there is another initiative, the Acreage Crop Reporting Streamlining Initiative that we started a year and a half ago, which is one of the reasons why we consolidated all those crop reporting dates down.

We are going to do a pilot project with that in the State of Kansas, in four counties, this Spring.

Where we hope to go with that is to actually allow the producers to do one stop shopping. As a producer yourself, if you have crop insurance, you now have to give two reports, one to FSA and one to your insurance agent. This will allow a producer to do one and ultimately do a report right from their farm office.

ACREAGE CROP REPORTING

Mr. VALADAO. To follow up on that, there is quite a bit of information when you go down to the Farm Service Agency that they have and ask for.

When we wait for NASS reports, it is almost like they are guessing. As much information as your Department has, why do we not go off that instead of NASS?

Mr. SCUSE. A good point. One of the things that we did when we started to put together the Acreage Crop Reporting Streamlining Initiative, we got multiple agencies into a room. NASS was one of those agencies, and NRCS was one, the Risk Management Agency and the Farm Service Agency that are under me.

There were some issues because four different agencies identified the same parcel of land four different ways. It was very difficult to combine the information that you would ask for.

What we were able to do was to get the four agencies to agree on one common land identifier. They can still use their own, but for purposes of cross reporting, there will be one common land identifier.

This is one of the things that we also pointed out to NASS, to your point, that with the MIDAS system, with the Acreage Crop Reporting Streamlining Initiative, with those two in place, we are going to be able to get data much faster and more accurate to NASS for more accurate crop reporting.

Mr. VALADAO. Thank you.

Mr. ADERHOLT. Ms. Pingree.

CROP INSURANCE FOR ORGANIC FARMERS

Ms. PINGREE. Thank you, Mr. Chair. Thank you very much for you all being here today and for your previous testimony. Appreciate that.

I want to ask a couple of questions about Risk Management. I was encouraged to see RMA's recent announcement on removal of the five percent premium surcharge assessed against all organic farmers seeking Federal crop insurance that starts in crop year 2014.

I appreciate this was in response to an earlier release by the Inspector General Audit of Organic Crop Insurance. As you know, the audit found that transitional crop yields for organic farmers using organic crop insurance generally exceeded actual production histories.

This arbitrary organic surcharge has been an issue I have heard a lot about in Maine and from farmers across the country. I am very pleased to see this progress.

I remain concerned that only about a quarter of organic farmers are enrolled in Federal crop insurance. In addition to eliminating the surcharge, are there other steps that RMA can take to increase organic crop insurance participation?

I know it is something that would be of great benefit, particularly with out unpredictable weather patterns. I think more people would like to participate but they are not there yet.

Can you talk a little bit about that?

Mr. WILLIS. I share your concern, approximately 25 percent of the acres that could be enrolled in the crop insurance program are enrolled.

You talked about eliminating the five percent surcharge. That was the first step. The yield differences you also referred to would be a second step.

Another complaint that organic producers often have about the program is they often receive a premium in the marketplace on production, and their crop insurance program, we are slowly trying to get there.

Currently, we have eight crops where farmers can elect to receive that organic price. What we are working on is kind of a two pronged approach to increase the number of crops.

Last year we funded a NASS survey of organic prices, and we are looking at that survey trying to determine which crops we can expand in the near future.

We have a list of those crops. I think in the next month we can announce some for 2014, some additional crops, almonds, apples, blueberries, wheat, and some stone fruits.

The other thing we are looking at doing is trying to create a policy where if producers have a contract with somebody to purchase, and there is a price in that contract, see if there is a way there to respect the contract they have within reason so they can also have an organic price.

I think our focus now is implementing the changes you discussed and also trying to have more crops receive the organic price.

Ms. PINGREE. Maybe just to drill down on that a little, it is my understanding it has been six years getting to the few crops that are defined, and I am heartened to hear you are going to add some more.

Not fully understanding the process that you go through, what makes it take so long, what is complicated about doing this?

Mr. WILLIS. I think there is a strong desire to make sure we have an accurate price because the last thing anybody wants is for the price to be too high or too low and to somehow drive production.

I think that is why a few years ago they contracted with NASS to get more information. We have individuals at RMA that look at all sorts of private sector information, NASS information.

It is just trying to get enough price data that we are confident enough we can offer that. It is really just getting confidence in the data. Obviously, the data on organic crops is thinner.

Ms. PINGREE. It is increasing given the expansion of the market and the more national sales that are going on on a lot of varieties of things that people grow.

On this suggestion, which does seem like it would be useful to look at a contract and then maybe use that as a determinant if there was an insurance need, does that happen in other ways?

I am not that familiar with how crop insurance works.

Mr. WILLIS. Yes, we have used it for other policies in the past, and we will kind of look at how we did it there, I think, to kind of set the parameters for how we do it in this situation as well.

Ms. PINGREE. It is within the parameters of appropriate insurance policy?

Mr. WILLIS. Yes, we have done it historically.

Ms. PINGREE. It would seem to me if that was allowable, then you could greatly expand the number of things you could cover because it does not have to just be corn or almonds or something that has a huge commodity market or big national sales. You could do lots of things that people do get contracts for every year, but we do not always think of it as prime crops.

I hope you will keep me updated. I am very interested in this. Thank you, Mr. Chair.

Mr. ADERHOLT. Thank you. Mr. Nunnelee.

SEQUESTRATION IMPLEMENTATION

Mr. NUNNELEE. Thank you, Mr. Chairman. Thank you, Mr. Secretary, for being here. And I want to go back to that very significant announcement you made in your testimony about your agency's ability to avoid furloughs. I want to thank you for the approach that you have taken, certainly my FSA agents in Mississippi and communicating to them, getting us through this, but I am curious about how did you plan for sequestration? How did you get to the point where it was not necessary to have furloughs in order to implement sequestration?

Mr. SCUSE. Well, we have worked, the three agencies under me, to make cuts and reductions since last fall, not knowing what may happen. And I think that is why when I was asked earlier about the impacts on RMA and the Foreign Agricultural Service, there were no furloughs for those agencies. But just the sheer size of the Farm Service Agency and the offices that we have throughout the 50 states, it was very difficult for them to make the same level of cuts that the other two agencies were to avoid the furloughs.

We have the ability to use CCC funding, the Section 714 funding, to cover some of our operational costs. What we were working with OMB on was that we felt that we have not received the cost recovery for our conservation programs that we have been doing. And we are permitted to recoup those costs under the CCC language or under the 714 language.

So, we made a request for OMB to allow us to use the 714 language to cover operating costs for our conservation programs and some of the other programs that are under CCC. They have agreed to allow us to do that, but I do not want the committee to believe for one minute that this is just money that fell from the sky because we have to do an offset for that money. And we were able to come up with an offset in order to receive the 714 money. So we just were notified yesterday by OMB that they did agree to allow us to use the 714 to cover our operating expenses for our conservation programs with the offset that we provided.

Mr. NUNNELEE. I cannot tell you how refreshing it is to hear you make the statement, "We started planning for sequestration in the fall." I cannot express my frustration at the long line of witnesses that we have had in various subcommittees that said, "Oh, we did not start planning for sequestration until two days before." So, thank you for your stewardship of the taxpayer dollars and managing a very difficult situation.

CROP INSURANCE

Let me move now to implementation of direct payments. I think it is obvious to a lot people that whatever we work out in the farm bill, direct payments are going to be a thing of the past. But when I talk to agri-business owners, when I talk to lenders, they have got to have some kind of certainty in order to make the loans to put the crop in the ground. So, just in general, where do you see us going in order to give farmers and lenders the certainty necessary to plant their crop in light of the fact that we are probably not going to have direct payments in a long-term farm bill?

Mr. SCUSE. I think that certainty can be provided through a strong safety net. We have a very healthy and strong crop insurance program. I think if you look at the banking industry today, many will require their producers to be covered with some sort of insurance for that certainty. If you look at the programs that I believe are in the President's recommendation, and I think were in the farm bills that the House and the Senate version that did not pass last year, there are the four programs. Three of those programs cover our livestock producers with the LIP, ELAP and LFP programs. So those programs I think will also provide some sort of certainty and insurance that if there are weather-related events, that there will be some sort of compensation. So, I think that certainty, sir, is in the safety net that is provided to our farmers and ranchers.

Mr. NUNNELEE. What about for those crops for which there is no insurance?

Mr. SCUSE. Well, we do have the NAP insurance through the Farm Service Agency, and I think that there are proposals or will be proposals in the coming farm bills that will allow us to strengthen that NAP insurance for those products that we do not currently offer crop insurance for.

Mr. NUNNELEE. Alright, thank you, Mr. Chairman.

Mr. SCUSE. You are welcome, sir.

Mr. ADERHOLT. Mr. Bishop.

MECHANICALLY-SEPARATED POULTRY

Mr. BISHOP. Thank you very much. Let me welcome all of you this morning. I am going to start off I think with Ms. Heinen. We are aware that the Food Safety and Inspection Service has decided to postpone a sampling of mechanically-separated poultry until it can consider the stakeholder comments on their proposed new rules, specifically, regarding that notice which was entitled, "The HACCP Plan Reassessment for Not Ready to Eat Comminuted Poultry Products and Related Agency Verification Procedures." Has the Foreign Agricultural Service evaluated the economic implications of what might essentially be destroying the export market of mechanically-separated poultry, which has implications for flooding the domestic market and reducing exports?

And the second part of that question is did FSIS discuss this with FAS, the international trade implications of the proposed new rules before they published the notice?

Ms. HEINEN. Well, as you know, Mr. Bishop, the FSIS has the mission to protect the safety of the U.S. public, and so I think they are doing what they feel is necessary to do that. On the export market, one of the things that is our biggest seller overseas is the confidence that our traders or our partners overseas, other countries, have in the safety and the quality of the U.S. product, and the confidence they have in our regulatory agencies. So, if this is the step that FSIS thinks they need to take, we support their efforts to improve the safety of our food.

Mr. BISHOP. But my question was whether or not they had discussed it with you, have you had any collaboration on it? Did they ask or inquire about what implications there might be?

Mr. SCUSE. Congressman, I personally have been involved in a discussion that we had with the industry with Under Secretary Hagen within the last month. We did have the conversation. The industry did report their concerns to us. Under Secretary Hagen expressed her concerns with not going forward with this, and the implications that should something happen that they could lose the market. I believe it is a $300 million market for the mechanically-separated poultry. And the fear is that should something happen in a foreign country, that not just a portion of that would be lost but a great deal of that market may be lost.

Mr. BISHOP. So you have been involved in those discussions?

Mr. SCUSE. Yes, sir.

BRAZILIAN COTTON

Mr. BISHOP. Thank you very much. Ms. Heinen, as you know, American agriculture has been openly criticized by international operations and eminent academicians for agricultural subsidy, which I call support, and other related programs which support and strengthen our food production capacity here in America. And we are not alone in this arena, as both developed and developing countries are offering their agriculture industries a wide variety of support and protection-like programs. I am concerned about nations like Brazil, which successfully brought the claim against the United States through the WTO on cotton. And also they are providing their key agricultural industries government support on their own in a direct attempt to compete with United States agriculture.

As such, our worldwide competitors on a number of levels are doing this, and we need to treat them as such. Where are we with the WTO Brazilian cotton issue? And are there any other similar cases on the horizon, particularly on the part of developing nations that could affect American agriculture?

Ms. HEINEN. Well, on the first case with Brazil, of course we still need to make changes in the cotton program.

Mr. BISHOP. Is your microphone on?

Ms. HEINEN. Is it on?

Mr. BISHOP. There, that is better.

Ms. HEINEN. We are still working with you to make appropriate changes so that we can comply.

The United States agricultural system is well understood in the WTO, and we are staying within our allowed rights within the WTO. We share your concern that some countries may not be doing this, and we have spent some time this year looking at some other countries and whether or not they are living up to their obligations. We are concerned in the case of Brazil about their premium for product flow—PEP—program, which we think in some cases may have been used inappropriately. So, we are watching this. We are analyzing different approaches countries are taking to ensure that they are living up to their WTO commitments as well.

Mr. BISHOP. Thank you. My time is up, and I will come back to tomato dumping from Mexico on the next round.

Mr. ADERHOLT. Mr. Fortenberry.

FSA COUNTY OFFICE CONSOLIDATION

Mr. FORTENBERRY. Thank you, Mr. Chairman. Good morning, everyone. Thank you for appearing today. A number of years ago, I held a town hall meeting in Allen, Nebraska. It is a town of about 350 people. And about 40 farmers showed up at noon. And I determined quickly that I had inappropriately mis-timed that town meeting because an hour before had been the meeting to discuss the closure of the Farm Service Agency in that county. And so when that was done, everybody came on over to talk about it with me.

Now, we got through that, that county agency was saved, and we actually were able to consolidate it with another nearby county, which at first evaluation did not appear as an office that would be necessary to close. Anyway, the point being that we tried to work creatively through what was a consolidation that is difficult to adjust to, made necessary because of the tensions and difficulties that we all have in the budget. But at the same time tried to creatively meet the need of the constituent in the area that we are servicing.

And so I think that is the spirit in which we have to all move forward here in terms of determining what is the highest and best uses of the limited resources that we have, and what needs to be transformed or renewed, we do so, and what needs to be changed, we embrace it and work creatively through it.

FAS INFORMATION AND DATA COLLECTION

With that said, in that regard, I want to turn to the Foreign Agricultural Service, a big portion of your work is statistical gathering, or at least it used to be as I understand that. Now, in this day and time in which we are integrated globally and, by the way, agricultural exports is essential to the well being of our nation. Let me point that out. It is one of the few things that we make on a large scale anymore, and it contributes significantly not only to our economic well-being at home but our positive trade balance as well.

So your integration throughout the world, working on the ground, ensuring the robust nature of our export programs and ensuring the quality of the delivery of our food overseas is vitally important. A component of that is statistical gathering but again in this day and time in which we are globalized, in a previous time you were the only entity out there that could possibly do this. Large major agricultural—international agricultural organizations do their own statistical gathering. Talk about the mission of that component of what you do, and what possible changes could be made?

Mr. HEINEN. Well, thank you and thank you for your kind words about our efforts in regards to exports. Yes, one of the things that our attaches overseas do is collect information about production—productions and policies in their country. And that information is sent back, analyzed in Washington and contributes to our overall monthly publications of the WASDE report, the supply and demand estimates.

You are absolutely right that many things have changed. I know in my first posting overseas in China, I was the expert in cotton. And I had London calling me and asking me about my estimates

at that time. And things have really changed. And I would say we do not go out and do the kind of collections that we might have done at one time, kind of field surveys and things. We rely more on talking with others who have collected information, be they the host governments or other agencies. We use a lot more remote sensing, geo-spatial information. And we try to accumulate that in a much more efficient way and use other sources. But we still—there is still a great deal I think of confidence in the numbers that USDA puts out.

Mr. FORTENBERRY. I guess that is the heart of my question. Do you still occupy a central place for the larger international agricultural community, trading, producers, markets? Is it a centralized core place as it once was? I am just not sure that is the case any longer.

Ms. HEINEN. I think we do still play a central role. There are other efforts going on that play other roles, but I think we play a central role in getting that confidence of what the situation is.

CONSERVATION RESERVE PROGRAM

Mr. FORTENBERRY. My time is running down so I do not mean to cut you off, but just get to a couple of other things. The CRP, I believe if I recall correctly, we topped out at about 39 million acres, and we have dropped down to about 28, is that correct?

Mr. SCUSE. Twenty seven, a little over 27.

Mr. FORTENBERRY. Is that number based upon your trajectories, your predictions stabilizing there?

Mr. SCUSE. We have about three million acres coming out this year, so we may have a drop.

Mr. FORTENBERRY. Not in that 27?

Mr. SCUSE. No, that is included in that 27. There will be about three million acres coming out. A lot of it will depend on, you know, where the commodity prices are, where the land actually is, but we may see an additional reduction. But we are going to start——

Mr. FORTENBERRY. What do your projections show over time as to where that number is likely to land?

Mr. SCUSE. Well, we have been seeing—I mean each year, we have been seeing a decrease in our CRP acreage. The President's proposal is 25 million acres. I think in the next two farm bills, the House and Senate version, they are looking at 25 million acres. That is probably close to where we will eventually be in the next couple of years.

Mr. FORTENBERRY. Thank you, Mr. Chairman.

Mr. ADERHOLT. Ms. DeLauro.

CROP INSURANCE REFORMS

Ms. DELAURO. Thank you very much, Mr. Chairman. My apologies, Secretary Sebelius is at Labor/HHS, so we are all kind of running back and forth here. So, I am going to use my five minutes, and I am going to ask—make it question concise, answers concise.

Mr. Willis, your testimony notes that a "reasonable rate of return for companies that provide crop insurance should be around 12 percent." So it appears that the Administration's proposal to establish this rate of return should not harm the ability of companies to offer these insurance policies. Is that correct? And I need a yes or a no.

Mr. WILLIS. Yes.

Ms. DELAURO. And your testimony indicates that the same is true for lowering the cap on federal dollars for the administrative costs of these companies?

Mr. WILLIS. Yes.

Ms. DELAURO. Is that accurate? Okay. I certainly hope that we can enact these kinds of commonsense savings in this effort. It is a program that has—estimated cost is about almost $59 billion, in any case.

CROP INSURANCE OVERSIGHT

Now, the GAO continues to find inadequate oversight of the Federal Crop Insurance Program. Crop insurance was one of the programs in GAO's "Cost-savings and Revenue-Enhancement Opportunities Report." Your fiscal year 2014 budget request includes the lowest staff level ever. As a matter of fact, the level of your budget is the same amount that goes back to 2004.

How will you implement the GAO recommendations to improve oversight with fewer RMA staff? How will this staff level affect your ability to strengthen oversight of the program? What has been done to improve the completion of field inspections after GAO's March 2012 report? How are RMA and FSA working together so this does not continue to fall through the cracks? How are you building on the existing data mining tools to better prevent fraud and abuse in the program?

Mr. WILLIS. Anywhere you want me to start?

Ms. DELAURO. How will you implement—you have lowered your staff numbers, I have talked about the size of your budget, the number of employees drops, lowest level ever, how are you going to implement the GAO recommendations to improve oversight with fewer staff? I read through the questions. So, let's go down the list.

Mr. WILLIS. Primarily, through technology. We are using more data mining that singles out those areas, individuals who are of the highest risk to the program. We identify those. We do spot checks. One way we are leveraging the money we have is we are not just having our sister agency, the Farm Service Agency, do those spot checks. We are working with our companies. They started out with a pool last year. They are increasing that pool this year. So, we are leveraging those individuals. We are also improving our IT system. That should help reduce mistakes. It should have some edits in there where if information comes in that is faulty, it is rejected. So, I think a lot of it is going to have to happen through technology improvements.

As far as the audit, I believe that is part of the new producer audit. What we have had is we have had the companies go back for I believe it is 2008 and 2009, and check 5,800 of those producers who were found to perhaps not be eligible for the new producer status. They should have finished that during the month of May. After that, we will send a new list for 2010, 2011 and 2012. And any producer who received the new producer status who should not, that will be corrected.

Ms. DELAURO. What I will do is—I wanted you to answer this morning, but I am going to send each of these questions because

I truly do want to know what the specifics are in terms of field inspections, et cetera, and the way in which we are going to do that.

Let me ask you this question if I can. You have got 500 people and $75 million. I want your professional opinion. I want your professional opinion. Do you believe that you can adequately oversee this vast industry with that number of people and at this budget level? I want your professional opinion, and I do not know if your professional opinion represents what is represented here in the budget?

Mr. WILLIS. We actually have 455 right now. Yes, I do, but I believe we will have to change the way we do business in some cases. We will have to use more technology to do that.

Ms. DELAURO. Do you need more money to be able to do that?

Mr. WILLIS. I think if we change the processes in certain cases we can do it. I think some of the examples with the data mining and leveraging resources, we have great private partners, I think we have to leverage them more.

Ms. DELAURO. Let me just note for the record that the budget for RMA was $75 million in 2012. It was $71 million in 2004. So, it has not grown very much. In 2014, you are asking for $71.5 million for 2014, which actually puts you at about the 2005 level. With the growth of technology, with the increase in technology, and that—again, in order to deal with the vastness of this effort and to be able to do what the GAO has been asking to do is to take a look at waste, fraud and abuse in this program. You are fine with this budget and with the staff that you have, and that is adequate and that is your professional opinion?

Mr. WILLIS. Yes.

Ms. DELAURO. Thank you, Mr. Chairman.

AGRICULTURAL EXPORTS

Mr. ADERHOLT. Let me switch over and focus a little bit on the U.S. agriculture trade policy. It was talked about a little bit earlier, but against the backdrop of the poor economy over the last few years, we can take pride in the positive impact of U.S. agriculture exports. I along with many of my other colleagues believe there is far greater potential for growth of U.S. exports simply because 95 percent of the world's consumers live outside the United States of America.

This is the second year in a row when we have not seen any new efforts, initiatives or plans by USDA to do more for agriculture exports. Just last month, OIG released a report on the matter of Foreign Agricultural Service reform, and said that FAS performance measures were not outcome-based and do not show how the U.S. is performing in given market compared to its competitors.

My question would be does USDA have a recent comprehensive plan or strategy for competing in the global marketplace against the Chinese, Brazilians, Europeans or other countries that focus on increasing greater market share on behalf of their producers?

Mr. SCUSE. Well, thank you for recognizing the exports and the growth in the exports. As I pointed out earlier, the last four years have been the strongest that we have ever had. We have done almost a half a trillion dollars worth of exports the last four years.

And when you look at this year again, we are looking at about $142 billion in trade, which would give us another record year.

I think if you look at what the Administration has done, we have the three FTAs that were passed. Congress passed the Korea, Panama and Colombia FTA. We have already seen tremendous growth in those three countries already. Our exports this past year were about $7.6 billion.

We are in discussions right now with the TransPacific Partnership. They are counting the United States, and I think the letter was just received yesterday where we are planning to engage Japan for inclusion in the TPP. There is a tremendous potential, especially now with Japan as part of the TPP for agricultural trade to get through some of the differences that we have.

The President also announced that we were engaging in the Trans-Atlantic Trade and Investment Partnership with the EU. The EU collectively is our fifth largest trading partner. We face many barriers today with the EU. And I think this is a great opportunity to break down some of those barriers that we currently are facing.

So there is a strategy within the Administration for us to build on the trade, the successes that we have had the last four years in trade. And we look forward to working with the rest of the Administration, especially the United States Trade Representative's office to get these agreements through so that we can further agricultural exports for our farmers and ranchers.

TRADE MISSIONS

Mr. ADERHOLT. Can you tell the subcommittee in particular what USDA is doing in fiscal year 2013 and 2014 and beyond to become more active on behalf of U.S. interests overseas and beyond what your current technical analysis or assistance is doing?

Mr. SCUSE. Well, Mr. Chairman, I personally have led two trade missions the last year. I led a trade mission to China in March, which was the largest trade mission that we had ever done. I had accompanying me several State Departments of Agriculture. And in December, I led a trade mission to Russia. Again, with 21 United States companies, and I believe five State Departments of Agriculture. We have a trade mission lined up for I believe the second week of June to Turkey. There has been a great deal of interest with again the State Departments of Agriculture, as well as other industry to participate in this trade mission. We are also working very hard with different groups on the trade shows, which is part of our MAP program.

So, we are working very hard to further U.S. trade. And I think if you look at what has happened the last several years, that is the result of the work and cooperation between us and the commodity groups, as well as others, to promote U.S. agricultural products.

AGRICULTURAL IMPORTS

Mr. ADERHOLT. As we have here just in the last few minutes talked a great deal about the growth and the overall success of our agricultural exports, USDA's February ERS Report on Agriculture and Trade predicts that U.S. agriculture imports will also be at record levels. The report estimates that agriculture trade balance

will be the lowest since 2009. What can USDA attribute this trend to? And should U.S. producers be concerned about the loss of the domestic share?

Mr. SCUSE. I do not think so. If you look at the types of products that we are importing into the United States, and if you look at the time of year that we are importing those products, for the most part a lot of them are products that we are not currently growing in the United States, especially those particular times of year. So, I do not see where our producers should be that concerned. Yes, there might be certain areas, certain segments of agriculture where there will be competition, but for the most part we are also exporting a great deal of products that we are importing, but at a different time of year.

Mr. ADERHOLT. What are some examples of the imports you are talking about that would not compete with our growers?

Mr. SCUSE. Well, if you look at from our South American countries, if you would look at the grapes and the strawberries, and the different types of fruits and vegetables that would come from other countries but come during winter months when our production would be at its very lowest, if at all. So that is an example right there of where we are not having the competition.

Mr. ADERHOLT. And you attribute that to we are doing that more now than we used to?

Mr. SCUSE. Yes, our demand for fruits and vegetables is increasing in the United States. If you look at what we are importing. Our demand from our consumers is also increasing just like many of the countries throughout the world. Their demand for our U.S. products is increasing.

Mr. ADERHOLT. Thank you. Mr. Farr.

IMPORTED FLOWERS

Mr. FARR. On that trade issue, I have a particular concern about flowers because I represent a lot of flower growers. Do you have flowers in the Department? Do you have flower displays, floral displays in the Secretary's office or anything like that? Your office?

Mr. SCUSE. We did yesterday.

Mr. FARR. Are those flowers from the U.S.?

Mr. SCUSE. Yes, sir.

Mr. FARR. Are you sure?

Mr. SCUSE. I think the flowers that we had on display yesterday were from——

Mr. FARR. Not just yesterday.

Mr. SCUSE. Well, I cannot say forever or for last week or the week before, but I think the flowers that we had yesterday were.

Mr. FARR. Could you check on that policy because we are trying to get—and the White House has a policy about serving all the food and wines have to be American, but they have in the past had at the expense of American flower growers, have had all these imported flowers. I would like to see some leadership on making sure that at least our government agencies are using domestically-grown flowers because we produce a lot of them.

INSURED CROPS

What crops are insured?

Mr. WILLIS. We have about I think it is—is it 300? About 300 crops are insured, sir.

Mr. FARR. Are insured?

Mr. WILLIS. Yes, sir.

Mr. FARR. Which ones are not? How many are not insured?

Mr. WILLIS. What we will find is a crop might be insured in one county, like an apple, because you have a lot of apple production. You have the data you need to create a policy. But you might move to a different county, and the apples are not covered because there is not the historical production data in those counties. So, you will have a lot of fruits and vegetables in particular that are covered in certain areas, but not covered in certain areas because the data is not available. So it is going to be where the crop is grown a lot.

Mr. FARR. Well, we grow 85 crops, and you can find anybody who will tell you what crop they are going to grow. They are going to grow three crops a year, they will not tell you what they are going to grow, what their next crop will be. So you do not have I mean those standard records. Why do we not have some data that allows them still to be in an insurance program?

Mr. WILLIS. I am not sure I followed that question, sir?

Mr. FARR. Take raspberries. Well, raspberries are a more permanent crop.

Mr. WILLIS. Yes, sir.

Mr. FARR. But lettuce?

Mr. WILLIS. If there is a county where there is a lot of lettuce growing, and it——

Mr. FARR. There is, it is called Monterey County. It grows 80 percent of the lettuce in the United States.

Mr. WILLIS. I think if the producer—many counties, and especially in California with lettuce, I actually visited there a few months ago, they do not want crop insurance simply because in the lettuce market in particular, they are more concerned about the price fluctuations, and they often destroy their crop when the price gets too low to keep the market in balance. And they have actually not asked for crop insurance for those crops. But where people ask for it, and there is data, we want to expand. We do not want to have people who grow a crop not have crop insurance available to them.

Mr. FARR. What about food safety insurance for contamination for recall, like spinach?

Mr. WILLIS. As I understand it, we do not have the legislative authority to do that right now, sir.

Mr. FARR. You need legislative authority for—to sell—but the market will sell it or they only sell insurance that is covered by—subsidized by USDA?

Mr. WILLIS. As I understand it, the Federal Crop Insurance Act does not allow the Department of Agriculture to work with our private partners and offer crop insurance that would help in cases of a recall, I think is a common example, or those types of situations.

NON-INSURED CROP ASSISTANCE PROGRAM

Mr. FARR. But if there is a natural disaster and something gets wiped out, then they can get access to the non-insurance, right?

Mr. WILLIS. If there is a natural disaster, we cover those types of losses. And if the Crop Insurance Program does not cover a crop in a county, as we talked about, the Non-Insured Crop Assistance Program, administered by Farm Service Agency, will step in and cover those crops.

Mr. FARR. What are the requirements for that?

Mr. WILLIS. For the Non-Insured Crop Assistance Program?

Mr. FARR. Yes, what are the requirements to trigger the authority to use that insurance?

Mr. WILLIS. The primary requirement is that the catastrophic level crop insurance policy that we would offer is not available for that crop in that county.

Mr. FARR. And it does not have to be, for example, you could not collect on the recall of the spinach?

Mr. WILLIS. It would again only be for losses from natural disasters.

Mr. FARR. And natural disasters has to have enough loss to trigger, it is a formula for declaring a natural disaster. It is not just any time you want to declare it.

Mr. WILLIS. They use a formula.

Mr. FARR. They use a formula of loss, of value of loss or life loss. The governor of the state has to declare it first, meeting state standards. Those state standards have to meet federal standards. And if they meet them, then there is a federal declaration. And you need that before you can trigger the insurance.

Mr. SCUSE. No, sir, for the NAP insurance, you do not need a declaration—a disaster declaration to be covered under that. It is catastrophic insurance, so you have to have a 50 percent loss or 55 percent reduction in the price.

Mr. FARR. Well, we had that with spinach, and there was no way of getting any help.

Mr. SCUSE. But the producers have to sign up for that insurance.

Mr. FARR. But that insurance is not sold, he just told us.

Mr. SCUSE. But through the county office, they could have been insured through the NAP program.

Mr. FARR. I do not think they have the actuarial information to provide that insurance, but I would like to look into that. My time has expired.

Mr. ADERHOLT. Mr. Nunnelee.

MECHANICALLY-SEPARATED POULTRY

Mr. NUNNELEE. Thank you, Mr. Chairman. I'd like to go back to a lot of questions that Mr. Bishop started concerning the HACCP Rule on poultry. I understand you answered Mr. Bishop's question that it effects approximately $300 Million worth of poultry exports. Do you believe there will be any retaliation from countries that are importing this poultry, if this rule were to be implemented?

Mr. SCUSE. I don't believe so. I think this is just the way we are trying to protect our trading partners as well as the industry. So I don't know that there would be any sort of retaliation for trying to protect our trading partners.

COMMUNICATIONS ON AGRICULTURAL EXPORTS

Mr. NUNNELEE. And then Mr. Bishop asked about communication between FSIS and your agency, specifically, as it related to the HACCP plan. I am interested more in general communication between the various agencies, you know, with USDA or outside USDA as it relates to agricultural exports as they consider regulations. Are you comfortable with the level of communication that exists, or should there be changes made as agencies are considering regulations affecting Ag exports?

Mr. SCUSE. Yeah. I appreciate the question, and it's one that we get often. I think we are working better together now than we probably ever have. I know with the FSIS with Under Secretary Hagen there, there's been a lot of involvement and back and forth between her agency and mine on issues.

We are working very closely with the United States Trade Representative's Office on all different areas, not just exports, but some of the trade barriers that we have with some of the other countries. So I think we have a really good working relationships with our sister agencies right now in trying to not just protect our consumers, but also make sure we are furthering U.S. trade as well?

ACREAGE CROP REPORTING STREAMLINING INITIATIVE

Mr. NUNNELEE. Then, let me shift gears. We have talked the last couple of years about redundancy in various reporting requirements. And we talked a bit last year about some successes that we have had, even in areas we had four different agencies giving different labels to the same parcel of land and how farmers tell me they are sending the same data set to numerous agencies, even within USDA. And I understand you are working on that. Can you just tell me what progress we have made since we met last year?

Mr. SCUSE. Again, we have made tremendous progress. Just the ability to get everybody to sit down in the room and come to an agreement on the identifier as well as the reporting dates, that was a big step. But, I mean, as I pointed out earlier, the acreage crop reporting streamlining initiative, we are starting a pilot program this year. If that pilot program goes well, then we can incorporate it into our MIDAS program where we are only going to have the one-stop shopping. As a farmer, myself, I don't like the fact I have to go give a report to the Farm Service Agency and my crop insurance agent.

So I understand the importance of one-stop shopping and eliminating the redundancy in some of these areas, but we are making progress. You know, I would hope that next year I could tell you that we are beyond the pilot project, but a lot of this also had to deal with getting the MIDAS project up and functional so that we could go ahead and do the acreage crop-reporting streamlining initiative and eventually incorporate it. So I understand your concern.

Mr. NUNNELEE. And I would just encourage you to continue to work diligently in that area. Earlier this year, Secretary Vilsack testified before this Subcommittee and talked about categorical eligibility for Food Stamp recipients. And the response was, well, we don't want these recipients to have to go in and fill out the same

information numerous times for various benefits. And I understand that.

I would just encourage you that if we were going to do it for the ones getting Food Stamps, let's make sure we tip to eliminate that redundancy for the ones growing the food that they are eating.

Mr. SCUSE. You have my commitment.

Mr. NUNNELEE. Thank you.

Mr. ADERHOLT. Ms. Pingree.

INSURED CROPS

Ms. PINGREE. Thank you, Mr. Chair. Just one more thing on crop insurance, and I appreciate there have been a lot of interesting conversations. So this is about diversified crop insurance. Certainly, a lot of farmers in Maine have gone to more of a diversified crop, several acres of mixed vegetables or different kinds of farm inputs, and it has been very successful for them.

In the market, this means that a lot of farms don't look like they used to where you just evaluate the value of soybeans or cotton or something in particular, but what I found during my brief tenure here in Congress is there are a lot of holes in the coverage available to diversified farmers. It should not be available to some farmers. It should be available to all types of farms, and it shouldn't insure the whole farm.

I know that in some states RMA has made available the adjusted gross revenue insurance, and the variation is called AGR Lite. But these seem to be very undersubscribed programs, very hard to use. So can you talk about some of the challenges in developing and administrating these programs, and what other work is being done since this is insurance that actually meets a growing number of farmer's concerns.

Mr. WILLIS. Yeah. Consistent in a way with I think your Local Foods Farm and Jobs Act that you have where you encourage us to work on a whole farm type policy. We have actually met with some of the stakeholders in that area, trying to determine what they do not like about the current policy you mentioned: Adjusted Gross Lite and AGR. In trying to figure out how we can develop a policy that works for them, obviously, this is an area where we have room to expand. We have room to improve our programs there.

One of the things I think would be a first step there, actually, was language in the House passed Farm Bill, the buyout for the Non-insured Crop Assistance Program, where producers would have better coverage under that. But what we are going to do on our end instead of waiting for a Farm Bill to pass, we have the authority to try to expand this and try to improve this program as it is.

We are going to try to first identify what exactly the problems are, because it's a growing segment, but they are all very different too. They are not the same. See if there is a way that we can address their needs.

Ms. PINGREE. Great. Well, I hope you will keep me in the loop. I am glad you are trying to make some progress, and it's good that everything doesn't wait for the Farm Bill, since we are all waiting for the Farm Bill.

FSA MICROLOAN PROGRAM

One other question is just on the micro loan program, the FSA loan is just a micro lending program, as you know, and it's been a great interest again in people in my area. My understanding is that you made more than a thousand micro loans in the first two months in the program. 30 of those were in Maine. The design seems innovative. It reduces the paperwork. It's great for new and beginning farmers who often have very limited capital accessibility or resources.

So I see that the direct farm operating loans are increased significantly by $200 Million in the President's budgets. What portion of this is likely to go to the micro lending program and how many farmers do you anticipated we might be able to serve in FY '14 if it goes through at this level? And what else can we be doing to support this?

I think it fills a very important need, and I am glad to see we have been able to use it in my state.

Mr. GARCIA. Thank you for your question, Congresswoman. Yes, ma'am. The Microloan Program has been very successful since we initiated the program here in January. To date, we have been able to approve up to 1,800 microLoans for around $25 Million. About 90 percent of those loans have been issued to beginning farmers, so it has been a very important program.

You mentioned some good aspects of the program: less paperwork. The loans are up to $35,000, and one of the major aspects of this program that producers were having difficulty in obtaining the loan was the experience eligibility of these loans. So, for beginning farmers, one aspect of the program is that they can seek the assistance of a mentor, another farmer that's been in business for a while to meet the eligibility.

The funding for this program comes out of the regular, Direct Operating Loan funds. So it is just part of that funding that we received for our direct loan programs. Of course, over 60 percent of the direct loan operating funds go to beginning farmers and SDA producers. So we will continue working with our Microloan Program. We have not set a cap. In other words, we have not targeted X amount of dollars within our operating loan budget for micro loans.

We have been making loans up to $35,000 in the past, but with different requirements than this particular program. It has been very successful for us.

Ms. PINGREE. So, even though you don't have a cap, just to clarify, if this number is expanded, there is a likelihood you would be able to see far more of these loans if they continue to be as popular as they are.

Mr. GARCIA. Yes, ma'am. They continue to be very popular within the first month. Gosh! We approved very many loans and it is just consistently growing. And this has really helped our small farmers and beginning farmers.

Ms. PINGREE. Right. Thank you very much.

Mr. GARCIA. So a successful program. Thank you.

Mr. ADERHOLT. Mr. Bishop.

Mr. BISHOP. Thank you very much.

STACKED INCOME PROTECTION PLAN

Let me try to get in two, quick questions. And before I get to tomato dumping issue, I want to talk about cotton and the STAX program. The House Ag Committee and the Senate Ag Committee in the version of the proposed Farm Bill included a new proposed stacked income protection plan called STAX. And it was designed to provide a fiscally responsible and effective income safety net for cotton producers as well as address issues raised about the Brazilian WTO case.

But it is not my understanding that wheat, corn, soybean and possibly other commodity groups have expressed an interest in being included in the STAX cotton proposal or similar proposal rather than participating in the proposed House-Senate commodity programs. Any thoughts about that?

Mr. SCUSE. There is an issue with the STAX program as drafted in the House in relationship to the reference price for the program. If there is a reference price included, that would cause us problems with our WTO commitments for Brazil. So the reference price inclusion is an issue for that program.

Mr. BISHOP. Thank you.

MEXICAN TOMATO ANTI-DUMPING CASE

Ms. Heinen, of course the Mexican tomato dumping issue and the Department of Commerce's activities, I am sure you are familiar with that. What has been USDA's role in the matter and what is the Mexican Government's plan, if any, to stop tomatoes from being illegally dumped in our country? And is this the sort of issue that the U.S. could or should seek relief from before the WTO and are there currently any cases, which we brought against other nations pending at the WTO to protect American farmers?

Ms. HEINEN. Well, as you noted, this is in the hands of Commerce. And we were pleased to see that they were able to find an agreement to this antidumping case. There have been developments in the tomato industry since the last agreement was signed; and, so, I think it was appropriate that they looked at some of those and came up with new ways of trying to include more of the growers in Mexico, and as well as increasing enforcement.

And the Mexican government has been a party to this in coming up with ways that they will increase enforcement and ensure that at least 85 percent, if not more people are signed up. There is also use of some of our instruments here. So, all in all, we hope that this agreement will bring a level playing field to our growers in Florida as well as in your state of Georgia.

CORN CROP

Mr. BISHOP. Thank you. Let me talk about corn for a moment. It has been estimated by some private analysts that planted corn acreage could exceed 95 million acres this year. Much of this increased acreage will likely come with expensive soybeans, which is a critical crop for domestic livestock and poultry, and for export.

Also, corn yields have stagnated, and if not in fact declined in recent years, although weather has perhaps has had some impact on that. As the Department developed contingency plans, if there's a

continued shortfall in the corn harvest of this fall, for example, are there non-environmentally sensitive acres in the CRP program that could be made available for crop production, what can USDA do to make sure that the supervised corn inventories and corn prices will return to a more normal, more acceptable levels in the coming years.

Mr. SCUSE. Congressman, we have one of the worst droughts in the history of the nation last year, I think everyone would agree. But we still ended up with the eighth largest corn crop in the history of the United States. Technology has brought us a long way, and if you will look at what the market has done in the last few months, you have seen the corn price drop from its high last summer of over eight dollars. So the market, I think, is adjusting, especially to the supply, the latest supply side, as well as those planning intentioned reports.

We believe that we will have an adequate supply as we stated last summer. We thought that we would have an adequate supply in spite of the drought. So we anticipate having adequate supplies of corn and soybeans, again. Technology has gone a long way to help us get to where we are today.

Mr. BISHOP. We are looking—going years forward, though. I mean, obviously, with 95 percent more acres planted that you are going to have a bigger supply. But that is temporary, and if land is being stagnated by over production of corn, what is going to happen in out years?

Mr. SCUSE. If you take away last year's drought and you look at the trend line for corn yields, they skyrocket. We have gone from 125 bushels to the acre just a few years ago to before last year. I think it was over 160 bushels, so the technology is boosting our yields at a tremendous rate, and we anticipate that to continue.

CROP INSURANCE IMPROPER PAYMENTS

Mr. ADERHOLT. Let me switch over a little bit and talk about in proper payments. Last month, USDA's OIG issued a report entitled, "U.S. Department of Agriculture Improper Payments Elimination And Recovery Act 2010 Compliance Review for FY 2012." According to this report, USDA delivers approximately $144 billion in public services annually through more than 300 programs. Of the 29 component agencies and offices that operate base programs, seven component agencies, including RMA and FSA, currently administer high risk programs that are vulnerable to significant and improper payments.

USDA estimated in FY '12 that these agencies' 16 total high risk programs made $5.5 billion in improper payments. That's a 5.11 percent error rate. Programs in this mission area don't come close to the school lunch or school breakfast programs, but it is imperative that we reduce or eliminate improper payments across the board, regardless of what they are. In regards to RMA, the report says, "RMA reported that FCIC improper payments were approximately $173 million, which was a 4.08 percent error rate."

However, because of RMA's sampling methods, OIG believes this estimate has been understated. The question is what is RMA doing to tackle this problem, and when do you expect to achieve improvements in this particular area?

Mr. WILLIS. Well, first of all, when spending taxpayers' dollar, one dollar improper payment is too much. So we take this very seriously. As you mentioned, last year's improper payment rate was 4.08. Some of the steps were taken to try to improve that. The new database, we think, that this will keep better track of yields, which will help us on that; but, also, with edit checks, if something is reported that doesn't fit in the system, it will get kicked out, and that will reduce our improper payment rate as well.

Precision agriculture technology: We are trying to move to where farmers who use that technology, yield monitors, acreage reporting, can do that more and more. We feel that will kind of eliminate opportunities when improper figures can be entered in and help us to improve integrity of the program.

Finally, in cases when there is a widespread problem, we have the ability to deny reinsurance to the companies if they are responsible for those problems, which means that if there is a loss, they are on the hook for that loss. So I think we are trying a lot of different steps to try to reduce that rate, but we share your concern. We would like to get that down from where it is today.

Mr. ADERHOLT. Oh. Let me just mention this. There was a Congressional Research Service Report from January that said some agencies, including USDA, have indicated that statutory or regulatory barriers have interfered with the ability to perform recovery audits.

For FSA repayments, does the agency have difficulty recuperating the funds?

Mr. SCUSE. We identified, I believe, because of the adjusted gross income—we identified approximately $135 million worth of receivables. And we have recovered so far $110 million of that money. So we are working and pursuing those accounts that are owed.

Mr. ADERHOLT. Very good.

CRP ADMINISTRATIVE COSTS

The budget request proposes to tap $50 million from the Environmental Quality Incentives Program, and that is to cover FSA's salary and expense cost of operating the conservation reserve program—the CRP. This is the first time that FSA has proposed to do this. I wonder if you could tell the subcommittee what's the background of wanting to do this.

Mr. SCUSE. Well, in many instances we have been conducting these programs and have not gotten the compensation from those programs for the cost of running and administering them. And so we're trying now in light of the budget situation to look at, make sure that we are recovering the expenses that we are incurring in some of these programs.

I mean we also do with the inspections with the Risk Management Agency. So we are looking at ways that we can make sure that when we go out and do those field audits, that we are going to actually recover the cost for doing those audits. So that is an example of where we wanted to make sure we are recovering our expenses.

Mr. ADERHOLT. Okay. My time is up, but I may want to follow-up a little bit later on that.

Mr. Farr.

Mr. FARR. Thank you, Mr. Chairman.

Mr. Bishop, I think if you want to stop the dumping of tomatoes, just have the American tomato growers produce a tasteful tomato. I think the first one that comes up with a good tomato will sell a lot of them.

I am sad that Mr. Nunnelee left because one of the things I was glad to hear was he took responsibility for the sequestration, they have been trying to blame that on the President and everyone else.

To think that sequestration had very little impact because you did not have to lay off or furlough people is a misnomer, because you point out in your testimony that the Secretary had interchange authority, to transfer funds from direct payment programs, the tobacco transition program, marketing access loans, the loan deficiency payments, storage and handling, the NAP and MILC, to back fill amounts sequestered.

You had authorities that other Secretaries did not have. I am sure it had some impact because I know the five percent cut in our own budget, our Congressional Office budget, had huge impacts.

I think we are going to see as California did after living with these furloughs, the voters got upset and just went to the polls and then raised taxes. It was not done by the legislature. It was done by the vote of the people.

CROP INSURANCE UNMET NEEDS

Mr. Willis, you have been a staff member on the Hill. You know legislators are always looking for ideas for legislation. I would be very interested if you could give me a letter of your feelings about unmet crop insurance needs.

We are moving into a new era of food safety. I think the recall of spinach that I saw, which was really a voluntary recall. We had a county that probably lost $100 million. Spinach growers, that is all they grow. Their insurance, if they had it, would not cover it because it was voluntary. Because it was not a disaster, we could not collect any of the programs here.

You have these kinds of issues that are coming up, incidents that are coming up where there is no insurance.

I am sure you know lots of those things. It would be appreciated if you could give me your professional judgment on what are the unmet needs in sort of the whole generic of crop insurance, all crops.

[The information follows:]

RMA is researching information to give a proficient response on unmet crop insurance needs. The information will be provided to the Subcommittee as soon as it is available.

Mr. BISHOP. Tasty tomatoes, too.

Mr. FARR. Insure a tasty tomato?

NUTRITIONAL QUALITY OF FOOD AID

I want to ask a question about food nutrition. I appreciate all the work the USA does to help feed the poorest and most vulnerable people in the world.

To make sure that we have the biggest impact, we need to have a high quality and nutritional food included in our donations to hungry families and children in emergency situations.

I am sure you have seen the studies that both Tufts University and GAO did looking into the cost effective ways to better match the nutritional quality of U.S. food aid with beneficiaries, and make sure that the food aid recipients are actually getting their nutritional needs met by our food assistance.

My question is what else can USDA do to improve the nutritional quality of food aid to make sure that the most vulnerable populations are getting the nutrition they need, to not just survive, but to thrive?

I would be particularly interested in what can be done for children, women, and expecting mothers.

Ms. HEINEN. Thank you. Congressman, we could not agree more, it is not just a matter of food but the type of food.

Currently, under our McGovern-Dole Program, we are doing pilot projects in five countries with six new products to try to meet those needs more precisely for those populations.

We are looking at supplements that will increase Vitamin A, or Zinc, and some of these other things that are lacking from their diet.

Mr. FARR. Are we just going to put vitamin pills in?

Mr. HEINEN. No. They are different products. There is one that is a peanut product. There is one that is a turkey spread that is part of the diet for the school feeding.

All of these have different nutritional components that we are trying to match to those specific problems that we see in those areas, which might be stunting, anemia, lacking B–12, different things they are missing.

We are trying to better match what the problems are within the areas with different types of nutritional supplements in the diets that we provide in the school feeding program.

We think some of these might be used more widely in some of the other feeding programs as we see what kinds of effects they might have.

Mr. FARR. I would be interested in that work, if you could send us a memo on it.

Ms. HEINEN. I would be happy to.

[The information follows:]

USDA - Foreign Agricultural Service
Micronutrient-Fortified Food Aid Products Pilot Summary

The Micronutrient-Fortified Food Aid Products Pilot (MFFAPP) is a $10 million effort to develop and field-test micronutrient-fortified products under the McGovern-Dole International Food for Education and Child Nutrition Program. The funds were appropriated in fiscal year 2011. USDA's Foreign Agricultural Service (FAS) executed one grant agreement in 2011 and five additional agreements in 2012. Programs are being implemented in Guinea-Bissau, Guatemala, Haiti, Cambodia, and Tanzania. USDA will provide a full report to Congress when they are completed. Below are examples of some current activities.

Guinea-Bissau - Dairy Paste: Under its 2011 grant in Guinea-Bissau, the International Partnership for Human Development, Inc. (IPHD) worked in 31 primary schools to distribute 720,000 servings of supplementary, dairy paste to 4,800 children during one school year. The paste contained iron, vitamin A, vitamin D, and zinc, all of which are critical for child growth and mental development. Pre-testing of children in Guinea-Bissau revealed that more than one half suffered from a vitamin A deficiency or anemia. A final report is due in spring 2013. IPHD began activities on its second grant in Guinea-Bissau in November 2012 and is expanding distribution to 1,200 preschool children and 600 lactating mothers. Distribution of the paste will end in May 2013 with results due in October 2013.

Guatemala - Turkey Paste: In September 2012, FAS staff travelled to Guatemala to monitor the Hormel Food Sales' (HFS) program field testing of *Spammy*, a nutrient-rich turkey spread. Two hundred students, aged three through six, received the product for 24 weeks. The *Spammy* was fortified with high levels of iron, Vitamin D, and Vitamin B12, all of which help to reduce stunting rates. Guatemala has the highest rate of stunting in the Western Hemisphere. In October 2012, HFS completed its distribution of 17,500 meals of *Spammy*. HFS 's final report is due in January 2014.

Haiti - Peanut Butter: In January 2013, FAS staff conducted a monitoring visit to a MFFAPP pilot implemented by Meds & Food for Kids (MFK) in Haiti. MFK is field-testing a supplementary food called *Mamba Lespri,* or "smart peanut butter," fortified with vitamin A, iodine, iron, and zinc. The micronutrients reduce stunting, anemia, and Vitamin A and iodine deficiencies. Distribution is to 1,200 Haitian school children, aged four through eight. Distribution of the product will end in June 2013 with final results due in January 2014.

Cambodia - Rice: PATH: A Catalyst for Global Health, received a $2.8 million grant and their distribution of fortified rice is on schedule in Cambodia. The *Ultra Rice* is fortified with iron and Vitamin A to address the children's anemia and Vitamin A deficiency. Distribution started in December 2012 to 4,000 students in eight schools. Distribution continues through July 2013.

Tanzania - Porridge: A MFFAPP pilot of $4.1 million was awarded to

Kansas State University (KSU) in FY 2012 for implementation in Tanzania. KSU's 3-year study will develop and field-test new formulations of three fortified blended foods (FBFs). These FBFs (sorghum-soybean, sorghum-cowpea, and corn-soy blend) will be made into porridge mixes for supplemental feeding and nutrition programs for infants and children below the age of five. In June 2014, distribution will begin to children identified as anemic and vitamin A-deficient. All three FBFs will include essential macronutrients (energy, protein, and fats) along with a vitamin and mineral premix containing high levels of iron and vitamin A.

Mr. FARR. I would appreciate it. Thank you.

Mr. ADERHOLT. Mr. Bishop.

EXPORTATION OF U.S. PEANUTS

Mr. BISHOP. Thank you very much. I was glad to hear you mention the health benefits of peanuts. I was pleased to learn that the Foreign Ag Service was a major impetus behind the re-opening of the foreign market for U.S. peanuts in Poland. That was a major coup.

On behalf of the peanut producers in the Southeast and Southwest that produce the majority of peanuts, and of course, in Southwest Georgia, Alabama and Mississippi, we all thank you.

With that said, I am told there may be further opportunities to expand the exportation of U.S. peanuts as well as cotton to other former Communist countries in Eastern Europe.

Are there any specific efforts underway in this regard and has the MAP Program been an effective tool for you for product expansion in Eastern Europe? Are there any efforts to expand peanut exportation globally?

Ms. HEINEN. Thank you for that. It was the hard work of our attache, I think, in Poland, that really made the difference there.

We do think the MAP Program has been highly effective in matching what we as a Government can do with what the experts in the industries can do.

We worked quite closely with the Peanut Association here to find opportunities for them in whole peanuts or in products, in food aid, in supplements.

I think Europe is still a good possible market, Eastern Europe. I hope some of the barriers will come down that we see in peanuts.

Mr. BISHOP. Are you familiar with peanuts and China?

Ms. HEINEN. China is a major producer of peanuts as well. We often have problems with things in China, and it is just a matter of working through the specifics of the commodities, the regulations. We still have hopes for that market.

Mr. BISHOP. I recently got some information that they were doing quite a bit of acquisition, and then all of a sudden, they stopped short. They have some delay, and the thought is it has something to do with the peanuts being sent through Vietnam, and they were having some issues with regard to the origin of it.

Are you familiar with that issue?

Ms. HEINEN. I am not but I would be happy to look into it and get back to you with specific information.

Mr. BISHOP. Thank you. This is something that is within the last six weeks.

TEMPORARY WORKER PROGRAM

Mr. ADERHOLT. Let me turn just a minute to an issue that has got a lot of attention on Capitol Hill over the last several years but in the last few months, it has really been a hot issue.

That has been the immigration issue. We are seeing signs that the House and Senate could take up legislation to work on some of these issues.

I know our Temporary Worker Program is very important to agriculture. We do need policies in place to encourage the flow of labor in and out of the country that is legal.

Any comprehensive immigration reform should allow an increase in H–2A and H–2B Visa's that reflect the needs of our industries and especially expediting the process during the agricultural seasons.

The question that I want to focus on is the comments that the Secretary supposedly made in a speech to the North American Agricultural Journalists as he was quoted in the Hagstrom Report saying USDA could partner with Labor and local USDA offices, and they could track workers, once they entered the United States.

Since your agencies would likely play a major role in that effort, could you talk a little bit about what the Secretary had in mind and what he envisioned?

Mr. SCUSE. I think as you pointed out, immigration reform is extremely important to the agricultural sector. We have different sectors within agriculture that are heavily dependent on a worker, guest worker workforce.

I think what the Secretary had in mind, when you look at our farmers and ranchers across the United States and you look at the comfort level they have in coming into the Farm Service Agency Office, they would feel much more comfortable visiting the County Farm Service Agency Office to do a reporting on the workers that they need for their farms and ranches, rather than going to another Federal agency office.

I think that is what the Secretary had in mind, to use our offices because of the comfort level the agricultural community has with it.

Mr. ADERHOLT. Is such a proposal possible under the make-up of staff and other resources available in the field?

In other words, would additional tasks take a field office away from their primary responsibility?

Mr. SCUSE. I do not think so, Mr. Chairman. I think we would be able to do that task with the current workforce that we have, even though in the last ten years we have downsized our workforce by 32 percent.

I still think with the workforce that we have and with the technology that we now have in place, I believe we would be able to do it.

I am going to take this opportunity to brag. The Farm Service Agency, those county offices and those staff in those county offices are second to none. They are truly outstanding people who do a great job every day for our farmers and ranchers.

Mr. ADERHOLT. Thank you. Mr. Fortenberry.

Mr. FORTENBERRY. Thank you, Mr. Chairman. I agree with that last assessment. The Farm Service Agency personnel are very, very dedicated, as are many of the various persons who are out in the field.

They have an affinity for the community. They work hard. I know any change is difficult a lot of times because these are friends and neighbors of a lot of folks in particular counties.

FARMER TO FARMER PROGRAM

A more narrow question, it is my understanding it is not directly under your jurisdiction, but if you have any input on it, the Farmer to Farmer Program is an USAID administered program, as I understand it.

Do you have any interaction with that particular program and have seen the benefits of it?

Ms. HEINEN. We do not have formal interaction in Washington but I have in my experiences overseas worked with a number of people who were part of that Farmer to Farmer Program, and learned things about what they were doing out in the field and worked with them to tell them what we see in the field.

OLD AND NEW OPPORTUNITIES

Mr. FORTENBERRY. Here is a broader point. I have asked everyone who has been here, including the Secretary, throughout these hearings, the same question. It is related to what I said earlier.

We have got to be about the business of being entrepreneurial and creative, letting go of what was old in order to reform to meet the growing change in demands of that which is new.

Sometimes when budgets are under stress or tension, it forces creativity. One of the ideas, it seems to me, to be important for a whole variety of reasons, not only in terms of promotion of our own products, person to person exchange, building of relationships that has national security implications, has trade implications, but to take the farmer who is interested in giving something to another person maybe in an impoverished area of the world, perhaps consider that as a component, if you would, of the Foreign Agricultural Service or in some way integrated into your efforts.

I think it is one of those areas that we could look at that meets multiple objectives of what agriculture is already doing, not just in terms of trade policy and economic well being for us and others, but also the building of relationships to the transfer of real means of assistance to other people.

It builds out their capacity, it ensures that we have not only communications but trust. That is essential to international stability. That is essential to our national security.

We have 12 Nebraska National Guard members, for instance, right now who are farmers or have farm backgrounds in Afghanistan, some of the last troops that were there trying to build out economic capacity.

This is related in more ways than just to our trade. It is related to the broader purposes of Government.

As we are all examining how we get away from stove piping and silos and think about broader implications, here is what I am submitting to you as an idea of a particular program that has some history, that might be a way to think creatively to achieve these other objectives as a component of the Foreign Agricultural Service.

Mr. SCUSE. We do have two other programs. We have the Cochran Program where we bring Government officials from foreign countries in here to train them on ways that we do things here in the United States through our regulatory process and others.

We also have the Borlaug Program where we will bring scientists and researchers from other countries into the United States to work with our scientists and researchers on projects.

I do not want you to think we are not working with the other countries. I get your point. Farmer to Farmer would be another very good way to do that. There are programs that we do have where we do bring people in.

Mr. FORTENBERRY. Would you take that idea back and ruminate on that? Let's see if we cannot develop something here that makes sense for all the various objectives I laid out. Could we do that?

Mr. SCUSE. Yes.

Ms. HEINEN. If I might add, I think our farmers are some of our best envoys overseas.

Mr. FORTENBERRY. There you go, that is what I was looking for.

Ms. HEINEN. Many of our cooperator groups do take farmer groups overseas.

INTERNATIONAL FOOD AID

Mr. FORTENBERRY. I recognize that and the benefits to that, we do not measure them.

One more quick question, if I could, Mr. Chairman. Regarding the food assistance changes that you were discussing earlier in terms of delivery, changing the way in which we deliver in emergency situations, I think it is important to make sure that we still have an American brand on that.

Again, we are delivering emergency assistance for the broader purposes of humanity, humanitarian reasons, trying to help people who are in need. That is our fundamental purpose. That is who we are as Americans.

It does help, I think, if other people know this is coming from the generosity of the American taxpayer.

Mr. ADERHOLT. Mr. Fortenberry, we will let you have the last word. Thank you. I appreciate the panel being here.

Under Secretary Scuse, thank you for your work and your service along with each of you in your respective agencies and what you do for agriculture for America and around the world.

Again, we thank you for being here, and we look forward to working with you as we continue on with the fiscal year 2014 budget. Thank you.

Mr. FORTENBERRY. Mr. Chairman, I would like to thank you and the members of the Committee for a very good hearing. Thank you very much.

Mr. ADERHOLT. Thank you.

Questions for the Record
USDA Farm and Foreign Agricultural Service Mission Area
FY 2014 Budget House Agriculture Appropriations Subcommittee Hearing
April 25, 2013

Questions Submitted by Mr. Aderholt

Payment Error Rates

Mr. Aderholt: Provide a table that shows all payment error rates for fiscal years 2011 and 2012 in those seven or more programs under FSA's purview that have been identified as susceptible to significant improper payments, including CCC Marketing Assistance Loan Program, CCC Milk Income Loss Contract Program, CCC Loan Deficiency Payments, CCC Direct and Counter-Cyclical Payments, CCC Conservation Reserve Program, Miscellaneous Disaster Programs, and CCC Noninsured Crop Disaster Assistance Program.

Response: The information is provided for the record. N/A represents no measures due to low outlays. For the disaster programs, only Livestock Forage Disaster Program was measured since a full statistical sample of all disaster programs was not cost effective.

[The information follows:]

Farm Service Agency Program Error Rates		
PROGRAM	FY 2011 ERROR RATE	FY 2012 ERROR RATE
Marketing Assistance Loan Program	0.52%	0.08%
Milk Income Loss Contract	2.00%	N/A
Loan Deficiency Payments	N/A	N/A
Direct and Counter-Cyclical Payments	0.05%	0.50%
Conservation Reserve Program	1.77%	0.36%
Supplemental Revenue Assistance Payments	2.90%	
Livestock Forage Disaster Program		2.16%
Noninsured Crop Disaster Assistance	8.97%	7.00%

Mr. Aderholt: What are the payment error rate goals for all programs under FSA's purview in fiscal years 2013 and 2014?

Response: Projected error rates for fiscal years 2013 and 2014 are provided for the record.

[The information follows:]

Farm Service Agency Program Projected Error Rates		
PROGRAM	*FY 2013 PROJECTED ERROR RATE*	*FY 2014 PROJECTED ERROR RATE*
Marketing Assistance Loan Program	0.49%	0.48%
Milk Income Loss Contract	1.80%	1.79%

Farm Service Agency Program Projected Error Rates (Continued)		
[illegible]	[illegible]	[illegible]
Loan Deficiency Payments	0.00%	0.00%
Direct and Counter-Cyclical Payments	0.00%	0.00%
Conservation Reserve Program	0.00%	0.00%
Miscellaneous Disaster Programs:		
Supplemental Revenue Assistance Payments	2.70%	2.80%
Livestock Forage Disaster Program	2.10%	2.00%
Noninsured Crop Disaster Assistance	4.00%	4.00%

Mr. Aderholt: What is the payment error rate, both as a percentage and in dollars, for FSA?

Response: As of the FY 2012 Improper Payments Information Act (IPIA) review cycle, FSA has identified seven programs as being susceptible to significant improper payments. The programs and Corresponding data on error rates are as follows. N/A represents no measures due to low outlays.

[The information follows:]

Farm Service Agency Error Rates and Dollars		
PROGRAM	*FY 2012 ERROR RATE*	*Improper Dollars*
Marketing Assistance Loan Program	0.08%	$2,351,609
Milk Income Loss Contract	N/A	
Loan Deficiency Payments	N/A	
Direct and Counter-Cyclical Payments	0.50%	$18,757,534
Conservation Reserve Program	0.36%	$6,063,750
Livestock Forage Disaster Program	2.16%	$10,175,804
Noninsured Crop Disaster Assistance	7.00%	$4,777,673

Mr. Aderholt: What is the payment error rate, both as a percentage and in dollars, for CCC?

Response: The information is provided for the record. N/A represents no measures due to low outlays.

[The information follows:]

Farm Service Agency Error Rates and Dollars		
PROGRAM	*FY 2012 ERROR RATE*	*Improper Dollars*
Marketing Assistance Loan Program	0.08%	$2,351,609
Milk Income Loss Contract	N/A	
Loan Deficiency Payments	N/A	
Direct and Counter-Cyclical Payments	0.50%	$18,757,534
Conservation Reserve Program	0.36%	$6,063,750
Livestock Forage Disaster Program	2.16%	$10,175,804
Noninsured Crop Disaster Assistance	7.00%	$4,777,673

Improper Payments in FFAS Program

Mr. Aderholt: The Improper Payments Information Act (IPIA) of 2002 requires Federal Agencies to evaluate programs to determine whether internal

controls are sufficient to prevent issuing improper payments. FSA and RMA have a few relatively high improper payment rates in their programs. In March 2013, USDA's OIG issued a report entitled: "U.S. Department of Agriculture Improper Payments Elimination and Recovery Act of 2010 Compliance Review for Fiscal Year 2012." According to the report, USDA delivers approximately $144 billion in public services annually through more than 300 programs. Of the 29 component agencies and offices that operate these programs, 7 component agencies - including RMA and FSA - currently administer "high-risk" programs that are vulnerable to significant improper payments. USDA estimated in fiscal year 2012 that these agencies' 16 total high-risk programs made $5.5 billion in improper payments, a 5.11 percent error rate.

A Congressional Research Service report from January 2013 said that some agencies, including USDA, have indicated that statutory or regulatory barriers have interfered with their ability to perform recovery audits. For FSA overpayments, does the Agency have any difficulty recouping funds?

Response: FSA rarely encounters statutory or regulatory barriers in the pursuit of overpayments.

If an overpayment is established, from no fault of the customer, and the overpayment is not discovered within 90 days of the payment issued, the producer can be removed from liability based on the Finality Rule which is described as follows: The Department of Agriculture Reorganization Act of 1994, Section 281 provides that "Each decision of a State, County, or area committee or an employee of such a committee, made in good faith in the absence of misrepresentation, false statement, fraud, or willful misconduct shall be final not later than 90 calendar days after the date of filing of the application for benefits, [and] no action may be taken to recover amounts found to have been disbursed as a result of the decision in error unless the participant had reason to believe that the decision was erroneous." Since the "Finality Rule" was enacted in 1994, 196 receivables have been written off totaling $501,812.

Prior to the 2008 Farm Bill all receivables over 10 years old were written off if the receivable was not secured by collateral, a judgment or pending litigation. With the 2008 Farm Bill, the elimination of the 10-year statute of limitation enhanced the pursuit of overpayments. The Farm Service Agency pursues all overpayments until it is determined to be uncollectible because of death of the customer, bankruptcy discharging the debt or inability to pay (no assets).

All customer payments generated by FSA are automatically offset and reduced against any open receivables the customer may have in FSA's receivable system.

FSA's pursuit of overpayments is in accordance with the Debt Collection Improvement Act. Delinquent receivables are referred to Treasury and the Treasury Offset Program (TOP) to ensure federal payments are offset. After due process has been given to the producer (initial notification, first and second demand letter) annual receivable letters are mailed to the producer with outstanding receivables. If the producer has moved and has not provided updated information to FSA, LexisNexis is utilized to help locate the producer.

Mr. Aderholt: Please provide the Subcommittee with a status and update to the FSA related issues raised in the report entitled "U.S. Department of Agriculture, Fiscal Year 2011 Improper Payments Elimination and Recovery Act of 2010 Compliance Review" issued March 14, 2012 by the Office of the Inspector General.

Response: In response to Improper Payments Elimination and Recovery Act of 2010 Compliance Review for Fiscal Year 2012, Report Number 50024-0004-11, FSA has developed Corrective Action Plans for each program outlining planned actions for FY 2013 that include:

- Develop comprehensive internal control and quality assurance processes and systems as outlined in its FY 2012-2016 Strategic Plan.
- Continue integrating individual performance results related to reducing improper payments into employees' annual performance ratings.
- Provide improper payment training to field personnel on control procedures and potential risks of non-compliance with tailored training targeted to field offices where improper payments were identified. FSA target completion date is September 30, 2013.
- Issue additional notices and handbook amendments to field offices strengthening and reinforcing program policies and procedures. FSA target completion date is September 30, 2013.

Delinquency Rate in FSA Loan Programs

Mr. Aderholt: FSA has made progress in bringing down the delinquency rates for the direct and guaranteed loan programs. Less than 20 years ago, the delinquency rate was as high as 20 percent of total direct dollars. USDA reported last year at this time that the delinquency rate for direct loans was roughly 6.2 percent of direct loan dollars were outstanding and 1.4 percent of the guaranteed loan dollars were outstanding. Congress is interested in assessing the progress in this area and to make sure that USDA is doing all that they can to keep delinquency rates down.

The Subcommittee asked a number of questions last year regarding delinquency rates for direct and guaranteed loan programs. USDA responded with data as of February 29, 2012 or a little over a year ago. What was surprising was the percentage of the total direct loans that were delinquent. According to your response, 21,150 direct loans out of a total of 123,967 direct loans outstanding were delinquent. This equates to a total of 17 percent delinquent. In terms of direct loan dollars, the percentage is 6.2 percent, a number that has gone down quite a lot over the years.

Explain how such a high percentage of direct loans from last year were considered delinquent?

Response: The dollar delinquency rate has been reduced significantly over the years. The majority of FSA's annual loan installments are scheduled for payment on January 1st of each year. This is consistent with most borrowers' calendar tax year. Since most payments come due on January 1st, the February monthly management report typically shows the highest delinquency of the year as many farmers and ranchers are still holding commodities for sale. By the end of the fiscal year many of these accounts

are paid current. The amount of actual losses on these accounts continues to be less than 3 percent annually.

Mr. Aderholt: Have the number or percentage of direct loan delinquencies gone down over the past year?

Response: As of February 29, 2012, FSA reported 17 percent of its direct loan portfolio and 6.2 percent of its direct dollars as delinquent. By September 30, 2012 (end of Fiscal Year 2012), the direct loan delinquency rate was 13.10 percent (16,569 of 126,499 loans) and the direct dollar delinquency rate was 5.44 percent ($452,432,617 of $8,324,196,755).

Mr. Aderholt: What is FSA doing to better control the delinquencies - is it a need for improvement in the approval process or what?

Response: Delinquencies have declined steadily over the past several years. FSA believes that the first year delinquency rate indicates that the loan approval and underwriting process is functioning well, given the Farm Loan Program mission of financing farmers who do not meet commercial standards. This is a reflection of FSA's strategy to link employee performance to the accomplishment of performance goals, so that employees are held accountable for decisions that impact program performance (i.e. delinquency and repayment rates). These goals are a key part of the accountability strategy, and are quantitative measures that demonstrate results. Each State Executive Director and their Farm Loan Programs staffs are accountable for meeting the following delinquency related goals as of the end of each fiscal year:

- First Year Delinquency Rates - reduce first year delinquency rates on new loans or maintain at a ceiling of no more than 8 percent. As of April 30, 2013, the national first year delinquency rate was 5.2 percent. FSA continue to closely monitor States with first year delinquency rates higher than 8 percent.

- Portfolio Delinquency Rates - reduce dollar delinquency rates or maintain at a ceiling of no more than 8.5 percent. As of April 30, 2013, the national delinquency rate was 6.1 percent. FSA continue to closely monitor States with delinquency rates higher than 8.5 percent.

- Delinquency Servicing Processing Times - process at least 68 percent of primary loan servicing applications within 60 days. As of April 30, 2013, 78 percent of primary loan servicing applications are being processed within 60 days. The goal for Fiscal Year 2014 is 75 percent, 83 percent for Fiscal Year 2015, and 90 percent for Fiscal Year 2016. We continue to closely monitor States with processing time frames higher than 68 percent.

- In addition, FSA loans are subject to the Debt Collection Improvement Act which means that any delinquent accounts are subject to offsets of other government payments including FSA program payments, IRS tax returns, and in some cases Social Security payments. Only recently FSA delinquent accounts became eligible for offset of non-federal wages, all tools to assist FSA in reducing delinquent accounts.

Immigrants, Immigration Policy and the Role of USDA Field Offices

Mr. Aderholt: As the House and Senate Committees debate potential changes to the Nation's immigration policy, the Secretary of Agriculture continues to make a push for a means to address labor shortages and the need for that labor to harvest crops, especially since immigrant populations typically fill many of the jobs. The House and Senate will take up legislation to address some of these challenges. Temporary worker programs are important for Agriculture. The federal government needs policies in place that encourage the flow of labor in and out of the country, legally. Any comprehensive immigration reform should allow an increase of H2A and H2B visas that reflect the needs of our industries, and especially expediting the process during agricultural seasons.

In regards to comments made by the Secretary in a speech to the North American Agricultural Journalists, he was quoted as saying that USDA could partner with the Department of Labor and local USDA offices could track the workers once they entered the United States.

Since the Secretary alluded to FSA as playing a major role in such an effort, please explain to the Subcommittee what the Secretary believes that role to be?

Response: Immigration reform is very important to farmers, farm workers and the nation's food supply. The current proposal is for FSA field offices to assist agricultural employers with the H2A registration process. Among the things FSA would do under the proposal is to confirm employer status, assign ID numbers and provide technical assistance.

Mr. Aderholt: Does USDA believe that FSA could serve a role in tracking immigrants under the current make-up of staff and other resources available to those in the field? Specifically, would such an additional task take the field staff away from their primary responsibilities?

Response: FSA employees perform a variety of duties that support the agricultural industry. The Senate bill proposes that the Secretary shall monitor the movement of nonimmigrant agricultural workers. The expectation is that the Department of Labor and Homeland Security will manage and oversee enforcement functions. As the bill takes shape, USDA is committed to working with lawmakers to ensure that they have the necessary technical support to craft immigration reform legislation that benefits the agricultural industry.

Modernize and Innovate the Delivery of Agricultural Systems (MIDAS)

Mr. Aderholt: The House Report accompanying the FY 2014 House Appropriation Bill (H.Rept. 112-542) clearly stated that the Committee viewed the MIDAS initiative as the top administrative priority for USDA and this position remains unchanged. In delivering vital mission-based services directly to farmers and ranchers, this program will likely represent the greatest efficiency improvement amongst any other streamlining effort at USDA.

After inclusion of the FY 2013 appropriation, Congress will have invested an estimated $300 million in the timely and successful implementation of MIDAS.

Mr. Aderholt: Is MIDAS on schedule to launch the first live use of the system this fiscal year?

Response: MIDAS delivered the first deployment to the field during the week of April 22, 2013. This deployment was delivered nationwide and provides FSA's county office staff with:

1. The ability to manage Farm, Tract and Field data all in one integrated system;

2. The Farm Records system embedded with Geospatial Information Systems (GIS) visualization with maintenance ability using GIS integrated with the SAP (MIDAS) software. This allows a user to edit Common Land Unit (CLU) boundaries, conduct farm/tract re-constitutions and other related work that used to be done in separate, disparate systems, reducing both time and effort and improving quality and producer satisfaction.

3. A "one-stop-shop" for producers, providing a producer the ability to update producer or farm information at any county office, not just their servicing county office.

Mr. Aderholt: The Administration is proposing a decrease in base funding for this project of $21.1 million for the MIDAS initiative. Can FSA confirm that this proposed reduction will not negatively affect the current schedule and spending plan? In other words, can FSA assure the Subcommittee that the Agency will not come back to the Subcommittee later in the year and ask for a lesser reduction?

Response: The MIDAS initiative will operate within the President's FY 2014 Budget level. A portion of the available resources will likely be used for on-going enhancements of the system. FSA encountered challenges in building certain aspects of MIDAS, and this led to modest schedule delays in FY 2013. As a result, FSA is now re-baselining the initiative, to quantify the remaining work to achieve the system's full capabilities. At this time, the unknown is the extent of the enhancements that may be required to implement the next Farm Bill.

Mr. Aderholt: Looking at the current timeline, when does USDA expect to have everything in place for this system so that farmers and ranchers will be able to conduct most, if not all, of their interaction with USDA from their homes and/or offices?

Response: MIDAS will be implemented in multiple phases and will allow FSA state and county office employees to work with farm records and customer data more efficiently. The MIDAS functions in Phase One simplify the process of viewing and updating producer farm records and aerial maps through Geospatial Information Systems (GIS). Further, it will help the agency build better business partnerships and fiduciary records and improve industry-dependent crop tables. Over the coming months, additional phases will be introduced that will improve acreage reporting, marketing assistance loans and other management and functional priorities.

MIDAS improvements also allow producers to conduct business in any FSA service center because all FSA offices will be able to download and share information.

Through MIDAS and other initiatives, FSA will continue to improve customer service through improved online access. This includes a customer-facing portal that allows at-home access for producer reporting that will be introduced in a subsequent phase.

Mr. Aderholt: When might FSA start to demonstrate measurable savings from the implementation of this system?

Response: As MIDAS is fully implemented, customers will experience better and faster service when they visit an FSA office. In addition to this contributing to better service being provided to farmers and producers, this will also improve time spent servicing customers and provides associated savings through the efficiencies gained.

Mr. Aderholt: Provide a comprehensive overview of MIDAS implementation, including timelines, cost by fiscal year, appropriations by fiscal year, purchases (hardware/software), personnel (permanent, temporary, contract), travel, training, etc.

Response: The implementation overview deliverables and timeline are as follows:

Farm Records Release (Release 1.0; Phase 1): On April 22, the MIDAS project successfully launched the first phase of Release 1. As of July 1, the total number of users with access to the system is more than 9,000 across the nation. User access is dependent on the successful completion of training. This initial go-live release delivered Farm Records with GIS Integration, Business Partner and Product Master.

AR/IR Release (Release 1.0, Phase 2): This delivery will provide acreage reporting and inventory reporting (AR/IR) with GIS Integration and related analytics.

This delivery provides the FSA Service Center personnel in State and County offices:

- A re-engineered and improved process to manage non-acre commodities;
- A single, integrated system with GIS capabilities included to create and change acreage and inventory reporting;
- Enhanced reporting capabilities (analytics) for both acreage and inventory reporting;
- A "one-stop-shop" for producers, providing a producer the ability to file farm records and acreage reports at any county office location, not just the location in which their farm(s) reside(s).

Cost by fiscal year, appropriations by fiscal year and details of purchases follow.

[The information follows:]

MIDAS Funding Summary

MIDAS FY09-FY13 Summary						
Category	FY09	FY10	FY11	FY12	FY13	Total
One time expenses	$6,119,043	$39,995,283	$40,811,308	$121,737,169	$81,917,853	$290,580,656
Planning, project management	$3,197,778	$9,219,064	$5,592,034	$7,052,329	$2,000,000	$27,061,205
Lean Six Sigma	$1,902,497	$1,546,196			$0	$3,448,693
Requirements, design		$9,000,000	$23,643,606	$1,858,370	$0	$34,501,976
Development, testing, training curriculum, data remediation, and deployment			$0	$72,605,604	$46,955,411	$119,561,015
Organizational change management, training delivery		$1,283,375	$1,289,485	$6,097,551	$6,775,788	$15,446,199
Independent Validation & Verification		$4,890,887	$1,925,412	$5,026,500	$400,000	$12,242,799
Hosting Services (includes hardware acquisition)		$1,133,681	$2,198,642	$7,794,079	$14,588,570	$25,714,973
Software and Tools Support	$750,000	$10,912,845	$5,915,556	$19,342,217	$10,690,679	$47,611,298
Contracting costs	$268,768	$2,009,236	$246,572	$1,960,519	$507,405	$4,992,499
Recurring expenses	$0	$1,378,767	$4,267,549	$3,777,211	$4,755,799	$14,179,326
Government Salaries & Expenses		$1,378,767	$4,267,549	$3,777,211	$4,755,799	$14,179,326
Operations and Maintenance expenses	$0	$0	$0	$0	$0	$0
Operations and Maintenance		$0	$0	$0	$0	$0
Total	$6,119,043	$41,374,050	$45,078,857	$125,514,380	$86,673,652	$304,759,982

Mr. Aderholt: According to the budget, the FSA is requesting an increase of $11.9 million to fund IT transformation and modernization projects. How much of the $11.9 million budgeted increase is for MIDAS?

Response: In FY 2014, FSA is requesting a net increase of $4.9 million to fund critical IT transformation and modernization projects to support core FSA operations. None of the $4.9 million is for MIDAS. The $4.9 million will be used for the continuation of contract services that support non-MIDAS modernization, development and maintenance efforts that support program and business areas such as Farm Loan Programs, Financial Services and Administrative Management.

Mr. Aderholt: Provide a copy of all vendor contracts for MIDAS implementation for the record.

Response: The information is provided for the record.

CLERK'S NOTE: Due to its large size, this information is on file with the Committee on Appropriations.

Mr. Aderholt: How much is needed in fiscal year 2013 for IT modernization/MIDAS?

Response: The FY 2013 amount for MIDAS is $86,673,652. The FY 2013 S&E base funding for MIDAS was $99,766,889. During the final week of FY 2012, USDA/FSA/MIDAS negotiated with SAP for a SAP software maintenance contract. The contract was awarded on Sept 29, 2012. Initially, to satisfy the Agency's need for software licensing and maintenance in FY 2012, the negotiating team intended to seek a small contract for FY 2012 and then expand the scope of the contract in FY 2013. However, as negotiations took

place an opportunity arose to leverage the contract into a larger one to achieve cost savings (approximately $35 million).

Since the additional $13,093,237 was funded in FY 2012, the FY 2013 S&E base funding for MIDAS was adjusted to $86,673,652.

Mr. Aderholt: What are the out-year costs to maintain MIDAS?

Response: FSA encountered challenges in building certain aspects of MIDAS, and this led to modest schedule delays in FY 2013. As a result, FSA is now re-baselining the initiative, to quantify the remaining work, as well as ongoing operational needs to maintain MIDAS. Once the re-baselining process is complete, FSA will have estimates of the out-year costs to maintain MIDAS. We will provide an updated timeline once the re-baseline is finalized.

FSA's Management of the Farm Storage Facility Loan Program

Mr. Aderholt: OIG took a sample of loans and reviewed how FSA approved and processed 30 loans (totaling $4.89 million), as well as how the agency serviced 10 delinquent loans (totaling $728,078). OIG found that FSA county employees did not always process, approve, and service these loans according to the agency's policies and procedures. These errors resulted in $2.2 million in unsupported disbursements.

In July of last year, OIG audited the Farm Storage Facility Loan Program to see if FSA field offices were following the necessary policies and procedures to ensure that this program was operated with minimal risk. In the 30 loans sampled, OIG found that 25 or 83 percent had errors, including:

- The agency approving loans without having documentation on file to support the borrower's eligibility;
- Making obligations that exceeded allowable amounts, and,
- Disbursing loans without sufficient documentation to support final facility costs or adequate release of liability.

Nine months have passed since OIG released this report. What corrective actions has FSA taken to strengthen the oversight and accountability of the program?

Response: OIG closed the audit on August 24, 2012. FSA implemented new policies and procedures to strengthen the oversight and accountability of the program, including providing additional training to State and County Office employees. FSA developed a web-based training that is required to be completed by all employees who are assigned responsibility of working with the program. Annually, the National Office will select a sample of Farm Storage Facility Loans to measure and evaluate the effectiveness of policies and procedures to ensure proper internal controls are in place for loan processing and servicing.

Mr. Aderholt: Has the Agency reconsidered changing this program to a guaranteed program? If so, what would be the change in cost and loan availability?

Response: Based on current Statute the Farm Storage Facility Loan Program, which operates a direct loan program, is not authorized to operate

as a guaranteed loan program. However, we note that the FSFL Program continues to operate with a negative subsidy rate which means that the direct loan program is making a positive rate of return for taxpayers.

Conservation Reserve Program (CRP)

Mr. Aderholt: Please provide FSA's analysis of the cost of administering the Conservation Reserve Program.

Response: FSA uses several methodologies to analyze costs for its various programs. Before 2007, administrative costs were determined using a workload system that took into consideration the hours per contract and application completed by the county employees and a percentage basis of the total program time was used for calculation of the Federal employee's hours and cost. Beginning in 2008, FSA has been moving towards a cost modeling system that uses the time and attendance system to record employee hours and costs by program, the Financial Management Modernization Initiative (FMMI) as well as units from program applications. The data are then fed into an automated system to give FSA both direct and fully burdened (full salary, benefit and operating) costs per unit data for each program. This methodology is still being refined as we had limited data for 2011, but improved cost per unit data for 2012. These data will allow us to compare various areas for efficiencies and cost effectiveness. Future enhancements will bring program dollars into the calculations to give us additional functionality and data for review.

Mr. Aderholt: Please provide a table showing the cost of administering CRP for the past five fiscal years as well as the estimated cost of operating the program in fiscal years 2013 and 2014.

Response: The information is provided for the record.

[The information follows:]

FY 2008	$35,055,294
FY 2009	$35,177,312
FY 2010	$46,992,523
FY 2011	$64,737,773
FY 2012	$61,397,348
FY 2013 Estimated	$56,571,618
FY 2014 Estimated	$53,390,482

Note: Information provided for FY 2008 - FY 2010 are for State and County Office CRP activity only and do not include Headquarters costs. The cost for other fiscal years provided is for direct (State and County salary & benefits) costs only.

Mr. Aderholt: How much does it cost to conduct a general sign up?

Response: In FY 2012, the direct (salary & benefits) cost of General Sign Up was $12,940,899.

Mr. Aderholt: How much does it cost to administer continuous sign ups?

Response: In FY 2012, the direct (salary and benefits) cost of Continuous Sign Up was $8,319,629. The fully burdened cost of Continuous Sign Up will be available with additional time.

Mr. Aderholt: How much is required to administer the Conservation Reserve Enhancement Program (CREP)?

Response: Conservation Reserve Enhancement Program (CREP) is part of the Conservation Reserve Program. Direct (salary and benefits) costs required to administer CREP for FY 2012 were $3,700,700.

Mr. Aderholt: Please provide a list of current CREP agreements, including state, purpose, cost and cost-share amounts.

Response: The table below lists current CREP Agreements, including the state for each project and the estimated total Federal and State costs (when fully enrolled). New enrollment for some of the projects has ended. Except for the following CREPs, the primary purpose of all projects is to improve Water Quality: AR CREP II (Wildlife), CO CREP I (Water Savings), CO CREP II (Wildlife), CO CREP III (Water Savings), ID CREP (Water Savings), KS CREP (Water Savings), ND CREP (Wildlife), NE CREP II (Water Savings), and SD CREP (Wildlife).

[The information follows:]

CREP State/ Date Signed	Total Project Cost (Est. $ Millions)	
	USDA	STATE/ LOCAL
AR I - Bayou Meto 12/07/2001 - Primary purpose is water quality	$8.50	$1.70
AR II - Cache River / Bayou DeView Watershed 01/19/2007 - Primary purpose is wildlife	7.1	2.3
AR III - Illinois River 01/15/2009 - Primary purpose is water quality	19	6
CA - 01/18/2001 NO NEW CONTRACTS AFTER 12/31/2007- Primary purpose is water quality	19	5
CO I - Republican River 04/21/2006 - Primary purpose is water savings	52.8	13.5
CO II - High Plains 04/21/2006 - Primary purpose is water quality	19.9	5.4
CO III - Rio Grande Basin - Primary purpose is water quality	125	25
DE - 06/02/1999 - Primary purpose is water quality	8	2
FL - Everglades, and St. Johns Ocklawaha-Indian River Lagoon System 10/28/02 - Primary purpose is water quality	96	57
HI - 01/15/2009 - Primary purpose is water quality	53.6	13.4
IA - 08/17/2001 - Primary purpose is water quality	30	7.5
ID - Eastern Snake River Plain Aquifer 05/18/2006 - Primary purpose is water savings	183	75
IL - 03/30/1998 - Primary purpose is water quality	262	60
IN - 07/08/2005 - Primary purpose is water quality	14.6	5.6
KS - Upper Arkansas River 12/06/2007 - Primary purpose is water savings	18.2	4.5
KY - Green River 08/29/2001 - Primary purpose is water quality	88	22
LA - Lower Ouachita River Basin 04/22/2005 - Primary purpose is water quality	55	45

CREP State/ Date Signed	Total Project Cost (Est. $ Millions)	
	USDA	STATE/ LOCAL
LA II - Coastal Prairie 02/04/11 signup began 03/14/2011 - Primary purpose is water quality	18	7.7
MD - 10/20/1997 - Primary purpose is water quality	170	25
MI - 09/14/2000 - Primary purpose is water quality	130	35
MN I - MN River 02/19/1998 NO NEW CONTRACTS AFTER 12/31/2007 - Primary purpose is water quality	163	60
MN II - Mississippi River Sub Project 04/22/2005 NO NEW CONTRACTS AFTER 12/31/2007 - Primary purpose is water quality	200	50
MN II - Mo/Des Moines River Sub Project 04/22/2005 NO NEW CONTRACTS AFTER 12/31/2007 - Primary purpose is water quality	200	50
MN II - Red River Sub Project 04/22/2005 NO NEW CONTRACTS AFTER 12/31/2007 - Primary purpose is water quality	200	50
MO - 09/15/2000 - Primary purpose is water quality	66	17
MT - Missouri / Madison 09/10/02 - Primary purpose is water quality	41	16
NC - 03/01/1999 - Primary purpose is water quality	221	54
ND - 01/05/2001 - Primary purpose is wildlife	11	4
NE I - Central Basins Resources Project in central and eastern NE. 12/11/02 - Primary purpose is water quality	143	66
NE II- Platte Republican Resources Area 03/19/2005 - Primary purpose is water savings	122	36
NJ - Whole State 02/03/04 - Primary purpose is water quality	77	23

CREP State/ Date Signed	Total Project Cost (Est. $ Millions)	
	USDA	STATE/ LOCAL
NY I - NY City / Catskill 08/26/1998 - Primary purpose is water quality	8	3
NY II - Syracuse 12/07/2001 - Primary purpose is water quality	0.7	0.2
NY III - Statewide 10/29/03 - Primary purpose is water quality	60	15
OH II - Upper Big Walnut 04/19/2002 - Primary purpose is water quality	8.4	4.8
OH I - Lake Erie 04/18/2000 - Primary purpose is water quality	167	34
OH III - Sciotto River Basin 10/18/2004 - Primary purpose is water quality	151.3	56
OK - Spavinaw Lake & IL River/Lake Tenkiller Watersheds 04/23/2007 - Primary purpose is water quality	16.5	4.1
OR - 10/17/1998 - Primary purpose is water quality	200	50
PA I - Chesapeake 04/13/2000 - Primary purpose is water quality	129	71
PA II - Ohio River Basin 03/22/2004 - Primary purpose is water quality	99	46.7
SD - James River 10/23/09 - Primary purpose is wildlife	120.8	40.6
VA I - Southern Rivers 03/08/2000 - Primary purpose is water quality	87.4	35
VA II - Chesapeake Bay 03/08/2000 - Primary purpose is water quality	48.5	19
VT - Lake Champlain Basin and CT River Basin 09/24/2001 - Primary purpose is water quality	85	3.7
WA - 10/19/1998 - Primary purpose is water quality	199	42
WI - 10/26/2001 - Primary purpose is water quality	174	43
WV - 4/19/2002 - Primary purpose is water quality	25	5
TOTAL	$4,275	$1,284

Mr. Aderholt: Please list the conservation priority areas designated by the Secretary. Include those listed in statute.

Response: There are currently five National CRP Conservation Priority Areas (CPA) designated: Chesapeake Bay, Great Lakes, Long Island Sound, Longleaf Pine, and Prairie Pothole.

Mr. Aderholt: How many acres currently are enrolled in the Emergency Forestry CRP? Where are they located, and how much funding has been allocated to the program?

Response: As of April 25, 2013, nearly 230,000 acres were enrolled in the Emergency Forestry Conservation Reserve Program (EFCRP). Below is a breakdown of EFCRP contract and acreage distribution by state. Funding is generally allocated on a year-by-year basis to obligate for payments due in the next fiscal year (for already approved contracts and any errors, omissions or appeals). In fiscal year 2012, EFCRP had just under $6 million in outlays.

[The information follows:]

State	Number of Contracts	Acres Enrolled
Alabama	159	24,817
Florida	59	6,112
Louisiana	98	9,040
Mississippi	1,845	181,006
Texas	76	8,365

Mr. Aderholt: How many acres currently are enrolled in the Pilot Program for Enrollment of Wetland and Buffer Acreage in CRP? Where are they located, and how much funding has been allocated to the pilot program?

Response: Currently, 340,000 acres are enrolled. The total cost of these contracts over the 15-year contract period is estimated to be $642 million. The acres enrolled reduce downstream flood damage, improve surface and groundwater quality, recharge groundwater supplies, and provide vital wildlife habitat. Distribution of enrollment is provided for the record.

[The information follows:]

PILOT PROGRAM FOR ENROLLMENT OF WETLAND AND BUFFER ACREAGE IN CRP
ALSO KNOWN AS THE FARMABLE WETLAND PROGRAM
AS OF APRIL 2013

STATE	ACRES	OUTLAYS 1/
ALABAMA	14	16,999
ARKANSAS	2,169	3,817,820
COLORADO	157	156,257
IDAHO	6	8,103
ILLINOIS	614	1,929,586
INDIANA	984	3,146,034
IOWA	77,702	224,073,805
KANSAS	1,954	1,953,590
LOUISIANA	3,359	6,153,694
MARYLAND	5	9,387
MICHIGAN	77	143,466
MINNESOTA	51,011	100,449,409
MISSISSIPPI	10,988	19,852,140
MISSOURI	215	384,236
MONTANA	122	82,415
NEBRASKA	4,030	6,046,923
NORTH CAROLINA	58	94,489
NORTH DAKOTA	98,530	128,574,068
OHIO	255	1,117,648
OKLAHOMA	169	194,597
SOUTH DAKOTA	88,191	143,303,013
WASHINGTON	5	8,927
WISCONSIN	59	156,405
TOTAL	340,672	641,673,011

1/ Includes cost-share, incentives, and 15 years' rental payments for the 340,672 acres.

Mr. Aderholt: How many CRP contracts and acres were terminated early in fiscal years 2011, 2012 and 2013 to date?

Response: CRP acres under CRP contract that were terminated before scheduled expiration are provided.

[The information follows:]

2011	159,000 acres
2012	233,000 acres
2013	142,000 acres, as of the end of April

Since participants may terminate only part of the land under contract, we cannot provide an actual count of contracts terminated. Terminations may occur when a participant loses control of the land through sale or foreclosure, and the new owners do not wish to participate in CRP. Other terminations may occur for land acquired under eminent domain or land under lease for gas, oil, or mineral rights.

Mr. Aderholt: How many landowners participated in the transition option for beginning and socially disadvantaged farmers and ranchers in fiscal years 2011, 2012 and 2013 to date? How many acres were involved, and how much funding has been allocated to the program by fiscal year?

Response: During the two payment cycles (October 2011 and October 2012) to date approximately 280,000 acres have been enrolled for Transition Incentive Payments.

Approximately 1,709 beginning or socially disadvantaged (SDA) farmers or ranchers have signed the TIP contracts enabling them to farm the land that was previously enrolled in CRP.

Summary of the TIP program reflecting number of TIP contracts per State, dollars obligated, and dollars of pending TIP contract approval is provided for the record.

[The information follows:]

TIP Enrollment Activity

State Name	Number of Contracts	Contract Obligations
Alabama	29	$169,978
Alaska	2	50,042
Colorado	18	305,902
Idaho	45	875,694
Illinois	2	48,036
Iowa	87	1,231,050
Kansas	223	2,895,760
Kentucky	67	592,436
Michigan	4	30,718
Minnesota	116	1,418,526
Mississippi	13	160,110
Missouri	104	1,129,888
Montana	204	3,885,262
Nebraska	153	2,064,812
New Mexico	69	1,289,210
North	388	4,623,682
Ohio	13	68,490
Oklahoma	10	144,058
Oregon	8	223,150
Pennsylvani	34	234,858
South	19	222,344
Tennessee	10	40,462
Texas	50	665,598
Washington	7	172,204
Wisconsin	29	204,042
Wyoming	5	122,062
Total		$22,868,374

Mr. Aderholt: How many staff are dedicated to operating CRP? How many FTE work on CRP?

Response: FSA employees are required to work on multiple programs so few staff members are dedicated only to CRP operations. For FY 2012, however, the work completed for CRP required the equivalent of 778 direct (salary and benefits) FTE's.

Mr. Aderholt: The budget request proposes to tap $50 million from the Environmental Quality Incentives Program to cover FSA's salary and expense costs of operating the Conservation Reserve Program (CRP). This is the first time FSA has proposed to do this.

What is the basis of FSA's decision to make this proposal?

Response: Section 103 of the American Recovery and Reinvestment Act of 2009 first provided USDA, including FSA, with authority to use funds of the Commodity Credit Corporation to cover salaries and related administrative expenses, including technical assistance, associated with the implementation of certain programs established or amended by the 2008 Farm Bill. This authority has benefited the Foreign Agricultural Service, Animal and Plant Health Inspection Service, Agricultural Marketing Service, Office of the General Counsel, and the Farm Service Agency.

This authority was extended via Section 714 of the Fiscal Year (FY) 2011, FY 2012 and FY 2013 Agriculture Appropriations Acts. The FY 2014 budget proposes to continue the use of Section 714 authority for administrative costs of funding CRP and other mandatory programs funded by CCC.

Mr. Aderholt: What has changed over the past year to cause FSA to all of sudden need $50 million to manage a program it has been responsible for since 1985?

Response: FSA used Section 714 authority in both FY 2012 and FY 2013 in order to provide adequate funding to manage and execute the CRP program. In FY 2012, Salaries and Expenses (S&E) funds were required to fund unbudgeted civil rights costs that in turn required the agency to turn to the Section 714 authority to fund CRP administrative costs. In FY 2013, FSA took several steps to mitigate the impacts of sequestration and across-the-board rescissions, including imposing a hiring freeze, further reducing discretionary operating expenses and curtailing contract activity. Even with those reductions, a furlough of all FSA employees would have been necessary to operate at the net S&E funding level and service to the producers would have been disrupted. Given this tight budgetary situation, FSA requested and was approved to use Section 714 funding to support CRP administrative costs and this action prevented a furlough.

Mr. Aderholt: The budget justification states that FSA plans to allocate $301 million and 2,493 staff years to its conservation programs in fiscal year 2014. In fiscal years 2011, 2012 and 2013, FSA allocated between $306 and $308 million to its conservation programs.

Is the $50 million incorporated into the $301 million level for fiscal year 2014?

Response: The $50 million does not include the $301 million level for fiscal year 2014.

Mr. Aderholt: Why does FSA need a $50 million increase over FY 2012 and 2013 levels just for CRP?

Response: If the requested Salaries and Expenses budget level is enacted, we may not need to use Section 714 authority. However, to ensure that we can continue to manage and execute CRP and other conservation programs mandated by farm bill legislation, the agency needs to retain the flexibility provided by Section 714 authority.

Mr. Aderholt: What are FSA's other conservation programs?

Response: Under the Conservation Reserve Program, FSA administers the Conservation Reserve Enhancement Program (CREP), the Emergency Forestry Conservation Reserve Program and the Farmable Wetlands Program (FWP). In addition to CRP, FSA administers the Emergency Conservation Program (ECP), the Emergency Forest Restoration Program (EFRP), the Grassroots Source Water Protection Program (GSWPP), the Pilot Reforestation Program, and jointly administers the Grasslands Reserve Program (GRP) with NRCS. FSA also administers farm loan programs related to conservation.

Mr. Aderholt: How much does it cost to operate the other conservation programs?

Response: The direct (salary and benefit) cost to operate the other conservations programs in FY 2012 is submitted for the record.

[The information follows:]

Emergency Forest Restoration Program	Reforestation Pilot Program	Grassland Reserve Program	Emergency Conservation Program
$764,596	$117,012	$945,674	$7,033,409

Mr. Aderholt: Since land enrolled through the continuous program receives higher rental rates than land enrolled through general sign ups, how much of CRP's funding baseline is directed to it?

Response: The FY 2014 budget baseline projects rental payment outlays of $697 million for continuous signup in FY 2014, about 40 percent of total rental payment outlays.

Mr. Aderholt: How much funding is set aside for the highly erodible land initiative?

Response: While specific sums are not set aside for the Highly Erodible Land (HEL) initiative, FSA allocates acreage allotments and goals, and take into consideration the 750,000-acre-allocation for the initiative when accepting lands in general signup and expanding or developing other initiatives. Lands enrolled under this initiative are expected to have a similar cost to those enrolled under general signup and provide large reductions in soil erosion.

Mr. Aderholt: How much funding is set aside for the grassland and wetland habitat initiative?

Response: No specific sums are set aside for this initiative, but FSA takes into consideration the allocations for the various initiatives when accepting lands in general signup and expanding or developing other initiatives. This initiative, announced by the Secretary in March 2012, is funded through the Conservation Reserve Program (CRP) apportionment under the CRP Continuous Signup. The initiative increased acreage allocations for certain important conservation practices by 1,000,000 acres. These practice

allocation increases expanded potential enrollment for wetland restoration practices, practices under the State Acres for Wildlife Enhancement (SAFE), duck nesting habitat practices, upland bird habitat buffer practices and created a new acreage allocation for a continuous pollinator practice.

Mr. Aderholt: Why does USDA have to pay more for land enrolled through continuous sign ups?

Response: Continuous signup targets environmentally sensitive land, such as agricultural land prone to erosion, pasture or agricultural land that borders river or stream banks, wetlands, or field margins. These lands cost more to enroll for a few reasons.

- A high proportion of continuous signup lands are located in states where cropland rents are high, such as Iowa and Illinois, which account for 19 percent of total continuous signup acres. By contrast, they account for only 5 percent of overall enrollment.

- Continuous signup practices are predominantly small parcels of land carved out of existing fields. There is more up-front time invested by landowners in designing and implementing continuous practices than for general signup practices. For example, for a riparian buffer, it must be determined where exactly on the landscape the practice will be established, which water bodies to buffer, how wide of a buffer is needed, etc. In comparison, a typical whole-field enrollment only requires a decision on the cover type.

Mr. Aderholt: The 2008 farm bill set aside $100 million in CRP for mid-contract forest-management practices, including thinning and prescribed fire. The purpose was to improve wildlife habitat on CRP acres planted to softwood pines.

How many acres of CRP trees in the Southeast have been thinned? How many have been burned?

Response: Approximately 150,000 acres of CRP land in the Southeast have been thinned and about 87,000 acres have been burned.

Mr. Aderholt: How much funding has been dedicated to these purposes?

Response: Nearly $1.5 million in cost-share was paid to help CRP program participants complete these thinning and burning practices.

Mr. Aderholt: What actions has USDA taken to educate, provide incentives, and otherwise encourage forest management practices?

Response: Since the mid-1990s, FSA has been working with the southern forestry and wildlife communities to encourage greater application of customary forest management activities, such as thinning and prescribed burning, occurring on lands enrolled in the Conservation Reserve Program (CRP) to enhance soil, water, and wildlife benefits. Generally, this has taken the form of extending FSA capability by engaging in partnerships with State forestry agencies, State fish and wildlife agencies, and non-governmental organizations that provide additional outreach and assistance to producers and landowners. For example, technical assistance is provided by wildlife biologists in the Georgia Department of Natural Resources/Wildlife

Resources Division to CRP participants enrolled in Georgia's Bobwhite Quail Initiative. This combined effort encourages more tree thinning and prescribed burning that would not have occurred through CRP assistance alone.

FSA has also worked with the National Institute of Food and Agriculture, other USDA agencies, land grant universities, and the forestry community to highlight the economic benefit of reduced tree planting densities at establishment, thinning more trees per acre (particularly during the second thinning), and prescribed burning at frequent intervals to benefit those species dependent on pine savannah type habitat.

CRP cost share and incentive payments have proven effective in establishing CRP conservation covers. CRP financial incentives include payments made available at contract signing and practice installation.

Prior to 2008, CRP participants were assessed a payment reduction for tree thinning activities because this was considered a commercial use. Tree thinning is typically provided by independent contractors who pay the land owner because they are able to sell the wood that is removed.

Mr. Aderholt: What barriers has USDA encountered in trying to meet congressional intent?

Response: Landowner interest in forest management is conditional on many factors, but willingness to engage in costly forest conservation practices is mostly associated with economic considerations, which are outside the control of the voluntary program. During times of economic downturn, interest in forest management wanes as individual discretionary income is reduced.

These economic factors also influence the decision to convert cropland to forest cover. During periods of relatively high agricultural commodity prices, such as we are seeing now, landowners are less likely to enroll cropland in CRP.

Mr. Aderholt: Are current cost share incentives sufficient to encourage significant increases in management of CRP pines?

Response: Cost-share is generally not an influential factor in incentivizing CRP pine management because the producer often has no out-of-pocket expense and therefore does not earn cost-share. Generally, contractors perform thinning for the producer and pay the producer based on the market value of the trees removed.

OIG's Audit of FSA's Conservation Reserve Program

Mr. Aderholt: Last July, USDA's OIG released an audit that assessed the reasonableness of the soil rental rates that it pays producers who enter into contracts for the Conservation Reserve Program. Currently, this program enrolls about 27 million acres of land - acres that are rented out by USDA according to soil rental rates. OIG found numerous problems with how FSA calculated the rental rates. They found a number of problems and concluded that the process for determining the value of contracts could be improved and questioned the accuracy of $140 million paid to producers.

What steps is FSA taking on a systematic basis to ensure the accuracy of soil rental payments, including the implementation of stronger management controls in the process?

Response: FSA has made management decisions on all of the OIG recommendations in their July 2012 Audit Report and the subject audit was closed in its entirety in November 2012. FSA just completed the first round of updates to Soil Rental Rates since the audit. FSA began the process by setting the default county average soil rental rates for each county based on the 2012 NASS survey dryland cash rental rates (plus 10% for inflation over the life of the contract),which removed any historical biases from the rates. Then, specific guidance was issued to apply strict nationwide standards for documenting and reviewing any proposed alternatives to the rates. The process was carefully monitored by the Deputy Administrator for Farm Programs and clear records will be maintained. Additionally, FSA continues to work closely with NRCS to utilize the most relevant productivity factors for individual soil rental rates, and in the future may more widely utilize the National Commodity Crop Productivity Index (NCCPI) as it is more thoroughly vetted.

Mr. Aderholt: Does FSA have any plans to modify any existing contracts or will changes only impact future CRP sign ups?

Response: FSA does not plan to modify any existing contracts and any changes will only affect future CRP sign ups.

Transitioning Borrowers to Private Credit

Mr. Aderholt: Please provide the Subcommittee with a status of the Final Rule implementing the graduation provisions of the 2008 Farm Bill that became effective in February 2011. Specifically, how many FSA Farm Loan Program (FLP) borrowers transitioned to private credit? What might FSA do to increase this rate?

Response: At the time the 2008 Farm Bill was enacted FSA already had in place regulations governing graduation at 7CFR §765.101. The existing regulations prescribe a systematic process for review of borrower accounts for graduation based upon an objective evaluation of a borrower's finances and local credit availability. At the point that an FSA borrower finances improve at which they meet the credit standards established by local lenders FSA sends a prospectus including the borrower's financial statement to area lenders asking lenders if they would be willing to make a loan to refinance the FSA debt. The nature of the programs and farm business operations make it difficult to track exactly how many borrowers move to commercial credit. For example, over half of the operating loans are made for annual production purposes; a borrower may pay a loan in full at harvest and obtain commercial credit the following year, and FSA may not be aware of the commercial financing. However, FSA does monitor the turnover of borrowers in the portfolio. The data indicate that few borrowers spend an extended period of time in the direct loan portfolio. As of March 31, 2013, only 14 percent of the direct operating loan borrowers had been in the portfolio since September 30, 2000, and only 30 percent had been in the portfolio since September 30 2006. In the ownership loan portfolio, only 29 percent of the borrowers had been in the portfolio since September 30, 2000. These turnover rates indicate that the vast majority of borrowers are moving to commercial credit in a reasonable period of time. Regarding increasing the rate, FSA is increasing the emphasis on joint financing with other lenders. The agency

believes that this may lead to increased lender confidence in those borrowers who are progressing more rapidly and enable them to depend on commercial credit more quickly than they might otherwise.

FSA Loan Programs

Mr. Aderholt: Why do FSA's loan programs have a subsidy cost?

Response: The Federal Credit Reform Act of 1990 requires Federal Credit Programs to be budgeted based upon the projected cost of loans at the time they are made. The cost estimates are made using cash flow modeling and net present value calculations. The factors with the most significant impact on the subsidy rates are 1) interest rates, including the rates on loans and the projected cost of funds, and 2) events that modify the stream of collections back to the Treasury, including prepayments, restructuring of payments, delinquencies, and losses. The amount of Budget Authority ("subsidy") required to support Farm Loan Programs reflects reductions in cost as a result of continuing improvements in program efficiency and management. In FY 2009, $240.6 million in Budget Authority was required to support $4.57 billion in loans and guarantees made. In contrast, for FY 2014, only $91.5 million is required to support a potential program level of $5.5 billion.

Mr. Aderholt: How many loans in each FSA loan program are delinquent?

Response: The information is provided for the record.

[The information follows:]

USDA - Farm Service Agency
Agricultural Credit Insurance Fund (ACIF) Delinquent Loans
(September 30, 2012)

Program	Direct Loans	Guaranteed Loans
Operating	10,568 out of 77,012	674 out of 24,221
Farm Ownership	2,740 out of 36,686	548 out of 30,640
Emergency	2,716 out of 9,963	
Economic Emergency	367 out of 1,119	
Soil and Water	66 out of 492	

Mr. Aderholt: What is the delinquency rate on FSA loan programs?

Response: The loan delinquency rates as of September 30, 2012 for the major loan programs are submitted for the record.

[The information follows:]

USDA - Farm Service Agency
Agricultural Credit Insurance Fund (ACIF) Delinquent Rates
(September 30, 2012)

Program	Direct Loans Delinquency Rates	Guaranteed Loans Delinquency Rates
Operating	13.72%	2.21%
Farm Ownership	7.47%	1.79%
Emergency	27.26%	
Economic Emergency	32.80%	
Soil and Water	13.41%	

Mr. Aderholt: What is FSA doing to reduce the delinquency rate on direct loans?

Response: FSA Farm Loan Programs has developed management goals which have been incorporated into all Farm Loan Programs employees' performance plans. We continue to use supervised credit and technical assistance and the loan service programs mandated by statute to assist borrowers overcoming financial problems and meet their obligations with FSA. FSA also complies with the Debt Collection Improvement Act; the administrative and Treasury offsets increase collections and reduce delinquencies as well.

Mr. Aderholt: How many loans in each FSA loan program have defaulted?

Response: The information is provided for the record. FSA does not distinguish between delinquencies and defaults As of September 30, 2012, each major loan program had the following number of delinquent loans:

{The information follows:}

USDA - Farm Service Agency
Agricultural Credit Insurance Fund (ACIF) Delinquent Loans
(September 30, 2012)

Program	Direct Loans	Guaranteed Loans
Operating	10,568 out of 77,012	674 out of 24,221
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Economic Emergency	367 out of 1,119	
Soil and Water	66 out of 492	

Mr. Aderholt: What is the default rate on FSA loan programs?

Response: FSA does not distinguish between delinquencies and defaults. As of September 30, 2012, loan delinquency rates in the major loan programs were:

{The information follows:}

USDA - Farm Service Agency
Agricultural Credit Insurance Fund (ACIF) Delinquency Rates
(September 30, 2012)

Program	Direct Loans Delinquency Rates	Guaranteed Loans Delinquency Rates
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Mr. Aderholt: What is FSA doing to reduce the default rate on direct loans?

Response: FSA does not distinguish between delinquencies and defaults. FSA Farm Loan Programs has developed management goals which have been incorporated into all Farm Loan Programs employees' performance plans. We continue to use supervised credit and technical assistance and the loan service programs mandated by statute to assist borrowers overcoming financial problems and meet their obligations with FSA. FSA also complies with the Debt Collection Improvement Act; the administrative and Treasury offsets increase collections and reduce delinquencies as well.

Mr. Aderholt: What is the status of those loans that have defaulted?

Response: FSA does not distinguish between delinquencies and defaults. These accounts are in various stages of servicing including primary loan servicing, bankruptcy, and foreclosure. An important point to make is that many of the delinquent accounts have been suspended pending a determination if they would file a claim under any of the three civil rights settlement cases (Keepseagle, Pigford II, and Women and Hispanic). Once the claims period has expired for these three cases, FSA will be able to proceed with servicing the accounts.

Mr. Aderholt: Please describe the 7 different servicing methods FSA provides to producers. How many of these servicing options is a producer eligible to receive per loan? Do the servicing options ever extend the term of a loan beyond the relevant term limit?

Response: It is important to note that these servicing actions are not automatic. A realistic cash flow projection must reflect the ability to pay installments resulting from the servicing actions for any of these adjustments to occur. A description of direct loan servicing alternatives is as follows:

1. Homestead Protection - If borrower's homes are part of FSA loan security and because of foreclosure or voluntary conveyance FSA takes possession of it, the Homestead Protection will give borrowers the right to lease the house up to ten acres from FSA. The lease can be for up to five years if certain conditions are met. The purpose is to give borrowers time to make arrangements or look for financing so they can buy the house back from FSA. If borrowers are an American Indian or Alaskan native, Black or

African American, Native Hawaiian or other Pacific Islander, Hispanic, or a woman, borrowers can also give a member of their immediate family the right to buy the home under Homestead Protection.

2. Rescheduling - Chattel type loans can be rescheduled for up to 15 years from the date of rescheduling. This can be done an unlimited number of times in conjunction with Primary Loan Servicing.

3. Reamortization - Real Estate type loans can be rescheduled for up to 40 years from the date of the original promissory note. This can be done an unlimited number of times in conjunction with Primary Loan Servicing.

4. Deferral - Payments on loans may be partially or completely deferred for up to five years. This can be done an unlimited number of times in conjunction with Primary Loan Servicing.

5. Write-down - Debt is forgiven in cases where FSA will receive an equal or greater net return on the loans by reducing the debt and continuing with the account than it would realize through foreclosure. Borrowers are limited by statute to one instance of write down, but may receive write down on multiple loans in that instance. Borrowers who receive debt forgiveness may not receive additional FSA credit other than annual production loans.

6. Disaster Set-Aside (DSA) - Farmers who operate in designated disaster areas can have one payment moved to the end of the loan. There is a limit of one DSA per loan unless the loan is restructured through Primary Loan Servicing and then one installment may again be considered for DSA if there is another disaster.

7. Conservation Contract - The Conservation Contract program provides debt cancellation for a borrower in exchange for a Conservation Contract on land owned by the borrower. This can be done an unlimited number of times per loan, if new conservation measures are implemented on different real estate parcels.

Mr. Aderholt: Please describe FSA's policies and procedures for collecting on delinquent loans and those in default.

Response: FSA's loan servicing process is governed by specific statutory requirements (7 U.S.C. §1981d and 7 U.S.C. §353) When a borrower becomes financially distressed, or becomes 90 days delinquent, FSA must offer Primary Loan Service Programs and follow specific timeframes for notification, consideration and further action. If borrowers do not apply for Primary Loan Servicing, FSA will continue collection activities.

- Offsets - If borrowers are 90 days late in making their loan payment, FSA is required by the Debt Collection Improvement Act to start offsets of Farm Program payments, Social Security payments, tax refunds, and other government payments.

- Reporting delinquent federal debts- FSA reports delinquent loans to credit bureaus and to Treasury and other delinquent federal debt registries to prevent delinquent borrowers from receiving other government benefits and provide an incentive for them to cure their delinquency.

- Treasury Cross-Servicing and Debt Settlement - If borrowers default on their FSA loans and the problems cannot be corrected with FSA's Primary Loan Servicing options, then FSA proceeds to liquidate the loan security. If this happens, borrowers do have the choice of voluntarily selling the security or paying FSA the value of the loan security and keeping it. After liquidation of collateral, if the borrower does not voluntarily settle the debt, FSA is required to turn over loan collection to the Department of the Treasury. Treasury will use offset authorities including garnishment of wages, and private collection agencies in efforts to collect the remaining debt. Sometimes, as part of settling the balance on an account, a portion of the debt is forgiven or written off. As noted earlier, borrowers may only receive debt forgiveness once from FSA, and that will, by statute, prevent borrowers from getting most types of FSA loans in the future.

Mr. Aderholt: Please provide a ten-year table, including fiscal year 2004 through fiscal year 2013, showing the subsidy rate for all FSA direct and guaranteed loan programs.

Response: The information is provided for the record.

[The information follows:]

USDA - Farm Service Agency
Agricultural Credit Insurance Fund (ACIF) Subsidy Rates
(FY 2004 - FY2013)

ACIF Subsidy Percentages	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Farm Ownership:										
Direct	22.08	5.35	5.12	4.19	4.45	6.35	4.08	6.92	4.80	4.24
Unsub - Guaranteed	0.54	0.53	0.48	0.58	0.40	0.33	0.37	0.38	-0.01	-0.07
Farm Operating:										
Direct	14.42	10.09	9.95	11.69	12.69	11.79	4.74	6.06	5.63	5.57
Unsub - Guaranteed	3.33	3.23	3.03	2.47	2.42	2.49	2.34	2.33	1.74	1.19
Subs Guaranteed	12.77	13.31	12.50	10.07	13.34	13.79	14.06	13.83	N/A	N/A
Indian Land Acquisition	-0.78	5.27	4.01	21.15	3.15	6.29	-37.37	-6.53	-13.89	-14.85
Boll Weevil Eradication Program	-6.07	-5.68	-18.09	1.90	-0.27	-0.56	-1.14	-2.09	-2.16	-2.54
Emergency	13.83	12.94	10.94	11.77	11.15	14.22	3.69	10.49	5.01	3.80
Conservation:										
Direct							2.31	2.99	N/A	N/A
Guaranteed							0.37	0.38	-0.01	-0.28

Mr. Aderholt: Please provide a table for each FSA direct and guaranteed loan program showing the number of borrowers, the number of loans with outstanding balances, the number of delinquent loans, the total amount outstanding, the total amount delinquent and the percentage delinquent by number of loans and by total amount.

Response: The information is provided for the record.

[The information follows:]

FARM SERVICE AGENCY
AGRICULTURAL CREDIT INSURANCE FUND
COMPARISON OF LOAN DELINQUENCY RATES
As Of September 30, 2012

	Number of Borrower/Loans	Number of Loans Delinquent	Percent Delinquent # Loans	*Total Outstanding	Total Principal and Interest Delinquent	Percent Delinquent $ Value
Farm Ownership Programs:						
Direct	36,686	2,740	7.5%	$4,152,665,163	$76,754,548	1.85%
Guaranteed	30,640	548	1.8%	8,343,556,175	73,054,123	0.88%
Total, Ownership Programs	67,326	3,288	4.9%	12,496,221,338	149,808,671	1.20%
Farm Operating Programs:						
Direct (Includes Seed Loans)	77,012	10,568	13.7%	3,442,701,737	215,004,986	6.25%
Guaranteed	24,221	674	2.8%	3,151,537,973	69,325,274	2.21%
Total, Operating Loan Programs	101,233	11,242	11.1%	6,594,239,710	284,330,260	4.31%
Boll Weevil	4	0	0.0%	10,581,659	0	0.00%
Indian Tribe Land Acquisition	73	4	5.5%	28,222,346	122,082	0.43%
Soil and Water						
Direct	492	66	13.4%	6,584,954	1,257,431	19.10%
Guaranteed	0	0	0.0%	0	0	0.00%
Total, Soil and Water	492	66	13.4%	6,584,954	1,257,431	19.10%
Emergency Loan Programs:						
Direct Emergency Disaster	9,963	2,716	27.3%	537,640,484	117,059,261	21.77%
Direct Economic Emergency	1,119	367	32.8%	76,842,536	30,062,113	39.12%
Guaranteed Economic Emergency	3	0	0.0%	166,174	0	0.00%
Total, Emergency Loan Programs	11,985	3,083	27.9%	614,649,194	147,121,374	23.94%

Mr. Aderholt: Please update the table showing the farm loan outstanding balances and delinquency totals by state.

Response: The information is provided for the record.

[The information follows:]

As of 04/30/13	Direct Loans:		Guaranteed Loans:	
State Name	Total Outstanding	Total Amount Delinquent	Total Outstanding	Total Amount Delinquent
ALABAMA	$61,390,631	$3,046,660	$224,342,610	$3,503,258
ALASKA	7,464,964	1,013,704	0	0
ARIZONA	31,092,162	5,131,618	50,975,965	362,051
ARKANSAS	226,628,983	32,759,623	497,450,391	18,389,715
CALIFORNIA	175,931,864	38,739,437	232,210,069	10,388,600
COLORADO	87,191,360	2,818,354	160,046,187	237,732
CONNECTICUT	5,985,811	573,463	34,916,362	2,355,482
DELAWARE	4,349,131	38,603	20,572,563	393,674
FLORIDA	72,416,576	7,370,325	67,493,415	3,089,818
GEORGIA	156,895,526	16,752,630	262,485,941	4,848,419
HAWAII	16,790,106	325,338	17,782,530	1,921,163
IDAHO	97,459,199	2,187,002	184,256,970	764,304
ILLINOIS	228,996,286	2,342,193	604,981,779	918,656
INDIANA	128,179,485	1,294,720	444,683,177	2,621,188
IOWA	473,699,508	4,864,726	631,730,296	802,704
KANSAS	349,049,196	4,827,906	236,870,943	906,329
KENTUCKY	277,323,980	11,613,602	276,406,664	3,312,732
LOUISIANA	96,623,554	13,976,397	188,692,080	6,145,267
MAINE	40,808,298	3,522,140	24,033,178	494,127
MARYLAND	16,847,412	1,633,729	42,110,859	315,438
MASSACHUSETTS	48,524,140	6,041,323	33,815,882	391,499

As of 04/30/13	Direct Loans:		Guaranteed Loans:	
State Name	Total Outstanding	Total Amount Delinquent	Total Outstanding	Total Amount Delinquent
MICHIGAN	229,885,645	11,301,404	415,026,011	6,728,549
MINNESOTA	382,985,868	4,722,628	618,468,173	3,392,530
MISSISSIPPI	81,681,696	20,088,453	97,464,935	3,263,813
MISSOURI	219,771,647	2,389,658	477,033,072	3,435,503
MONTANA	127,444,430	6,503,461	207,550,550	1,235,782
NEBRASKA	404,550,370	3,900,001	453,740,167	1,450,704
NEVADA	14,373,078	1,109,687	27,397,387	26,275
NEW HAMPSHIRE	18,125,871	942,013	7,713,391	69,056
NEW JERSEY	26,911,112	4,575,486	37,719,972	794,177
NEW MEXICO	49,263,902	5,444,058	55,347,385	600,617
NEW YORK	201,656,212	20,743,476	252,310,461	4,180,009
NORTH CAROLINA	116,469,657	13,454,702	300,241,664	6,601,358
NORTH DAKOTA	218,615,855	9,040,279	220,364,533	81,281
OHIO	110,070,247	2,721,071	817,975,545	2,094,998
OKLAHOMA	498,937,919	20,520,361	347,759,839	9,051,368
OREGON	90,931,822	3,990,713	133,465,114	3,784,592
PENNSYLVANIA	270,372,109	6,085,795	186,938,550	2,275,165
PUERTO RICO	244,286,435	106,434,991	11,095,289	2,552,869
RHODE ISLAND	8,291,128	1,060,013	4,666,829	0
SOUTH CAROLINA	121,658,125	9,043,325	197,297,116	3,559,443
SOUTH DAKOTA	301,896,767	2,430,934	338,700,145	710,638
TENNESSEE	159,053,966	11,062,229	147,350,477	4,227,041
TEXAS	365,681,009	27,245,154	260,905,799	2,238,954
UTAH	146,149,635	2,558,573	83,388,174	608,251
VERMONT	66,628,403	750,989	107,750,029	489,040
VIRGINIA	131,215,149	5,235,806	127,267,757	1,792,906
WASHINGTON	89,744,356	5,193,321	117,785,310	3,890,278
WEST VIRGINIA	74,930,859	1,482,744	24,302,163	218,539
WESTERN PACIFIC	0	0	8,023	0
WISCONSIN	522,152,971	9,317,023	939,778,787	6,021,890
WYOMING	30,544,720	1,638,665	68,390,113	918,117
TOTAL	7,927,929,136	481,860,508	11,321,060,618	138,455,896

Mr. Aderholt: Please provide a table showing the number of loans with delinquencies of less than 3 months, between 3 and 6 months, between 6 months and 1 year, and greater than 1 year for each FSA direct and guaranteed loan program.

Response: Our delinquency aging is based on the borrower's entire direct loan account so we do not have information for each loan program, and we do not have aging data for the specific categories that were requested. The following table provides delinquency aging for direct loan borrowers.

[The information follows:]

Direct Loan Program (as of 04/30/2013):	
Past Due Category	Number of Borrowers
1 to 30 Days	756
31-90 Days	1,220
91-180 Days	142
181 Days or More	424
Other	6,369
Total	8,911

NOTE: "Other" includes all accounts that are flagged. Flagged accounts include "Foreclosure Action Pending," "Bankruptcy Action Pending," and a number of other flags used to reflect a borrower's servicing status. Flagged accounts are not assigned to a specific category to reflect the number of days the borrower is past due. FSA does not maintain delinquency aging information on guaranteed loans since the Agency doesn't maintain daily accounting records. (Guaranteed lenders are required to provide updated information on delinquent accounts every 60 days.)

Mr. Aderholt: Please provide a table showing each FSA direct and guaranteed loan program and the loan losses by amount and percentage for fiscal years 2009 through FY 2012.

Response: The information is provided for the record.

[The information follows:]

Direct Farm Loans Written Off
Operating Loans
Fiscal Years 2009 - 2012
(Dollars in Thousands)

Fiscal Year	Beginning Principal	Losses Paid (Principal and Interest)	Losses as Percent of Beginning Principal
2009	$2,241,990	$33,364	1.5%
2010	2,694,210	38,278	1.4%
2011	3,118,091	79,585	2.6%
2012	3,272,565	40,880	1.2%

Direct Farm Loans Written Off
Farm Ownership Loans
Fiscal Years 2009 - 2012
(Dollars in Thousands)

Fiscal Year	Beginning Principal	Losses Paid (Principal and Interest)	Losses as Percent of Beginning Principal
2009	$2,869,295	$7,977	0.3%
2010	3,128,672	10,267	0.3%
2011	3,579,960	18,414	0.5%
2012	3,821,503	11,296	0.3%

Direct Farm Loans Written Off
Emergency Loans
Fiscal Years 2009 - 2012
(Dollars in Thousands)

Fiscal Year	Beginning Principal	Losses Paid (Principal and Interest)	Losses as Percent of Beginning Principal
2009	$715,251	$4,720	0.7%
2010	650,120	27,396	4.2%
2011	585,191	19,744	3.4%
2012	520,540	22,596	4.3%

Direct Farm Loans Written Off
Economic Emergency Loans
Fiscal Years 2009 - 2012
(Dollars in Thousands)

Fiscal Year	Beginning Principal	Losses Paid (Principal and Interest)	Losses as Percent of Beginning Principal
2009	$110,337	$2,923	2.6%
2010	92,940	1,495	1.6%
2011	77,729	7,248	9.3%
2012	63,649	635	1.0%

Direct Farm Loans Written Off
Soil and Water Loans
Fiscal Years 2009 - 2012
(Dollars in Thousands)

Fiscal Year	Beginning Principal	Losses Paid (Principal and Interest)	Losses as Percent of Beginning Principal
2009	$12,694	$59	0.5%
2010	11,018	195	1.8%
2011	9,002	165	1.8%
2012	6,931	72	1.0%

Guaranteed Farm Loans Written Off
Operating Loans
Fiscal Years 2009 - 2012
(Dollars in Thousands)

Fiscal Year	Beginning Principal	Losses Paid (Principal and Interest)	Losses as Percent of Beginning Principal
2009	$3,088,052	$19,532	0.6%
2010	3,144,036	31,852	1.0%
2011	3,436,754	28,528	0.8%
2012	3,427,381	20,648	0.6%

Guaranteed Farm Loans Written Off
Farm Ownership Loans
Fiscal Years 2009 - 2012
(Dollars in Thousands)

Fiscal Year	Beginning Principal	Losses Paid (Principal and Interest)	Losses as Percent of Beginning Principal
2009	$5,838,427	$15,758	0.3%
2010	6,242,447	22,846	0.4%
2011	6,916,301	23,596	0.3%
2012	7,681,420	18,294	0.2%

Guaranteed Farm Loans Written Off
Economic Emergency Loans
Fiscal Years 2009 - 2012
(Dollars in Thousands)

Fiscal Year	Beginning Principal	Losses Paid (Principal and Interest)	Losses as Percent of Beginning Principal
2009	$433	$-13	-2.9%
2010	334	-76	-22.8%
2011	217	0	0.0%
2012	189	0	0.0%

NOTE: Negative losses indicate recoveries exceeded losses for the period.

Mr. Aderholt: Please update the farm loan programs obligations report by state provided last year for FY 2012 and FY 2013 to date.

Response: The information is submitted for the record.

[The information follows:]

FARM SERVICE AGENCY
FARM LOAN PROGRAMS OBLIGATIONS REPORT
FY 2012 AS OF SEPTEMBER 30, 2012
(DOLLARS IN THOUSANDS)

STATES	DIRECT OL		GUAR OL		DIRECT FO		GUAR FO		EMERGENCY		TOTAL	
	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT
ALABAMA	345	15,104	28	2,982	31	4,930	61	27,772	0	0	465	50,788
ALASKA	27	1,108	0	0	1	133	0	0	0	0	28	1,241
ARIZONA	158	7,720	25	9,823	2	480	8	2,555	0	0	193	20,378
ARKANSAS	515	41,474	259	78,378	30	4,302	120	68,601	28	2,591	952	195,346
CALIFORNIA	487	29,134	125	43,017	41	8,124	87	37,589	10	1,979	730	119,843
COLORADO	267	14,725	46	9,884	34	5,751	34	17,039	2	361	383	47,760
CONNECTICUT	21	1,056	11	1,223	2	340	5	3,108	1	389	40	6,113
DELAWARE	11	403	3	482	5	1,424	8	5,004	0	0	27	7,313
FLORIDA	263	19,195	46	13,476	20	3,165	14	3,943	2	500	345	40,278
GEORGIA	489	43,546	150	45,113	37	6,853	36	16,581	12	1,381	724	113,474
HAWAII	71	1,985	1	62	6	1,101	5	2,433	0	0	83	5,582
IDAHO	412	23,653	154	28,242	27	5,029	57	25,316	0	0	660	82,241
ILLINOIS	259	16,740	91	22,883	208	33,016	300	117,682	1	40	859	190,162
INDIANA	120	7,616	202	40,234	102	17,429	201	86,069	0	0	625	151,347
IOWA	1,361	71,884	189	38,437	338	56,074	208	92,140	3	125	2,099	258,640
KANSAS	624	36,441	116	18,362	198	26,551	78	21,178	2	285	1,018	102,817
KENTUCKY	1,563	57,749	115	21,873	99	16,919	122	39,274	0	0	1,639	135,715
LOUISIANA	284	16,469	183	50,918	4	350	12	5,037	10	1,085	473	73,859
MAINE	115	5,903	12	984	9	1,634	10	4,665	0	0	146	13,246
MARYLAND	31	2,642	7	1,213	5	2,068	7	4,175	1	211	54	10,308
MASSACHUSETTS	144	7,720	11	1,816	14	3,118	14	4,150	10	1,353	193	18,166
MICHIGAN	386	20,514	154	29,932	77	10,941	149	44,576	4	200	800	106,863
MINNESOTA	905	57,617	233	46,884	172	29,867	187	68,410	7	335	1,504	203,026
MISSISSIPPI	403	17,358	38	12,281	11	1,634	28	16,020	1	56	481	47,378
MISSOURI	537	25,863	172	34,094	162	21,962	231	72,378	1	24	1,103	154,308
MONTANA	307	20,852	88	19,868	45	9,027	58	28,532	1	313	499	78,592
NEBRASKA	1,312	73,941	99	21,539	203	39,268	111	52,252	0	0	1,725	186,900
NEVADA	81	3,694	5	1,797	8	1,129	8	2,196	0	0	102	8,815
NEW HAMPSHIRE	22	1,077	2	117	2	485	4	836	0	0	30	2,514
NEW JERSEY	59	3,592	12	2,025	5	836	8	2,436	17	1,723	101	10,412
NEW MEXICO	111	7,034	15	2,997	20	3,926	19	5,750	4	307	169	20,013
NEW YORK	254	15,398	108	17,074	34	5,208	70	24,100	16	1,847	482	63,534
NORTH CAROLINA	325	24,248	94	13,516	21	4,001	65	33,137	42	5,178	547	80,079
NORTH DAKOTA	371	26,262	107	26,141	83	9,176	32	14,435	11	794	584	76,809
OHIO	221	9,581	165	15,874	138	17,706	562	148,813	1	56	1,076	190,960
OKLAHOMA	964	49,011	107	26,074	301	47,204	75	29,453	9	646	1,456	152,389
OREGON	273	15,712	61	15,393	21	4,562	39	18,457	2	194	396	54,318
PENNSYLVANIA	464	27,606	51	9,859	44	10,317	44	13,795	9	1,751	642	63,328
PUERTO RICO	125	6,695	2	400	40	4,715	5	2,817	0	0	172	14,626
RHODE ISLAND	28	1,246	2	230	0	0	1	575	0	0	31	2,051
SOUTH CAROLINA	427	33,209	60	18,619	20	3,611	51	19,018	16	1,564	574	76,022
SOUTH DAKOTA	545	45,276	119	23,833	108	18,219	117	46,357	1	29	1,190	136,514
TENNESSEE	532	30,043	65	17,181	65	8,885	59	26,553	0	0	711	82,442
TEXAS	1,284	73,859	185	55,499	143	22,127	64	39,157	79	5,789	1,715	196,430
UTAH	543	26,523	31	6,095	41	6,512	36	16,188	0	0	651	55,318
VERMONT	97	5,607	53	6,855	9	1,458	34	9,296	0	0	193	23,216
VIRGIN ISLANDS	2	74	0	0	0	0	0	0	0	0	2	74
VIRGINIA	304	22,674	46	5,514	41	7,754	42	13,522	3	217	436	52,681
WASHINGTON	323	24,120	105	25,821	25	5,301	17	7,005	0	0	470	62,247
WEST PAC TERR	4	24	1	9	0	0	0	0	0	0	5	33
WEST VIRGINIA	336	9,742	3	292	24	2,941	12	3,876	0	0	375	16,850
WISCONSIN	1,080	60,875	236	46,761	170	29,831	328	144,652	3	62	1,787	282,181
WYOMING	58	3,884	24	3,936	14	3,240	18	10,555	0	0	114	21,613
TOTAL	20,413	1,169,232	4,250	933,880	3,231	520,812	3,850	1,499,491	309	31,436	32,053	4,163,852

FARM SERVICE AGENCY
FARM LOAN PROGRAMS OBLIGATIONS REPORT
FY 2013 AS OF APRIL 30, 2013
(DOLLARS IN THOUSANDS)

STATES	DIRECT OL		GUAR OL		DIRECT FO		GUAR FO		EMERGENCY		TOTAL	
	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT
ALABAMA	223	12,896	20	1,638	30	4,845	70	41,920	0	0	343	60,899
ALASKA	7	165	0	0	0	0	0	0	0	0	7	165
ARIZONA	122	4,599	22	12,048	0	0	6	2,764	0	0	150	19,412
ARKANSAS	266	23,524	169	58,309	26	3,174	100	64,930	15	514	576	148,751
CALIFORNIA	384	19,063	57	32,940	20	5,160	64	41,418	2	722	557	99,282
COLORADO	210	14,627	46	9,396	26	8,114	37	15,323	4	316	323	47,776
CONNECTICUT	10	355	6	960	1	250	1	584	0	0	18	2,149
DELAWARE	3	307	4	422	3	719	17	7,252	0	0	27	8,700
FLORIDA	151	12,875	24	6,514	16	2,918	14	8,199	4	152	209	30,657
GEORGIA	355	36,809	91	28,860	25	5,350	40	21,566	3	570	547	93,155
HAWAII	47	531	3	163	3	498	7	3,764	0	0	60	5,256
IDAHO	312	16,646	113	18,267	15	3,524	59	23,932	0	0	512	62,369
ILLINOIS	189	14,135	62	16,888	100	14,982	316	137,749	20	1,591	687	185,346
INDIANA	61	5,467	107	23,239	50	9,132	167	72,172	2	199	387	110,209
IOWA	969	55,268	103	25,033	120	21,251	215	91,282	15	390	1,412	196,224
KANSAS	396	27,279	53	10,561	77	11,599	60	17,874	32	2,859	618	69,963
KENTUCKY	900	40,202	96	13,478	65	10,521	96	37,933	19	820	1,169	102,955
LOUISIANA	179	12,097	109	29,757	3	791	11	3,698	0	0	302	46,343
MAINE	46	2,662	1	100	7	1,327	4	1,720	0	0	58	5,808
MARYLAND	21	1,695	8	689	10	2,461	25	13,416	0	0	64	18,279
MASSACHUSETTS	56	2,076	1	400	9	2,065	5	2,195	2	90	73	7,726
MICHIGAN	253	17,496	57	2,595	39	8,125	58	15,194	26	2,579	433	53,989
MINNESOTA	594	44,294	110	29,487	65	13,369	201	72,249	1	279	974	158,668
MISSISSIPPI	247	12,990	16	5,881	12	1,919	17	11,789	0	0	292	32,578
MISSOURI	340	20,027	116	23,588	101	13,801	169	62,642	2	207	728	120,065
MONTANA	219	13,691	60	17,922	31	5,461	52	27,336	3	469	365	64,878
NEBRASKA	996	66,541	54	22,894	58	12,904	94	47,781	1	169	1,233	150,390
NEVADA	71	2,130	1	376	5	595	12	7,253	0	0	89	10,484
NEW HAMPSHIRE	15	1,426	2	224	2	276	3	1,221	0	0	22	3,146
NEW JERSEY	40	2,843	2	285	5	1,091	3	1,261	4	186	54	5,667
NEW MEXICO	75	5,080	12	2,741	12	2,102	19	8,165	7	374	125	18,466
NEW YORK	134	9,216	45	5,036	25	3,852	45	13,803	7	467	262	35,244
NORTH CAROLINA	208	16,431	69	11,119	19	4,141	67	27,346	2	60	365	59,096
NORTH DAKOTA	239	20,810	78	17,769	37	6,026	28	12,882	4	554	386	58,031
OHIO	164	7,847	55	12,258	70	10,279	550	161,495	4	234	873	192,103
OKLAHOMA	583	31,367	50	13,147	107	16,228	55	23,108	26	2,829	821	86,679
OREGON	205	12,564	44	9,982	17	3,991	34	17,749	0	0	300	44,286
PENNSYLVANIA	322	16,997	42	7,301	36	8,463	44	16,134	2	176	446	49,071
PUERTO RICO	61	2,772	4	343	19	2,309	1	520	0	0	85	5,945
RHODE ISLAND	10	695	1	40	1	162	0	0	0	0	12	900
SOUTH CAROLINA	305	25,800	45	11,136	15	2,814	46	24,430	0	0	411	64,179
SOUTH DAKOTA	554	33,134	55	16,559	37	7,001	122	52,867	6	414	807	109,974
TENNESSEE	330	21,656	40	10,489	35	6,103	42	24,631	1	177	451	62,956
TEXAS	753	50,110	125	30,448	132	24,013	33	24,001	52	4,111	1,095	141,684
UTAH	339	15,075	20	7,669	16	3,278	22	13,805	6	267	403	43,092
VERMONT	50	2,859	30	5,183	7	1,419	30	9,316	0	0	117	18,776
VIRGIN ISLANDS	0	0	0	0	0	0	0	0	0	0	0	0
VIRGINIA	205	16,506	23	4,905	27	5,190	21	7,751	0	0	276	34,251
WASHINGTON	246	15,536	63	17,659	24	6,934	18	8,693	0	0	351	50,801
WEST PAC TERR	5	40	0	0	0	0	0	0	0	0	5	40
WEST VIRGINIA	166	8,373	5	555	5	1,555	11	3,490	0	0	192	11,974
WISCONSIN	602	34,422	165	40,192	83	9,648	338	175,726	21	2,822	1,187	265,675
WYOMING	40	2,763	11	984	6	1,552	13	8,255	3	667	73	14,220
TOTAL	13,301	842,472	2,611	834,481	1,856	268,579	3,469	1,489,451	296	25,563	21,332	3,255,545

Mr. Aderholt: For each FSA direct and guaranteed loan program, please provide a table by state showing the number of loans made and the amount to beginning farmers.

Response: The information is provided for the record.

[The information follows:]

FARM SERVICE AGENCY
FARM LOAN PROGRAMS BEGINNING FARMER OBLIGATIONS REPORT
FY 2012 AS OF SEPTEMBER 30, 2012

STATES	DIRECT OL		GUAR OL		DIRECT FO		GUAR FO		TOTAL	
	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT
ALABAMA	127	8,304,299	12	843,918	18	3,031,000	17	8,270,696	174	20,249,913
ALASKA	18	578,560	0	0	1	133,000	0	0	19	711,560
ARIZONA	47	5,242,210	12	6,246,700	2	480,000	1	423,370	62	12,392,280
ARKANSAS	281	27,888,000	134	37,322,866	20	2,672,240	46	26,924,069	481	94,807,175
CALIFORNIA	116	12,281,315	38	8,594,075	27	5,353,500	21	7,294,000	202	33,522,890
COLORADO	153	10,096,437	7	1,321,000	25	4,236,490	12	4,475,050	197	20,130,977
CONNECTICUT	5	156,700	2	272,630	1	279,800	0	0	8	709,130
DELAWARE	2	106,000	3	482,400	5	1,424,000	2	2,128,000	12	4,140,400
FLORIDA	117	9,852,520	9	1,945,300	9	1,378,000	5	871,500	140	14,047,320
GEORGIA	327	33,545,323	75	16,085,368	30	5,656,310	13	6,990,500	445	64,277,501
HAWAII	27	624,000	0	0	5	851,000	2	1,106,000	34	2,581,000
IDAHO	211	16,796,620	75	11,187,503	20	3,677,280	11	3,166,600	317	34,828,003
ILLINOIS	152	10,814,736	32	7,720,500	172	27,646,200	102	25,749,670	456	71,931,106
INDIANA	58	4,832,590	53	6,487,500	90	15,145,900	61	19,886,850	262	46,352,840
IOWA	978	58,099,491	80	11,797,095	278	45,901,999	78	23,956,075	1,414	137,854,660
KANSAS	333	19,685,696	45	6,556,487	151	19,944,350	39	5,823,150	568	52,009,683
KENTUCKY	759	35,043,670	41	7,118,345	68	12,685,750	48	16,496,966	916	71,344,731
LOUISIANA	140	11,717,570	104	24,107,315	3	282,200	2	318,000	249	36,426,085
MAINE	65	3,029,110	1	195,000	4	692,600	0	0	70	3,916,710
MARYLAND	12	885,850	3	411,300	7	1,827,500	4	2,776,000	26	5,900,650
MASSACHUSETTS	77	4,105,900	2	480,000	7	1,381,000	1	360,000	87	6,326,800
MICHIGAN	197	10,818,550	57	8,348,409	56	7,917,620	48	8,300,539	358	33,383,448
MINNESOTA	529	37,083,524	75	15,628,063	129	22,176,773	65	16,757,412	796	91,645,772
MISSISSIPPI	158	10,481,620	18	4,592,885	6	1,014,200	13	9,266,821	195	25,355,526
MISSOURI	262	17,344,350	67	14,620,039	135	18,091,020	81	17,162,575	545	67,217,984
MONTANA	176	13,668,780	31	5,237,258	39	7,868,330	28	11,037,189	274	37,811,557
NEBRASKA	884	51,013,807	30	7,378,240	162	31,799,070	29	9,928,700	1,105	100,119,817
NEVADA	41	2,194,905	2	560,000	6	928,000	4	659,500	53	4,332,405
NEW HAMPSHIRE	11	693,600	0	0	1	280,000	3	490,300	15	1,443,900
NEW JERSEY	31	1,425,400	3	275,000	4	598,000	0	0	38	2,298,400
NEW MEXICO	62	3,920,600	6	1,351,000	15	2,982,600	7	1,659,900	90	9,914,300
NEW YORK	121	7,005,300	22	2,574,000	22	3,453,550	11	1,608,000	176	14,640,850
NORTH CAROLINA	149	10,282,620	29	4,516,994	13	2,610,000	15	9,163,700	206	26,573,314
NORTH DAKOTA	235	19,569,080	44	8,558,151	50	7,604,960	9	2,650,415	338	38,382,586
OHIO	81	4,767,205	36	2,476,967	111	14,403,145	193	26,073,229	361	47,720,546
OKLAHOMA	482	24,525,630	23	5,029,227	201	32,990,670	23	7,011,976	729	69,557,503
OREGON	149	9,017,780	29	2,919,500	12	2,785,350	4	799,560	195	15,400,190
PENNSYLVANIA	239	13,407,370	27	2,172,788	27	6,618,975	18	4,296,368	311	26,495,481
PUERTO RICO	54	2,896,040	1	300,000	30	3,508,830	0	0	85	6,704,870
RHODE ISLAND	13	392,000	0	0	0	0	1	575,000	14	967,000
SOUTH CAROLINA	246	20,875,172	11	1,671,375	13	2,385,900	18	7,821,590	287	32,634,037
SOUTH DAKOTA	573	36,433,240	37	6,654,859	85	14,584,892	28	8,192,250	723	65,844,241
TENNESSEE	267	17,919,200	16	3,706,600	40	6,308,830	17	6,745,265	340	34,679,895
TEXAS	554	40,621,980	50	12,449,884	89	14,365,000	20	11,895,190	713	79,232,854
UTAH	265	15,215,870	7	1,064,703	32	6,348,620	7	2,119,652	311	23,768,845
VERMONT	50	2,583,800	17	2,338,800	6	873,000	10	1,366,765	83	7,262,365
VIRGIN ISLANDS	1	4,000	0	0	0	0	0	0	1	4,000
VIRGINIA	153	10,694,340	19	2,190,000	26	5,355,995	25	6,742,900	225	25,153,235
WASHINGTON	180	15,170,490	32	4,890,517	23	4,700,540	3	887,500	218	25,639,047
WEST PAC TERR	1	8,500	1	8,900	0	0	0	0	2	16,400
WEST VIRGINIA	181	4,421,740	0	0	16	2,425,500	6	1,303,650	186	8,150,890
WISCONSIN	607	32,532,400	74	12,001,273	127	23,296,110	71	19,183,966	879	87,013,749
WYOMING	35	2,906,035	7	1,031,756	11	2,587,510	7	4,524,500	60	11,049,800
TOTAL	10,949	711,677,835	1,490	283,891,270	2,435	404,759,899	1,169	355,044,608	16,043	1,755,173,212

FARM SERVICE AGENCY
FARM LOAN PROGRAMS BEGINNING FARMER OBLIGATIONS REPORT
FY 2013 AS OF APRIL 30, 2013

STATES	DIRECT OL		GUAR OL		DIRECT FO		GUAR FO		TOTAL	
	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT
ALABAMA	77	7,147,419	12	1,030,492	21	3,215,730	19	10,224,198	129	21,617,839
ALASKA	1	10,000	0	0	0	0	0	0	1	10,000
ARIZONA	27	3,228,630	9	4,961,375	0	0	4	1,319,159	40	9,507,064
ARKANSAS	154	17,005,950	102	33,512,591	18	2,085,730	47	30,036,660	321	82,640,961
CALIFORNIA	80	7,891,730	34	9,338,700	16	4,229,500	38	22,214,067	168	43,673,997
COLORADO	127	9,802,680	15	2,799,200	21	4,393,330	10	2,866,945	173	19,862,155
CONNECTICUT	3	122,000	2	400,000	0	0	1	584,000	6	1,106,000
DELAWARE	1	300,000	4	422,000	3	719,420	14	6,176,080	22	7,617,500
FLORIDA	89	8,124,050	9	1,144,000	9	1,517,700	4	1,668,000	111	12,453,750
GEORGIA	249	29,180,550	60	16,284,420	22	4,204,090	19	8,950,275	350	58,599,335
HAWAII	13	407,300	0	0	0	0	3	1,301,249	16	1,708,549
IDAHO	181	12,990,930	63	8,406,437	15	2,973,750	20	5,361,250	279	29,736,367
ILLINOIS	128	10,152,870	23	5,016,610	72	11,042,890	105	30,863,600	328	57,075,770
INDIANA	37	3,517,770	31	5,887,000	40	7,081,010	57	20,076,650	165	36,562,430
IOWA	741	47,775,460	44	8,352,130	94	16,353,030	71	27,535,916	950	100,016,556
KANSAS	184	13,184,540	16	4,443,500	54	8,158,900	22	5,277,613	276	31,064,453
KENTUCKY	416	24,070,970	38	5,291,639	46	7,599,900	40	13,338,768	540	50,301,277
LOUISIANA	103	9,037,365	75	19,435,390	2	600,000	5	1,651,000	185	30,723,755
MAINE	15	1,056,790	0	0	6	1,201,500	0	0	21	2,258,290
MARYLAND	10	870,000	3	215,055	7	1,865,000	18	9,941,122	38	12,891,177
MASSACHUSETTS	27	1,372,050	0	0	6	1,380,000	1	250,000	34	3,002,050
MICHIGAN	137	9,712,890	20	3,077,303	29	4,599,390	26	5,921,618	212	23,311,201
MINNESOTA	366	28,398,408	53	10,521,250	52	9,953,790	75	19,216,248	546	68,089,696
MISSISSIPPI	102	8,227,990	10	3,908,385	5	980,000	8	7,771,070	125	20,887,445
MISSOURI	172	13,301,670	53	9,581,075	80	9,691,083	69	17,050,622	374	49,624,430
MONTANA	132	9,635,250	28	7,552,743	23	4,127,940	21	6,992,082	204	28,317,995
NEBRASKA	678	46,891,810	33	11,232,880	40	8,837,050	29	10,322,230	780	77,283,970
NEVADA	31	1,497,050	0	0	4	547,650	7	3,690,688	42	5,735,388
NEW HAMPSHIRE	4	107,330	1	40,000	0	0	0	0	5	147,330
NEW JERSEY	21	945,000	0	0	4	791,000	2	261,000	27	1,997,000
NEW MEXICO	34	2,945,000	8	1,214,100	8	1,317,200	11	3,292,540	61	8,768,840
NEW YORK	57	3,712,850	14	1,138,300	19	2,460,780	13	2,129,000	103	9,440,930
NORTH CAROLINA	121	9,270,870	21	2,418,419	13	2,932,000	32	11,865,115	187	26,484,404
NORTH DAKOTA	173	16,532,270	34	6,699,630	28	4,641,280	11	5,214,725	246	33,087,905
OHIO	64	4,217,430	19	2,648,765	50	7,647,670	109	23,676,430	242	38,190,295
OKLAHOMA	266	15,269,620	15	3,541,170	78	12,429,109	23	8,267,299	382	39,507,198
OREGON	110	7,078,300	18	3,704,692	13	3,030,080	8	1,860,700	149	15,673,772
PENNSYLVANIA	189	8,119,860	16	1,316,100	24	5,703,700	20	6,281,699	229	21,420,959
PUERTO RICO	32	1,235,180	1	56,983	13	1,546,480	0	0	46	2,838,643
RHODE ISLAND	6	352,500	1	40,000	1	162,000	0	0	8	554,500
SOUTH CAROLINA	187	15,666,830	14	3,494,300	10	2,162,100	23	14,293,970	234	35,596,200
SOUTH DAKOTA	379	25,465,720	22	3,200,400	29	5,470,910	33	13,329,231	483	47,466,261
TENNESSEE	171	12,620,660	16	2,395,621	26	4,277,730	29	15,979,185	243	35,262,196
TEXAS	356	27,297,890	51	11,766,390	94	17,809,070	8	4,938,100	509	61,813,450
UTAH	186	11,221,360	6	2,959,925	11	2,375,400	3	1,319,500	189	17,876,205
VERMONT	30	1,240,010	8	812,500	5	1,138,500	10	1,626,250	53	4,817,260
VIRGIN ISLANDS	0	0	0	0	0	0	0	0	0	0
VIRGINIA	92	8,049,510	10	1,538,850	21	4,132,740	7	2,860,000	130	16,580,100
WASHINGTON	110	10,155,490	25	4,022,850	20	4,924,630	8	2,790,000	163	21,792,970
WEST PAC TERR	3	23,060	0	0	0	0	0	0	3	23,060
WEST VIRGINIA	66	2,506,950	3	165,000	6	1,125,400	5	1,576,600	83	5,374,050
WISCONSIN	349	20,474,000	37	7,938,032	42	6,897,210	52	17,206,209	480	52,413,450
WYOMING	22	2,295,420	5	480,330	3	850,000	1	175,000	31	3,800,750
TOTAL	7,272	531,595,972	1,082	234,104,532	1,205	211,103,352	1,140	409,554,772	10,699	1,386,358,628

Mr. Aderholt: For each FSA direct and guaranteed loan program, please provide a table by state showing the number of loans made and the amount to socially disadvantaged farmers.

Response: The information is provided for the record.

[The information follows:]

FARM SERVICE AGENCY
FARM LOAN PROGRAMS SOCIALLY DISADVANTAGED OBLIGATIONS REPORT
FY 2012 AS OF SEPTEMBER 30, 2012

STATES	DIRECT OL		GUAR OL		DIRECT FO		GUAR FO		TOTAL	
	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT
ALABAMA	136	3,464,262	1	25,000	16	2,500,500	15	5,948,830	168	11,938,592
ALASKA	11	538,510	0	0	0	0	0	0	11	538,510
ARIZONA	91	2,143,010	8	4,337,200	1	180,000	1	153,000	101	6,813,210
ARKANSAS	157	6,180,770	14	3,318,726	15	1,848,340	13	9,766,000	199	23,113,836
CALIFORNIA	271	10,272,095	57	20,246,599	20	4,838,350	26	13,754,000	374	48,311,044
COLORADO	67	1,852,918	4	316,750	6	1,024,638	3	1,744,050	80	4,938,516
CONNECTICUT	6	368,000	1	25,000	1	279,800	0	0	8	692,800
DELAWARE	3	54,000	1	296,000	3	900,000	3	2,128,000	10	3,378,000
FLORIDA	124	7,640,210	10	2,449,000	10	1,535,660	2	530,500	146	12,155,370
GEORGIA	145	10,275,967	15	4,378,440	12	1,332,660	9	5,137,250	181	21,124,317
HAWAII	62	1,894,820	0	0	6	1,101,000	4	2,152,430	72	4,948,250
IDAHO	89	1,779,840	9	886,896	5	1,095,980	6	1,785,160	109	5,524,876
ILLINOIS	27	346,620	3	975,000	8	1,589,850	6	2,911,880	44	5,823,050
INDIANA	24	594,400	8	1,120,500	5	951,200	4	2,091,260	41	4,757,360
IOWA	136	2,750,830	1	371,000	22	3,486,520	8	2,491,859	167	9,100,209
KANSAS	90	2,623,774	5	1,237,500	32	4,364,080	9	858,910	136	9,054,264
KENTUCKY	238	5,389,830	2	320,000	22	3,659,250	11	2,276,690	271	11,645,770
LOUISIANA	126	5,452,470	57	14,954,694	2	234,200	8	4,272,050	196	24,913,404
MAINE	29	1,024,500	1	195,000	6	873,600	0	0	36	2,193,100
MARYLAND	3	30,000	1	80,000	2	470,000	4	2,776,000	10	3,356,000
MASSACHUSETTS	24	1,152,300	0	0	4	896,000	3	1,141,000	31	2,989,300
MICHIGAN	81	1,719,330	3	319,250	11	1,595,540	1	140,000	96	3,774,120
MINNESOTA	102	3,857,505	5	756,300	16	2,414,420	4	1,060,428	127	8,088,353
MISSISSIPPI	114	3,613,020	2	650,300	3	404,000	2	2,017,525	121	6,681,545
MISSOURI	126	2,321,260	12	1,469,500	23	2,699,250	19	6,167,238	180	12,847,258
MONTANA	109	5,056,710	8	1,112,580	10	1,567,000	7	3,396,250	132	11,152,540
NEBRASKA	154	4,523,830	0	0	11	2,284,080	6	1,986,900	181	8,793,810
NEVADA	27	752,410	0	0	3	352,000	3	1,145,500	33	2,249,910
NEW HAMPSHIRE	2	45,000	0	0	0	0	1	205,000	3	250,000
NEW JERSEY	22	889,800	2	280,300	1	183,000	1	310,000	26	1,662,800
NEW MEXICO	72	3,543,230	3	861,300	13	2,563,750	5	2,399,450	93	9,367,440
NEW YORK	23	1,054,750	3	178,300	7	1,003,000	4	1,413,500	34	3,649,250
NORTH CAROLINA	85	2,861,553	13	2,852,628	7	1,586,520	15	8,411,766	100	14,712,466
NORTH DAKOTA	53	1,489,730	3	796,500	3	616,000	0	0	59	2,902,230
OHIO	82	1,190,974	3	336,375	24	3,063,470	38	8,093,116	127	12,685,575
OKLAHOMA	494	20,790,896	25	4,673,377	228	36,669,000	28	10,186,567	775	72,319,834
OREGON	56	2,403,230	1	1,130,000	6	1,194,000	4	911,560	67	5,638,790
PENNSYLVANIA	99	8,928,040	3	283,500	18	4,186,700	3	706,700	123	12,107,940
PUERTO RICO	123	6,234,810	2	400,000	40	4,714,570	5	2,817,000	170	14,166,380
RHODE ISLAND	11	457,000	0	0	0	0	1	575,000	12	1,032,000
SOUTH CAROLINA	115	7,540,763	3	256,300	8	1,257,500	11	3,373,514	137	12,428,094
SOUTH DAKOTA	166	9,416,350	12	1,671,336	24	4,546,812	2	420,000	204	15,056,492
TENNESSEE	138	3,918,620	2	778,300	14	2,324,080	9	3,242,000	133	10,263,100
TEXAS	436	12,947,250	8	1,675,436	56	8,358,850	16	13,457,660	516	33,439,196
UTAH	82	1,154,870	1	50,000	1	16,250	1	227,000	85	1,447,920
VERMONT	14	785,700	2	40,000	2	108,000	1	75,000	19	988,700
VIRGIN ISLANDS	2	74,000	0	0	0	0	0	0	2	74,000
VIRGINIA	73	4,502,700	2	295,300	15	2,714,730	9	2,377,000	99	9,889,430
WASHINGTON	145	8,241,950	9	1,647,000	12	2,836,000	2	519,000	168	13,316,950
WEST PAC TERR	4	24,200	1	8,900	0	0	0	0	5	33,100
WEST VIRGINIA	63	1,474,500	0	0	8	1,173,500	0	0	71	2,648,000
WISCONSIN	159	7,767,820	11	1,813,720	45	7,495,500	13	3,511,000	228	20,607,940
WYOMING	13	243,370	1	230,000	2	574,000	1	265,000	17	1,312,370
TOTAL	5,044	194,498,163	336	79,539,461	809	130,230,312	345	138,513,585	6,534	542,781,521

FARM SERVICE AGENCY
FARM LOAN PROGRAMS SOCIALLY DISADVANTAGED OBLIGATIONS REPORT
FY 2013 AS OF APRIL 30, 2013

STATES	DIRECT OL		GUAR OL		DIRECT FO		GUAR FO		TOTAL	
	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT	NO	$ AMT
ALABAMA	80	2,990,700	1	122,400	10	1,296,600	8	3,969,980	99	8,379,680
ALASKA	1	20,000	0	0	0	0	0	0	1	20,000
ARIZONA	80	1,573,360	1	1,302,000	0	0	0	0	81	2,875,360
ARKANSAS	81	6,100,540	7	1,822,436	7	1,057,950	28	19,554,070	123	28,534,996
CALIFORNIA	222	7,496,820	48	20,284,150	13	3,315,500	31	20,557,623	314	51,653,893
COLORADO	49	2,896,800	3	546,500	7	1,850,000	4	2,019,670	63	6,914,970
CONNECTICUT	2	101,000	1	100,000	0	0	0	0	3	201,000
DELAWARE	2	6,500	2	104,000	0	0	6	2,276,000	10	2,386,500
FLORIDA	56	3,307,605	8	1,250,000	7	1,374,000	6	3,422,297	77	9,353,902
GEORGIA	123	9,774,570	8	3,142,000	12	1,770,380	8	4,761,242	151	19,448,172
HAWAII	46	818,560	1	61,930	3	497,500	4	2,067,249	54	3,445,239
IDAHO	73	2,102,470	9	2,130,489	3	585,000	4	1,403,178	89	6,221,118
ILLINOIS	18	488,770	0	0	6	706,350	6	1,222,000	30	2,417,120
INDIANA	6	398,000	0	0	3	523,000	3	822,730	12	1,743,730
IOWA	82	2,044,440	0	0	10	1,628,110	5	1,063,775	97	4,736,325
KANSAS	67	1,886,200	0	0	15	2,046,800	9	1,398,225	91	5,331,225
KENTUCKY	143	3,702,710	5	1,360,000	12	1,413,000	6	2,388,786	166	8,864,496
LOUISIANA	76	4,622,980	33	9,086,712	1	300,000	4	1,816,000	116	15,825,692
MAINE	14	583,130	0	0	4	916,000	0	0	18	1,499,130
MARYLAND	9	458,000	0	0	5	1,136,000	12	8,921,122	26	10,515,122
MASSACHUSETTS	12	523,190	0	0	2	535,000	1	250,000	15	1,308,190
MICHIGAN	36	1,110,530	0	0	6	838,250	4	539,250	46	2,488,030
MINNESOTA	72	3,200,970	2	213,000	5	1,008,400	4	1,399,000	83	5,827,270
MISSISSIPPI	80	2,821,840	0	0	6	979,800	3	1,330,630	89	5,132,270
MISSOURI	59	1,645,180	11	2,143,885	17	2,220,890	18	6,662,700	105	12,672,655
MONTANA	83	3,896,630	14	3,508,188	6	1,317,000	5	2,420,600	108	11,141,418
NEBRASKA	118	4,028,880	3	367,080	6	1,153,820	3	585,850	130	6,145,630
NEVADA	28	506,030	0	0	0	0	0	0	28	506,030
NEW HAMPSHIRE	3	120,000	0	0	0	0	0	0	3	120,000
NEW JERSEY	9	348,000	0	0	1	275,000	0	0	10	623,000
NEW MEXICO	36	2,105,000	3	146,300	7	1,600,500	6	924,850	52	4,777,650
NEW YORK	12	563,790	2	280,000	2	380,000	1	275,000	17	1,498,790
NORTH CAROLINA	33	1,776,160	8	1,153,459	2	380,000	17	5,168,636	60	9,478,255
NORTH DAKOTA	47	2,888,630	3	355,000	2	543,500	2	944,875	54	4,530,005
OHIO	43	751,860	1	95,075	13	1,317,930	11	1,719,770	68	3,884,635
OKLAHOMA	328	15,318,960	24	4,336,895	54	8,676,579	27	12,711,498	433	41,043,932
OREGON	42	1,508,170	0	0	2	492,000	2	1,416,000	46	3,416,170
PENNSYLVANIA	89	4,517,041	1	25,000	9	1,942,200	7	2,924,000	106	9,408,241
PUERTO RICO	61	2,772,300	3	243,025	19	2,309,180	1	520,000	84	5,844,505
RHODE ISLAND	4	437,500	0	0	1	162,000	0	0	5	599,500
SOUTH CAROLINA	82	8,119,270	5	288,850	7	1,169,000	11	3,321,800	105	13,899,920
SOUTH DAKOTA	101	4,845,310	9	1,837,650	6	996,250	7	2,796,172	123	9,979,882
TENNESSEE	52	2,626,670	3	108,900	5	547,500	4	1,785,640	64	5,068,710
TEXAS	207	8,082,280	3	287,500	39	5,929,750	9	8,543,880	258	22,843,410
UTAH	72	1,962,790	0	0	4	618,000	0	0	76	2,580,790
VERMONT	4	242,500	2	158,000	1	300,000	3	318,500	10	1,019,000
VIRGIN ISLANDS	0	0	0	0	0	0	0	0	0	0
VIRGINIA	56	3,622,730	0	0	4	542,500	2	915,000	62	5,080,230
WASHINGTON	112	8,156,980	13	2,422,600	11	2,346,000	3	1,265,000	139	12,193,580
WEST PAC TERR	5	40,000	0	0	0	0	0	0	5	40,000
WEST VIRGINIA	39	1,113,800	1	120,000	1	117,850	1	302,100	42	1,653,550
WISCONSIN	87	3,532,390	2	270,000	9	1,226,430	12	4,678,300	110	9,707,120
WYOMING	18	1,169,730	1	200,000	1	250,000	1	801,000	21	2,420,730
TOTAL	3,260	141,124,528	241	59,723,313	366	60,396,499	309	146,046,200	4,176	407,290,538

Mr. Aderholt: Please provide a ten-year funding history of the down payment loan program.

Response: The information is provided for the record.

[The information follows:]

Down Payment Loans:	
Fiscal Year	Amount Obligated
2003	$8,103,520
2004	6,455,626
2005	6,138,460
2006	4,825,083
2007	4,723,240
2008	13,144,965
2009	133,678,735
2010	170,004,815
2011	182,615,000
2012	175,475,000
2013*	22,904,000

NOTE: FY 2013 data is as of March 31, 2013.

Mr. Aderholt: How many producers received down payment assistance through this program in fiscal years 2009 through 2012 and how many are estimated to receive it in fiscal year 2013?

Response: The information is provided for the record. We cannot estimate how many down payment loans will be made in FY 2013, but as of 03/31/2013, we have made 151 down payment loans.

[The information follows:]

Down Payment Loans:	
Fiscal Year	Number of Loans
2009	977
2010	1,225
2011	1,246
2012	1,187

Mr. Aderholt: What is the average amount in down payment assistance provided to producers?

Response: The average amount of a down payment loan was $136,826 in FY 2009; $138,779 in FY 2010; $143,518 in FY 2011; and $147,830 in FY 2012. So far in FY 2013, the average down payment loan is $151,675.

Mr. Aderholt: For the Supplemental Revenue Assistance Payment Program or SURE, FSA documents carry a statement that says: "Producers considered socially disadvantaged, a beginning farmer or rancher, or a limited resource farmer may be eligible for SURE without a policy or plan of insurance or NAP coverage." What additional risks are borne by this policy and under what authority allows FSA to take on this increased risk?

Response: Section 901 (g)(3) of the Food, Conservation, and Energy Act of 2008, also known as the 2008 Farm Bill, waives the risk management purchase requirement for socially disadvantaged, beginning farmers or ranchers and limited resource producers enabling them to maintain assistance under SURE. This does not extend the agency's risk to provide coverage under NAP or a crop insurance policy. It allows these producers to maintain the eligibility to participate in SURE.

Mr. Aderholt: As USDA shifts more ownership and operating loans to beginning farmers and/or members of socially disadvantaged groups, is the Agency doing so at the risk of not supporting a greater share of small and medium size producers that are capable of delivering greater returns on investment and delivering greater efficiency and productivity?

Response: The direction of funding to beginning and socially disadvantaged (SDA) farmers is a statutory requirement (7 U.S.C. §1994(b)(2) and 7 U.S.C. §2003). The 2008 Farm Bill increased the reservation of funds for beginning farmers (Food, Conservation and Energy Act of 2008, Sec. 5302(b)). Since the average age of farmers in the last Census of Agriculture was 57, and beginning farmers cite credit as one of the largest barriers confronting them (according to the National Young Farmer Coalition's 2011 study "Building a Future with Farmers"), a focus on beginning farmers in particular is consistent with efforts to strengthen, support and increase the number of small and medium sized producers. It should be noted that improvements in program performance over the past several years (as noted in the Chairman's statement prior to question 7) have occurred simultaneously with the shift toward increased financing of beginning and SDA farmers, particularly in the direct loan program. This is an indication that these producers are performing well, and are likely as or more productive and efficient than those producers financed prior to implementation of the statutory funding targets for beginning and SDA farmers.

CCC Expenditures

Mr. Aderholt: What is the annual cost to cover the contracts that the CCC has with the commercial warehouse operators for the storage of Government-owned commodities?

Response: The costs to administer the Cotton, Processed Commodities, Peanut, Sugar and Uniform Grain and Rice Storage Agreements in FY 2012 (a total of 6,429 agreements) was $1,347,785.

Mr. Aderholt: Provide a table for the record that shows the location of each facility along with the annual cost for each facility.

Response: CCC does not rent warehouse space to store commodities. Instead, CCC enters into various storage agreements (grain and rice, sugar, processed commodities, cotton, and peanuts) under which CCC only pays the warehouse operator when there are CCC-owned commodities in store. At this time, CCC is not accruing storage charges, as it has no inventory. The Farm Service Agency's website provides locations of facilities that have storage agreements with CCC.

The information is provided for the record.

[The information follows:]

Clerk's Note: Due to its large size, this information is on file with the Committee on Appropriations.

Mr. Aderholt: Provide a table for the record that shows CCC owned inventories by commodity and by location.

Response: CCC does not currently own any commodity inventories.

CCC Subsidizing Bio-Based Jet Fuel

Mr. Aderholt: According to page 24-6 of the fiscal year 2014 explanatory notes, the CCC will make available up to $170,000,000 to subsidize the production of bio-based jet fuel in an agreement with the Department of Energy and the Navy.

What is the status of this project?

Response: The project is in the planning phase. The Department of the Navy is finalizing contract administration arrangements with the Defense Logistics Agency. The Farm Service Agency has drafted the Interagency Agreement between the Commodity Credit Corporation and the Department of the Navy. The agreement is under review by both parties for comment or concurrence.

Mr. Aderholt: How much bio-based jet fuel have they produced?

Response: A contract has not been awarded and no bio-based jet fuel has been produced for this project.

Mr. Aderholt: What is the overall cost to U.S. taxpayers to subsidize the production of bio-based jet fuel?

Response: The Memorandum of Understanding signed by the Secretary of the Navy, Secretary of Energy and Secretary of Agriculture in June 2011 commits $510,000,000 to the bio-based jet fuel project.

Mr. Aderholt: How did the USDA arrive at $170,000,000?

Response: The $510,000,000 is divided equally among the three participating parties at a cost of $170,000,000.

Mr. Aderholt: As the notes state, there is "no existing viable commercial source for the large-scale production of such fuel." Why does the Department believe that such a large-scale production can lead to an economically viable production model?

Response: Given the current economic environment, significant start-up risks, and competitive barriers posed by the firmly established crude oil markets, industry will not assume all of the uncertainty and risk associated with providing a commercially viable production capability for advanced drop-in biofuels. Therefore, it is necessary that the Federal Government cooperate with industry to create a strong demand signal and make targeted investments to achieve economically viable production capacity.

Mr. Aderholt: Under the Department's justification of the use of CCC funds for this purpose, what would Section 4(e) of the CCC Charter Act authorize and what would it not authorize?

Response: The bio-based jet fuel project is authorized under Section 5(e) of the Commodity Credit Corporation Charter Act, which authorizes the Commodity Credit Corporation to develop or aid in the development of new and additional domestic markets.

Discrimination Lawsuits and Settlements

Mr. Aderholt: The New York Times published an article ("U.S. Opens Spigot After Farmers Claim Discrimination" - April 25, 2013) detailing the paper's in-depth investigation of USDA's settlement of a few high profile discrimination settlements that could cost as much as $4.4 billion. This article includes some troubling statements from current and former officials that, if true, indicate millions of taxpayer dollars wasted because of fraud and abuse.

Please provide USDA's position on the claims made in this article.

Response: USDA has made it a priority to ensure that all Americans working with the Agency get equitable service. USDA has taken steps to prevent discrimination from happening in the future, but we also recognize the importance of providing a path to justice for those who alleged that they were discriminated against in the past and can provide appropriate evidence of the alleged discrimination.

An important part of this process came through settlements with certain African-American, Native American, Hispanic and female producers. But prior to opening the Pigford II and other claims processes, USDA ensured that each would be led by a neutral, third-party adjudicator. USDA ensured that each of the processes require documentary evidence in order for a claimant to prevail. Finally, all potentially fraudulent claims are referred to the appropriate federal authorities for investigation.

Mr. Aderholt: What additional controls or reviews have been put in place to discover additional cases of wrongdoing in claims or payments made?

Response: Each claims process was designed with two important goals in mind. First, to provide a pathway to justice for those who were wronged in the past. Second, to do so in a way that safeguards taxpayer dollars and contains adequate protection from fraud and abuse. Each claims process has

been led by a neutral, third-party, independent adjudicator. Each claims process requires documentary evidence in order for a claimant to prevail.

USDA and all parties involved take allegations of fraud seriously, and each of the claims resolution processes reflects a desire to provide a path to justice while preventing fraudulent claims. Each claims process empowers the Claims Adjudicator to require a claimant to submit additional documentation and evidence if, in the Adjudicator's judgment, the additional documentation and evidence would be necessary or helpful in deciding the merits of the claim, or if the Adjudicator suspects fraud regarding the claim.

Referrals of any claims that appear fraudulent are made by USDA and/or the Adjudicator to USDA's Inspector General, the Department of Justice, the appropriate US Attorney's Office, or any other appropriate agency. The Department of Justice and/or the appropriate US Attorney's Office on their own initiative may consider claims that appear fraudulent and/or refer them to an appropriate law enforcement authority.

In December 2012, GAO released a report finding that the claims process for Pigford II provides reasonable assurance that fraudulent or otherwise invalid claims could be identified and denied. In addition, the USDA Office of Inspector General has also performed detailed audits of the claims process.

Mr. Aderholt: In response to questions raised about the use of the Judgment Fund to pay settlements, please provide an OGC opinion as to how USDA justified using this fund under 31 U.S.C. 1304.

Response: USDA does not have the legal authority to make any decisions concerning the Judgment Fund. The Department of Justice possesses broad and plenary litigation authority. See 28 U.S.C. §516. The Judgment Fund was established, in part, to provide settlement in cases where the Government is being sued or is likely to be sued. For all settlements in cases involving the Government, the attorneys of the Department of Justice examine the underlying cause of action, assess litigation risk, and decide whether the rendering of a final judgment against the United States under such a cause would require a payment from the Judgment Fund. See 28 U.S.C. §2414; 31 U.S.C. §1304(a).

National Agricultural Imagery Program (NAIP)

Mr. Aderholt: How much did FSA spend on the National Agricultural Imagery Program in fiscal years 2011 and 2012 and how much does the Agency plan to spend in fiscal years 2013 and 2014? Please provide detail on the types of expenses in this program.

Response: The information is provided for the record.

[The information follows:]

NAIP Funding Summary - Amounts in Thousands ($000)

Funding Source	FY 2011 Actual	FY 2012 Actual	FY 2013 Plan	FY 2014 President's Budget
S&E				$10,141
Advances & Reimbursement (NAIP Partnerships) a/	$4,830	$5,400	$2,995	5,400
CCC Section 4	11,641	11,747	9,624	
Total, FSA Funding	16,471	17,147	12,619	15,541

a/ NAIP Partnerships include 3 Federal Agencies (US Forest Service, Natural Resources Conservation Service & Department of the Interior).

Improper Payments in FFAS Program

Mr. Aderholt: The Improper Payments Information Act (IPIA) of 2002 requires Federal Agencies to evaluate programs to determine whether internal controls are sufficient to prevent issuing improper payments. FSA and RMA have a few relatively high improper payment rates in their programs. In March 2013, USDA's OIG issued a report entitled: U.S. Department of Agriculture Improper Payments Elimination and Recovery Act of 2010 Compliance Review for Fiscal Year 2012. According to the report, USDA delivers approximately $144 billion in public services annually through more than 300 programs. Of the 29 component agencies and offices that operate these programs, 7 component agencies including RMA and FSA currently administer high-risk programs that are vulnerable to significant improper payments. USDA estimated in fiscal year 2012 that these agencies' 16 total high-risk programs made $5.5 billion in improper payments, a 5.11 percent error rate.

Programs in the Farm and Foreign Agricultural Mission Area don't come close to the School Lunch or School Breakfast Programs at 15.53 and 25.18 percent respectively, but it is imperative that USDA reduce or eliminate improper payments across the board. In regards to RMA, the report says -- RMA reported that FCIC improper payments were approximately $173 million, a 4.08 percent error rate. However, because of RMA's sampling methods, OIG believes that this estimate may have been understated.

Please describe the sampling model evaluated by USDA's OIG.

Response: In response to the Improper Payments Information Act of 2002 (IPIA) RMA developed a sampling plan to review one third of the participating insurance companies each year and draw a random sample of policies with indemnities to test for improper payments. Each year 250-300 random polices are assessed and the results from these reviews are combined with results from the previous two years to determine a rolling 3-year average error rate. This rolling error rate is used to calculate the program error percentage which is applied to the year being reported in the USDA IPIA Corrective Action Plan.

Mr. Aderholt: Please describe the actions RMA is taking to develop a new sampling method in order to arrive at a more accurate means of calculating improper payment rates.

Response: The current approved methodology is sound and reflects the errors found in our random samples of indemnities paid. OIG recommended that RMA expand the sampling to include the premium dollars for policies with no indemnities. RMA continues to work with OIG and the Department to address this issue balanced with the available resources for conducting the review work.

Mr. Aderholt: Of the 4.08 percent error rate, what is the breakdown between the overpayments and underpayments?

Response: RMA determined that 3.75 percent of improper payments were attributed to overpayments and 0.33 percent to underpayments.

Mr. Aderholt: Provide a detailed explanation of what the RMA has done in each of the last three fiscal years to improve program integrity in the crop insurance program, including efforts to identify the causes of improper payments and actions taken to reduce improper payments?

Response: RMA has initiated or continued successful efforts to limit improper payments over the past three fiscal years. RMA continues to make improvements through its Information Technology Modernization project to check, edit and accept incoming program data to limit errors before they can create improper payments. This helps RMA keep up with the increasing volume and complexity of the data needed to run the expanding crop insurance program. RMA also continues to use data mining to identify and correct the root causes of improper payments. In 2010 we restructured the quality control requirements for the Standard Reinsurance Agreement to improve the efficiency and effectiveness of reviews. Lastly, RMA has identified that simple unintentional errors (data input, certification, etc.) account for the vast majority of the errors identified in all reviews. RMA has undertaken a review of the Actual Production History program with the intent of converting it to a historical data driven program rather than the annual certifications it relies on today. This is a long-term effort that will require regulatory and other fundamental program changes to implement, but is expected to dramatically reduce the errors that commonly occur in the program today.

Mr. Aderholt: What is the payment error rate, both as a percentage and in dollars, for RMA?

Response: The current reported error rate is 4.08 percent. Applied to the 2010 indemnities the dollar error would be $173.4 million.

Mr. Aderholt: What are the reasons that the Noninsured Assistance Program error rate is so high? What are you doing to address this payment error rate?

Response: Noninsured Crop Disaster Assistance Program (NAP) improper payments were primarily attributed to administrative errors that included:

- Incorrect total production used to calculate payment;
- Incorrect crop acreage used to calculate payment; and
- Application for payment filed late.

To address these issues FSA has undertaken Web modernization projects delivered in FY12-FY13 enabling Noninsured Assistance Program applications processing. The Web-enabled applications were enhanced to reduce manual data entry errors, and prevent a payment from being issued without an acreage report on file. The Web-enabled NAP applications provide a timelier and more accurate delivery of benefits to producers. The NAP improper payment rate has declined from 11.65% in 2010 to 7% in 2012.

Federal Crop Insurance Corporation Fund

Mr. Aderholt: What is the reason for the $564,000,000 beginning-of-year balance in the Federal Crop Insurance Corporation Fund for fiscal year 2013 that is shown in the project statement on p. 23-15? Does the FCIC Fund typically carry an end-of-year balance in excess of $550,000,000? Why?

Response: FCIC carries forward select funds annually. At a minimum, FCIC will carry forward $538 million. Section 1504 (a) of the Federal Crop Insurance Act (Act) authorizes capital stock of $500 million and an additional $38 million is available from paid-in-capital. In addition, contingency funds are held, as authorized by section 516(c) of the Act. Contingency funds totaled $26 million at the end of FY 2012, and grow on average by about $2 million annually from the collection of civil fines and penalties. Contingency funds would potentially be used to offset expenses incurred by FCIC to administer an Approved Insurance Provider's book of business in the event of a catastrophic event such as insolvency or operational deficiency.

Mr. Aderholt: Provide a detailed breakout of the $67,500,000 and $55,860,000 Federal Crop Insurance Act Initiatives for fiscal years 2011 and 2012 as shown in the project statement. How will the $58,500,000 be spent in fiscal years 2013 and 2014?

Response: The information is provided for the record; however, please note that the FY 2013 estimate was reduced by the amount sequestered and the FY 2011 and 2012 amounts represent actual dollars spent.

[The information follows:]

FEDERAL CROP INSURANCE INITIATIVES

	FY 2011 Actuals	FY 2012 Actuals	FY 2013 Estimated	FY 2014 Estimated
Section 515: Data Mining	$4,000,000	$4,000,000	$4,000,000	$4,000,000
Information Technology	9,000,000	0	0	0
Section 516, Policy Consideration and Implementation	3,453,502	3,087,581	3,500,000	3,500,000
Section 522, Research & Development	19,409,542	19,395,282	19,062,000	20,000,000
Section 523, Pilot Programs	19,987,548	19,431,594	20,000,000	21,000,000
Section 524, Education and Information Programs	9,999,821	9,946,027	10,000,000	10,000,000
TOTAL	65,850,413	55,860,484	56,562,000	58,500,000

Mr. Aderholt: Provide a detailed breakout of the $20,000,000 in Program Related IT for fiscal year 2013. What is RMA buying with these funds? What is the plan for the $20,000,000 expenditure for this purpose in fiscal year 2014?

Response: Since FY 2012, RMA has used its authority to use up to $20 million per year from the fees collected from catastrophic or buy-up policies. The usage is limited by statute to support data buys and information technology systems that directly support the activities and functions that maintain crop insurance policies, such as developing or establishing premium, rates, yields and other provisions of insurance. The fees are also used for systems that support exceptions to the standard policy provisions that are developed through Written Agreements approved by RMA Regional offices. Finally, the fees are used to support modifications of existing RMA systems to allow producers to directly transmit their data to USDA, consistent with and furthering the goals of the acreage crop reporting streamlining initiative. For FY 2014, RMA plans to spend the $20,000,000 similar to the breakout below.

[The information follows:]

FY 2013 Program Related IT

Systems Development and Enhancement	$6,500,000
Infrastructure/Security Support	4,000,000
Software Maintenance	3,000,000
Tools/Maintenance Agreements	1,000,000
Data Purchasing	950,000
Microsoft Licensing	250,000
Reserve	4,120,000
FEDSIM Contract Fee	179,400
	$20,000,000

Mr. Aderholt: What is the purpose of the other adjustments line that is shown for fiscal years 2011 through 2014 in the project statement shown on p. 23-15?

Response: The other adjustments line for fiscal years 2011 through 2014 in the project statement shows collections from producer paid premium and fees.

GAO's Annual Report on Federal Government Overlap and Duplication

Mr. Aderholt: The Government Accountability Office (GAO) publishes an annual report on ways the Federal government might find savings by eliminating overlap, duplication or generally unnecessary programs. In particular, GAO's 2013 Annual Report published in April 2013 suggests that the Agency should explore applying limits on premium subsidies to individual farmers participating in the federal crop insurance program, similar to the payment limits for other farm programs, and could save billions of federal dollars over 5 years.

Is this something that RMA has looked at as a means to save money on the mandatory side?

Response: The Administration has proposed a general reduction in premium subsidies as an alternative.

Mr. Aderholt: What would be some of the ramifications of such a proposal?

Response: Some of the ramifications, negative impacts or additional program costs incurred within the crop insurance program under such a proposal include:

- Inequitable treatment of producers. Currently, the program requires small, medium and large farms to pay the same premium rate for the same risks and receive the same subsidy percentage, but total premium changes

depending on quantity of the commodity to be insured thus allowing each producer to tailor coverage to their operation. By treating producers differently, this removes program flexibility and consistency regardless of the size of operation and fails to recognize the economic value of varying farm operations.

- Disproportionate impact to certain commodities or regions of the country due to the inherent nature of the commodities grown, economic and agronomic practices of the types of farms in specific areas, or producer's cash flow and credit needs.
  - The GAO report fails to consider the impact on the availability of credit to the agricultural sector given the proposal. For example, states like Arizona, Florida and Hawaii for which high-value specialty crops are grown would be impacted differently, and states that grow crops like fresh market tomatoes, peppers, onions, macadamia nuts, fresh market beans and various citrus crops all would see disproportionate impacts.
  - Also, states like North Dakota, South Carolina, Mississippi, Utah, Michigan and Texas that have high-value row crops and/or higher risk crops that include cotton, sunflowers, potatoes and canola.
- Significant administrative burdens in tracking, monitoring and controlling the proposed subsidy limits since many crop insurance programs have varying features by crop or commodity with different sales periods, planting dates, premium billing dates and insurance periods.
  - These different program features would make it almost impossible for agents to provide accurate yearly quotes to producers to make sound, informed buying decisions for an upcoming cropping season.
  - This in turn concerns by agricultural lenders to have any certainty in providing operating loans using crop insurance as collateral as they will not know in many cases how a subsidy limit might impact their perspective borrower in any given year.
- Program complexity resulting from the creation of additional entities and other attempts to get around income limits is almost certain to occur. This would require more resources to monitor and maintain program integrity by identifying activities solely to maximize subsidy benefits.
- Potential for lower participation rates in the program leading to potential ad-hoc disaster requests as producers likely purchase lower coverage levels, or exit the program leaving potential gaps in the safety net. To the extent this occurs, it raises unknown questions and issues for altering the risk pool of producers remaining in the program leading to potential premium rate impacts or changes depending on the magnitude or changing characteristics to the risk pool.

Proposed Legislation

Mr. Aderholt: RMA assumes fiscal year 2014 savings related to five legislative proposals, including savings of $219 million in 2014 and 2.4 billion over 10 years in the crop insurance program that will lower producer premium subsidy two percentage points for policies where the government subsidizes more than 50 percent of the premium.

When will the legislation be submitted?

Response: The Administration will work closely with Congress to provide technical assistance regarding the specific legislative language needed to implement the proposals contained in the President's fiscal 2014 budget. We note that the 2014 budget proposal lowers the producer premium subsidy by 3 percentage points and saves $4.2 billion in 10 years.

Mr. Aderholt: How did the program arrive at this savings estimate?

Response: In developing the estimated savings from the proposed reductions in premium subsidy, RMA used the USDA baseline for 2014 and subsequent fiscal years to obtain baseline expenditure estimates. The proposed reductions in premium subsidy were then applied to the 2012 distribution of policies, adjusted to the baseline estimates for the 2014 and subsequent fiscal years. Certain behavioral assumptions were incorporated, in particular, that some portion of producers would either reduce their choice of coverage or even drop out of the crop insurance program altogether because of the reduction in premium subsidy. The projected expenditures following the reduction in premium subsidy allowing for behavioral changes were then compared to baseline expenditures to determine the estimated savings.

Mr. Aderholt: If this legislation were to be submitted, and enacted, how long would it take the RMA to revise rules/regulations to make this change?

Response: The premium subsidy percentages are contained in the actuarial documents that are part of a Federal crop insurance policy. The Federal crop insurance policy is a contract between the producer and the Approved Insurance Provider, thus changes to the components of the contract including premium subsidy must be made by the contract change date specified in the policy. For most spring-seeded crops (e.g., corn, soybeans, cotton) the contract change date is the November 30 immediately preceding the calendar year in which the crop is planted. Thus, revised actuarial documents would have to be issued no later than November 30, 2013 for the premium subsidy reductions to effect 2014 spring planted crops. For most fall-seeded crops (e.g., winter wheat) the contract change date is June 30 of the calendar year in which the crop is planted. Thus, for fall-seeded crops the revised actuarial documents would have to be issued no later than June 30, 2013 for the premium subsidy reductions to effect 2014 fall planted crops.

Mr. Aderholt: What are the circumstances where the government currently subsidizes more than 50 percent of the premium?

Response: The table below provides the premium subsidy percentages by policy type and coverage level. The shaded cells are those for which the current premium subsidy exceeds 50 percent and are impacted by the proposed three percentage point reduction in premium subsidy. The information is provided for the record.

[The information follows:]

Government Share of Premium Subsidy by Insurance Plan and Coverage Level

Plan Type	Sub Type	Unit	50%	55%	60%	65%	70%	75%	80%	85%	90%
Individual	Yield	OU/BU	67%	64%	64%	59%	59%	55%	48%	38%	
		EU	80%	80%	80%	80%	80%	77%	68%	53%	
	Revenue	OU/BU	67%	64%	64%	59%	59%	55%	48%	38%	
		EU	80%	80%	80%	80%	80%	77%	68%	53%	
		WU	80%	80%	80%	80%	80%	80%	71%	56%	
	HPO	OU/BU	67%	64%	64%	59%	59%	55%	48%	38%	
		EU	80%	80%	80%	80%	80%	77%	68%	53%	
		WU	80%	80%	80%	80%	80%	80%	71%	56%	
Group	Yield	Other					59%	59%	55%	55%	51%
	Rev	Other					59%	55%	55%	49%	44%
	HPO	Other					59%	55%	55%	49%	44%

OU: Optional Unit, BU: Basic Unit, EU: Enterprise Unit, HPO: Harvest Price Option, WU: Whole Farm Unit

Mr. Aderholt: What is the date that this legislation would have to be enacted in order to produce savings of $219 million in fiscal year 2014, or would RMA be able to achieve these savings regardless of date of enactment?

Response: The estimated savings of $219 million in fiscal year 2014 is the result of the proposed two percentage point reduction in premium subsidy for policies with the Harvest Price Option. In developing this estimate, it was assumed that the proposed reduction would apply only to spring-seeded crops for 2014. The contract change date for most spring-seeded crops is November 30. Thus, legislation containing the proposed reduction would have to be enacted prior to November 30, 2013.

Mr. Aderholt: What are the estimated savings in each of the out years 2-10 to arrive at the $2.4 billion figure?

Response: None of the savings estimates on the five crop insurance proposals in the 2014 budget equal to $2.4 billion over 10 years. The fiscal

year savings estimates for 2014 budget proposals related to premium subsidy reduction on buy up coverage are provided in the table below. Information is provided for the record.

[The information follows:]

Estimated Savings from Proposed Premium Subsidy Reductions (Dollars in Millions)											
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
3% over 50%	293.8	368.2	402.2	412.4	425.1	441.3	450.1	462.4	473.4	483.9	4,212.8
2% on HPO	219.2	275.3	306.5	314.3	323.9	336.2	343.0	352.4	360.8	368.8	3,200.4
Total	513.0	643.5	708.7	726.7	749.0	777.5	793.1	814.8	834.2	852.7	7,413.2

Mr. Aderholt: Another legislative proposal involves the establishment of a "reasonable rate of return to participating insurance companies" or a cap of 12 percent.

How would this proposal work?

Response: RMA would reduce the subsidy percentages for the relevant coverage levels.

Mr. Aderholt: When will the legislation be submitted?

Response: The Administration will work closely with Congress to provide technical assistance regarding the specific legislative language needed to implement the proposals contained in the President's fiscal 2014 budget.

Mr. Aderholt: How did the program arrive at this savings estimate?

Response: The USDA baseline for 2014 and subsequent fiscal years includes the estimated underwriting gains of Approved Insurance Providers (AIPs), reflecting baseline estimates of premium, AIP risk retention, and the targeted rate of return of 14.5 percent. Projected AIP underwriting gains under this proposal were generated by applying the proposed 12 percent rate of return to the baseline estimates of premium and AIP risk retention. The projected AIP underwriting gains were then compared to baseline estimates to determine the estimated savings.

Mr. Aderholt: If this legislation were to be submitted, and enacted, how long would it take the RMA to revise rules/regulations to make this change?

Response: The Standard Reinsurance Agreement (SRA) is a contractual arrangement between the government and the Approved Insurance Providers. The reinsurance year runs from July 1 through June 30 of the subsequent calendar year. Any changes to the SRA must be in place before July 1 to take effect; otherwise implementation would be delayed until the next reinsurance year. Thus, for the proposed change to be implemented for the 2014 reinsurance year, a revised set of risk-sharing terms would need to be in place on or before June 30, 2013.

Geographic Breakdown of Obligations and Staff Years

Mr. Aderholt: The crop insurance program Geographic table shows $3,719,817,000 and $3,118,406,000 of undistributed obligations for fiscal years 2011 and 2011 respectively.

Please provide a table that breaks these costs down by Delivery Expenses, FCIA cost, Interest, Underwriting (gains/losses), and other expenses for each of fiscal years 2010 and 2011.

Response: The undistributed figure provided on the Geographic table for fiscal year 2012 was incorrect, undistributed obligations were actually $3,118,676,000. The information is provided for the record.

[The information follows:]

Undistributed Obligations
Federal Crop Insurance Corporation Fund
(Dollars in thousands)

	2011 Actual	2012 Actual
Delivery Expenses	$1,383,342	$1,373,000
Federal Crop Insurance Act Initiatives	64,712	55,860
Underwriting Gain/Losses	2,271,763	1,669,816
Program Related IT	0	20,000
Total, Undistributed Obligations	3,719,817	3,118,676

Mr. Aderholt: Provide a comprehensive description of what is included in "other expenses".

Response: These other expenses represent a compilation of monthly settlements with the Approved Insurance Providers, escrow, off-setting collections, debts from CAT fees, overpaid indemnities, and/or judgments.

Ten-Year Table of Reinsured Company Financial Performance

Mr. Aderholt: Federal crop insurance is available to producers through private insurance companies that market and service policies and also share in the risk. Provide a ten-year table for the record, to include fiscal year 2012 actuals that shows how much the government has gained/lost and how much private insurance companies have gained/lost.

Response: The information is provided for the record.

[The information follows:]

REINSURED COMPANY FINANCIAL PERFORMANCE
2002 - 2012 REINSURANCE YEARS
AS OF 3/8/2013

(Dollars in Thousands)

YEAR	GROSS PREMIUM	GROSS LOSSES	GAIN GROSS /(LOSS)	FCIC SHARE OF NET GAIN/(LOSS)	COMPANY SHARE OF NET GAIN/(LOSS)
2002	$2,911,719	$4,061,673	-$1,149,954	-$1,102,644	-$47,310
2003	$3,436,194	$3,257,721	$178,473	-$210,406	$388,879
2004	$4,186,488	$3,292,725	$893,763	$203,258	$690,505
2005	$3,945,481	$2,341,070	$1,604,411	$689,438	$914,973
2006	$4,709,426	$3,551,301	$1,158,125	$336,171	$821,954
2007	$6,547,314	$3,465,111	$3,082,203	$1,510,358	$1,571,845
2008	$9,832,211	$8,719,143	$1,113,068	$17,489	$1,095,579
2009	$8,947,537	$5,212,681	$3,734,856	$1,436,896	$2,297,960
2010	$7,594,142	$4,251,988	$3,342,154	$1,426,979	$1,915,175
2011	$11,965,708	$10,827,436	$1,138,272	-$553,967	$1,692,239
2012*	$11,081,388	$15,727,130	-$4,645,742	-$3,540,696	-$1,105,046
TOTAL	$75,157,608	$64,707,979	$10,449,629	$212,876	$10,236,753

Source: 1989 - 2011 Reinsured Company Financial Performance Report
* 2012 as of March 8, 2013 Reinsurance Run

Ratio of Portfolio Size to Staff and IT Budget

Mr. Aderholt: For the record, please provide the Subcommittee with a table that shows a five year history of the size of the crop insurance portfolio (i.e., total liabilities), the total funding for administration and operating budget, subset of information technology expenditures, and FTE.

Response: The information is provided for the record.

[The information follows:]

(Dollars in Thousands)

	2009	2010	2011	2012	2013
Total FCIC Liability	$79,547,556	$78,089,674	$114,095,059	$116,880,247	$116,085,800
Discretionary A&O Appropriation	$77,177	$79,991	$79,000	$74,900	$69,104
Information Technology (IT)*	($14,962)	($15,913)	($14,856)	($13,382)	($9,443)
Staff Years	481	501	505	470	455

* Discretionary IT only, does not include mandatory sources of IT.

GAO Reports Relating to Crop Insurance

Mr. Aderholt: Please provide the Subcommittee with a summary of GAO's report entitled "Savings Would Result from Program Changes and Greater Use of Data Mining" published in March 2012, and provide a summary of detailed actions RMA is taking to address the concerns in the report.

Response: In the report GAO-12-256 CROP INSURANCE: Savings Would Result from Program Changes and Greater Use of Data Mining, the GAO evaluated the: (1) effect on program costs of applying limits on farmers' federal subsidies, as limits are applied to other farm programs; and (2) extent to which USDA uses key data mining tools to prevent and detect fraud, waste, and abuse in the program. The GAO concluded that significant program savings were possible if premium subsidies to producers for the purchase of crop insurance were limited. GAO also concluded that, although RMA has made substantial progress in developing data mining tools to detect and prevent fraud, waste, and abuse, the Agency's use of those tools lagged behind their development, largely because of competing priorities.

The GAO provided four recommendations for the USDA specific to the RMA and the Farm Service Agency (FSA).

GAO RECOMMENDATION 1: For the list of farmers with anomalous claim payments, encourage the completion of FSA county office inspections during the growing season by requiring FSA state offices to monitor the status of their completion.

USDA Response: RMA produces an annual spot-check list of farmers with anomalous claim outcomes that historically was provided solely to FSA for further investigation. As noted in the GAO report, FSA offices have had difficulty completing all of the inspections because of resource limitations and competing priorities. However, FSA agreed with the recommendation and updated written procedure to require FSA state offices to monitor county offices in completing the inspections. New guidance was issued April 2012 to require (1) State Offices to monitor the completion of spot checks for all counties, and (2) State Offices to submit reports to the National Office identifying spot checks for all counties in the State that have not been completed.

In light of the success of the spot-check program and to alleviate FSA resource limitations, RMA and the Approved Insurance Providers (AIPs) broadened the use of data mining to help direct (AIP) efforts at detecting and investigating suspect behaviors. In particular, AIPs are now responsible for conducting 50 percent of the spot-check list reviews for policies with claims in excess of $10,000 and 100 percent of the reviews for policies with claims less than $10,000. The reinsurance agreement between RMA and the AIPs requires the companies to conduct comprehensive reviews. Thus, we anticipate that AIP involvement will have a significant beneficial impact on the success of the spot-check program.

GAO RECOMMENDATION 2: Maximize the use of the list of farmers with anomalous claim payments by, for example, ensuring that insurance companies receive the results of all FSA field inspection in a timely manner and directing insurance companies to review the results of all completed FSA field inspections before paying claims that occur after inspections showed the crop was in good condition.

USDA Response: RMA is developing a new system for managing the results of quality control reviews, including spot-check list inspections. The new system will be used by both FSA and AIPs for reporting quality control review results. It will enable more efficient and timely entry of review results. As important, the new system will facilitate the analysis and sharing of review results among RMA, FSA and the AIPs to safeguard program integrity. The FSA component of the new system was recently implemented and is now being used by FSA offices to report the results of their spot-check list inspections. We anticipate testing of the AIP component will begin late summer or early fall of 2013.

GAO RECOMMENDATION 3: Increase the use of the list of agents and adjusters with anomalous losses through actions, such as directing insurance companies, during annual performance evaluations of insurance agents and adjusters, to focus more of their attention on the list of agents and adjusters with anomalous losses.

USDA Response: Beginning with the 2013 reinsurance year, RMA issued new guidance to the AIPs which provided more stringent requirements for training, monitoring and evaluating agents and loss adjusters. The new guidance also contains more extensive reporting requirements for reviews of agents and loss adjusters and remedial actions taken to address performance issues.

GAO RECOMMENDATION 4: Develop a mechanism, such as a revised electronic form, to collect additional data from insurance companies in order to facilitate the use of the companies' reviews in data mining.

USDA Response: RMA is continually looking for ways to streamline the review process in order to gain efficiencies for RMA and AIPs. We have recently begun the development of a new system for AIPs to report the results of all of their quality control reviews, not just the data mining reviews. The new system will include more comprehensive reporting requirements for AIPs and an appropriate database structure to allow efficient analysis of review results. This will facilitate the development of improved internal controls and more rapid identification of program weaknesses. We anticipate testing of the new system will begin in late summer or early fall of 2013.

PL 480, Title II – Administration's Food Aid Proposal

Mr. Aderholt: The President's Budget includes a proposal to transfer funding out of the PL 480, Title II, Food for Peace Program in the Agriculture Appropriation and into three separate accounts at USAID. With such a move, specific changes are proposed such as: (1) at least 55 percent of food and shipping costs will be used for domestic commodities, (2) no monetization of commodities to be used for developmental programs, and (3) a shift of more assistance in the form of local-regional food purchases, use of cash, and/or use of food vouchers.

As noted in the Under Secretary's testimony, USDA's Economic Research Service estimates that for every $1 billion of agricultural exports, an estimated 6,800 jobs are supported and an additional $1.29 billion in economic activity is generated. The way the program is currently structured, it doubles the return on the American taxpayer's investment by supporting jobs and farmers here at home, while still accomplishing the goal of contributing to food security abroad.

With budget reductions in all sectors and millions of Americans struggling to find work, would it be a wiser use of money to maximize our investment at home while also contributing to the needs of those overseas?

Response: The P.L. 480 Title II food aid reform will provide assistance to an estimated two to four million more people annually and food aid will be more timely and cost-effective in emergency situations. Mandatory spending – and the deficit – will be reduced by an estimated $500 million over a decade. The reform will make the best of the constrained funding environment while improving program efficiency.

U.S. commodities will continue to be used in the modified program. In FY 2014, at least 55 percent of the funding transferred from the Title II program will be used to purchase U.S. commodities and freight. The United States has also invested in the development of nutritious foods that meet specific needs of the food aid recipients. These fortified products are processed within the United States and require little or no preparation by the recipients. The Administration expects that these products will be required by U.S. food assistance programs over the long term. The impact of the reform on U.S. agriculture will be small given that Title II commodities currently account for less than two-tenths of one percent of U.S. agricultural production and about one-half of one percent of U.S. agricultural exports.

Mr. Aderholt: How does USDA foresee its role changing in providing international food assistance given the Administration's reform proposal?

Response: USDA will continue to administer the Food for Progress and the McGovern-Dole International Food for Education and Child Nutrition programs. USDA will continue to purchase U.S.-sourced commodities for the McGovern-Dole program, the Food for Progress program, and for a portion of the assistance provided through International Disaster Assistance. Funding for P.L. 480 Title II will be transferred to USAID accounts, where it will provide life-saving assistance to two to four million more people annually. From these USAID accounts, Food Aid will have the flexibility to use the right tool at the right time, making programs more effective, and aid in emergency situations more timely.

Mr. Aderholt: The President's FY 2014 budget proposal shows that USDA would obligate roughly $255 million out of the Commodity Credit Corporation for the Food for Progress program. Does USDA believe that the Department can continue to effectively and efficiently invest $255 million in the Food for Progress program on development projects? If so, why would USDA not recommend that the Administration simply expand this ongoing program at USDA instead of sending an additional $250 million over to USAID for the same purpose under a new program?

Response: Within the constraints of the program's authorization, USDA efficiently and effectively invested FY 2012 funding for the Food for Progress program and can continue to do so. In addition to USDA's program requirements, USDA and USAID worked closely with our in-country offices to strengthen the whole-of-government approach to providing development assistance by concentrating resources in areas of greatest need, as well as areas that yield the highest return on investment. Food for Progress grantees are required to obtain USDA approval for sale tenders and bids, ensuring that grantees use appropriate sales practices and receive prices consistent with reasonable local market prices. USDA maintains a sales performance tracking system that monitors the efficiency of monetization. During FY 2011 and FY 2012, the recovery of procurement and shipping costs increased by 11 percent over the FY 2007 to FY 2009 recovery rate.

Through the provision of U.S. agricultural commodities, Food for Progress assists developing countries and emerging democracies in introducing and expanding private enterprise in the agricultural sector. USAID is the U.S. Government lead on developments, including food security, maternal and child health, agriculture, and resilience issues that have been the focus of P.L. 480 Title II development programs. Under the reform, USAID's office of Food For Peace, which has administered P.L. 480 Title II development programs since 1985, will continue to manage these programs using the more flexible Development Assistance authorities instead of Title II authorities. The intent of the P.L. 480 Title II reform is to enable experts to select the right to most effectively address non-emergency food security needs, rather than limiting the United States to a commodities only approach. While the management of these programs by USAID's Office of Food for Peace will not change, reallocating these funds to these USAID foreign assistance accounts will allow USAID to address the same development goals and issues, through implementing partners that receive Title II, at a much lower cost and with greater effectiveness.

Mr. Aderholt: How much did USDA spend on administrative costs in FY 2012 to carry out PL 480 Title II? What are USDA's estimates for administrative costs if the President's food aid reforms are enacted?

Response: The USDA administrative costs in FY 2012 related to PL 480 Title II were $9.7 million. Given that the proposal is still under consideration for FY 2014, USDA has not completed a full analysis of the changes in administrative costs.

Mr. Aderholt: Please provide a ten year history of like a ten year history of:

1. The cubic tons of cargo shipped every year under Title II.
2. Annual percentage of #1 which is shipped on U.S. vessels.
3. Percentage of total Title II funds that went to purchase U.S. commodities.

Response: Volumes have ranged between 1.5 million metric tons and 3.3 million metric tons. In FY 2012, 80.72 percent of the P.L. 480 Title II volume was shipped on U.S.-flagged ships. The information is submitted for the record.

[The information follows:]

P.L. 480 TITLE II VOLUMES PER YEAR

YEAR	VOLUME (Metric Tons)	% US FLAG*
2012	1,573,539	80.72%
2011	1,473,720	68.13%
2010	2,372,768	86.37%
2009	2,510,419	83.89%
2008	2,351,959	78.74%
2007	1,998,248	83.69%
2006	2,734,025	76.47%
2005	2,853,562	68.72%
2004	2,974,884	74.15%
2003	3,330,503	72.02%

* Percentage is based on tonnage that departed U.S. ports during the fiscal year.

During FY 2003-2012, the cost of commodities during each year represented an average of 41 percent of total funds used to purchase U.S. commodities. The balance of Title II funds were used to support programming of U.S. commodities (e.g. ocean transportation, inland transportation, warehouse storage, etc.) and related sector interventions (e.g. agriculture and nutrition). The following table shows the percentage of funds used for commodities for each year.

[The information follows:]

Actual Usage Per Year

2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
48%	45%	39%	31%	41%	45%	37%	39%	45%	41%

U.S. Agricultural Trade Policy

Mr. Aderholt: Agricultural trade has been one of the few bright spots in the economy. U.S. agricultural exports have achieved record levels by exceeding $478 billion over four years and Ag exports are on track to set a new record this year. Against the backdrop of a very poor economy in the past four years, the Agriculture community can take pride in the positive impact of U.S. agricultural exports. A number of trade experts believe that there is far greater potential for growth of U.S. exports simply because 95 percent of the World's consumers live outside of the United States and the world markets will demand the high quality products produced by U.S. farmers, ranchers, and producers. This is the second year in a row when Congress has

failed to see any new efforts, initiatives or plans by USDA to do more for U.S. agricultural exports.

Just last month, OIG released a report on the matter of Foreign Agricultural Service performance and said that FAS' performance measures were not outcome-based and do not show how the U.S. is performing in a given market compared to its competitors.

Does USDA have a recent comprehensive plan or strategy for competing in the global marketplace against the likes of the Chinese, Brazilians, Europeans, or other countries that focus on increasing greater market share on behalf of their producers? If so, how are you utilizing resources to support this strategy?

Response: Additionally, FAS has a strategic plan for 2012-2016 which outlines the agency's strategy for competing in the global market place. FAS prepares and updates annual country strategies for the 96 countries where USDA has a presence including China, Brazil and the European Union. The country strategies include detailed goals, objectives, and performance measures. They also outline when and how program resources in FAS and throughout the Department are used. These strategies are internal documents that include sensitive information, and are not publicly available due to competition concerns. USDA's strategies for competing in a global marketplace include negotiating new market access through trade agreements and implementing agreements ratified by Congress. Fueled by new trade agreements with Panama, Colombia and South Korea, American agricultural exports are surging - with more than $478 billion in exports over the last four years.

Mr. Aderholt: If the USDA does have a comprehensive plan or strategy for the promotion of U.S. exports, please submit a copy of the document(s) for the record.

Response: The information is submitted for the record. The FAS strategic plan for 2012-2016 outlines the agency's strategy for trade promotion and export expansion and is publicly available on the FAS website at: http://www.fas.usda.gov/FAS_SP2012-2016Final5-16-12.pdf.

Mr. Aderholt: FAS is charged as the lead USDA agency for the U.S. agriculture export strategy. In particular, what did the Agency do differently in fiscal year 2012 or what does it plan to do differently this year, next year and into the future to facilitate agricultural exports?

Response: This year, FAS adjusted strategically to best promote American farmers and ranchers in the global agricultural arena in the face of serious management challenges. We aligned Washington staff under a new strategic plan focusing on 3 core areas of action: Agency decisions were made under a new management structure designed to ensure all expenditures of funds were mission critical and complied with the strategic plan. In this way we were able to keep the 96 overseas offices open and provide top-notch and continued services to American farmers and ranchers. Our agricultural Attaches and Washington-based staff, operating with restricted travel and promotion funds, were focused on the highest priority activities, assisting exporters in getting hundreds of shipments released from ports, resolved technical and sanitary and phyto-sanitary issues, and implementing trade agreements. We focused on new trade agreements under the TransPacific

Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP) and focused our efforts on prioritized trade barriers that we felt had the highest probability of being resolved and offer significant opportunities for increasing exports. In the coming year, we will continue management efforts to focus our limited funding on high priority activities, including negotiations under TTIP, new outreach initiatives to small and medium sized businesses, and expanded efforts in Africa.

Mr. Aderholt: What in particular is USDA doing in fiscal year 2013 or 2014 and beyond to become more active on behalf of U.S. interests overseas and beyond the current technical analysis or assistance provided to producers, manufacturers, and cooperators?

Response: Every day, FAS staff in Washington and around the globe, work tirelessly to advocate for American agricultural interests by breaking down market barriers, identifying market opportunities and reporting on market information in the 163 counties FAS covers. The Administration identified the International Trade Enforcement Committee as a priority, and FAS is an integral part of this initiative. FAS is highly engaged in the TPP,and TTIP negotiations. We are deeply involved in multilateral fora such as the Bali ministerial to ensure agricultural interests are represented. FAS works with other USDA agencies, specifically in the Research, Education and Economics and Natural Resources Management mission areas, to ensure technical assistance is best positioned to benefit U.S. interests overseas.

Mr. Aderholt: USDA's February 2013 Economic Research Service Report on agriculture trade predicts that U.S. agricultural imports will also be at record levels. The report estimates that the agricultural trade balance will be its lowest since 2009. What can USDA attribute this trend to and what attributes may serve as indicators that U.S. producers are losing domestic market share?

Response: The agricultural trade surplus is forecast at $30 billion in FY 2013, which is the fifth largest level ever recorded. This surplus is a significant improvement compared to a few years ago, particularly in 2005 and 2006 when the surplus was under $5 billion.

While exports are forecast to reach a record high in FY 2013, imports are also forecast to reach a record. This is partly due to relatively high global agricultural commodity prices which impact not only U.S. export values but import values as well. Much of the growth in imports over the past several years is focused on products that are not produced in the United States. Rubber, coffee, cocoa, essential oils, and bananas and other tropical products have seen sharp increases in recent years. Many major import products such as bananas and fruits and vegetables are imported on a counter-seasonal basis and do not directly compete with U.S. fruits and vegetables. Imports of other high-value products such as wine, tree nuts and essential oils are also expected to be up.

Import volumes of some products that directly compete with U.S. agricultural products, such as grains and feeds, are expected to increase this year. However, this is primarily due to last year's severe drought, which reduced U.S. supplies. Thus, this year's high imports do not necessarily indicate a permanent loss in U.S. market share. Assuming normal weather conditions this growing season, grain imports should fall in fiscal year 2014. Although

grain and feed imports are forecast at $11.6 billion, this is far below the grain and feed export forecast of $32.8 billion for FY 2013.

Mr. Aderholt: Please provide a detailed description of FAS' Country Strategy Support Fund, examples of activities supported, and funding level for fiscal years 2011 through 2013 to date.

Response: The Country Strategy Support Fund (CSSF) provides funding FAS foreign offices (FAS/F) to carry out activities that support the goals outlined in an office's Country Strategy Statement. Last year, FAS/F in more than 65 countries received CSSF. CSSF is used for activities that support trade policy and market access goals, work to remove non-science-based sanitary/phytosanitary (SPS) or technical barriers to trade (TBT), increase market intelligence, facilitate trade, promote trade capacity building, support strategic communication, and build food security and sustainable agriculture programs.

CSSF activity types and projects include:

- Market access: CSSF is used to address entry issues for U.S. food and agricultural products, opening new sales opportunities. For example, FAS/F may bring foreign government officials to inspect and audit U.S. processing plant facilities. This allows foreign officials to learn about U.S. regulatory standards and see U.S. processes work first-hand. Funds were also used for biotech training and border monitoring.
- SPS barriers and TBT: FAS works to promote science-based standards in foreign markets. Working with U.S. Government technical agencies, FAS trains foreign officials to accurately test for pesticide residue levels in imports, so U.S. products are not rejected based on inaccurate test results. CSSF is also used to translate foreign government technical regulations or for World Trade Organization (WTO) trade notifications.
- Market knowledge/intelligence: FAS/F uses CSSF to purchase trade data, trade journals, or pay other expenses incurred in gathering marketing intelligence. CSSF is used to develop and maintain trade contacts databases and foreign buyer lists. In China, CSSF was used to learn about the food processing industry. This industry is a potential buyer of U.S. agricultural inputs as well as a potential competitor.
- Trade facilitation: CSSF enables face-to-face meetings between foreign buyers and U.S. exporters. This includes funding USDA participation in trade shows, retail promotions, and chef training/recipe contests to show people how to prepare U.S. foods. FAS/F also uses CSSF to pay for staff to accompany foreign importers to the U.S. on buying missions where staff help facilitate one-on-one meetings with U.S. sellers.
- Trade capacity projects provide technical assistance that supports U.S. trade policy objectives by enhancing developing countries' ability to import. For example, FAS/F can conduct an assessment of a host country's cold chain logistics. A market without adequate refrigerated warehouses and transportation limit high value imports. FAS/F supported cold chain training in China, Mexico, and the Philippines in 2012. This supports U.S. exports of chilled and frozen products.
- Strategic communication: CSSF is used by FAS/F to educate government officials, private sector companies, media, or the general public on U.S. trade policy positions to build support and, thereby, enhance acceptance of U.S. agricultural products. Examples include: bringing media teams to the U.S to educate key journalists on U.S. lifestyle, biotech, health and nutrition; and holding seminars across Japan, aimed at consumer groups and consumer media. The topics addressed can encompass a range of food safety

issues, including food additives, biotechnology, and safe handling of foods.
- Food security programs provide funding for projects such as seminars on sustainable agriculture.

The amount of CSSF funding for fiscal years (FY) 2011 to 2013 to date is:
- 2011, $1.5 million;
- 2012, $2.35 million; and
- 2013 to date, $1.5 million.

Non-Tariff Trade Barriers

Mr. Aderholt: The Secretary was quoted last year in saying that the number of non-tariff trade barriers had risen to close to 1,500 in 2011. What was the number of non-tariff trade barriers at the end of 2012 and the current figure for 2013 to date?

Response: WTO Members are obligated to notify changes in sanitary, phytosanitary, and standards related measures that may affect trade, as well as changes in tariff quotas, export subsidies and domestic support commitments. The figure cited by the Secretary refers to the number of WTO SPS, TBT, and Committee on Agriculture (COA) measures reviewed by FAS in 2011. In FY 2012, FAS staff reviewed 1,412 such foreign measures (1,234 of them SPS and TBT measures), and raised 319 related issues (257 of them SPS and TBT) with foreign countries. From October 1, 2012 through March 30, 2013, FAS had reviewed 801 measures (709 SPS and TBT) and raised 116 (84 SPS and TBT) with foreign countries.

Mr. Aderholt: Which top three trading partners account for the most non-tariff trade barriers?

Response: The Office of the U.S. Trade Representative (USTR) Report on Sanitary and Phytosanitary Measures (SPS Report) and the Report on Technical Barriers to Trade (TBT Report) help focus engagement by U.S. agencies, including FAS, in resolving trade concerns related to non-tariff barriers.

The SPS Report describes significant barriers to U.S. food, farm, and ranch exports arising from measures that foreign governments apply on the grounds that such measures are necessary to protect human, animal, or plant life or health. FAS and other agencies learn of issues directly from concerned U.S. businesses and industries, farm and consumer organizations, and other stakeholders. U.S. agencies also rely on an extensive network of U.S. Government (USG) officials stationed around the globe, particularly in embassies that house both State Department and FAS representatives.

In addition, the United States receives formal notifications under WTO procedures when WTO Members are considering making changes to their SPS measures. The United States submits comments to the relevant WTO Member on the potential trade effects or scientific concerns that may arise from the changes it is considering. In 2012 alone, an interagency group coordinated by FAS reviewed 908 SPS notifications by 50 WTO Members and provided comments to these trading partners on 119 proposed or in-force SPS measures. The three leading recipients of U.S. Government comments included the Republic of Korea, the European Union, and China.

The TBT report focuses on significant foreign trade barriers in the form of product standards, technical regulations and testing, certification, and other procedures involved in determining whether products conform to standards and technical regulations and actions the United States is taking to address these barriers. Russia, Indonesia, and Vietnam are the main countries against which the USG has been raising TBT issues in the framework of the WTO TBT Committee.

Mr. Aderholt: Which top three trading partners account for the greatest market loss in terms of dollars as a result of their non-tariff trade barriers?

Response: Neither the USTR's Report on Sanitary and Phytosanitary Measures (SPS Report) nor the Report on Technical Barriers to Trade (TBT Report) specify market losses. However, they do highlight trends which have the potential to negatively affect trade and pose significant market losses for the United States. The leading cross-cutting SPS barriers arise in connection with export certification requirements, agricultural biotechnology, bovine spongiform encephalopathy (BSE), avian influenza (AI), and maximum residue levels (MRLs) for pesticides.

Similarly the TBT Report highlights trends which have the potential to negatively affect trade and pose significant market loss for the United States. Chile and Peru are important in this regard because of their stringent nutritional labeling requirements for processed foods high in fats, sugar, sodium, and trans-fats content. Additionally, Peru maintains mandatory labeling and a moratorium on foods derived from genetic engineering. Turkey and India are also highlighted in the TBT Report for their trade restrictive measures on genetically engineered products.

Mr. Aderholt: What is the current process for USDA to resolve a non-tariff trade barrier?

Response: FAS strives to prevent trade barriers by providing technical assistance to foreign governments in the development of science-based regulatory systems, and the operation of WTO Enquiry Points for notifying trading partners of measures that could affect trade. FAS employs its worldwide network of attachés, its frequent communication with private sector stakeholders, and formal WTO notification procedures to monitor foreign trade and regulatory actions before they affect trade. FAS submits WTO comments to challenge proposed SPS and TBT measures that are unnecessarily trade restrictive, and raises issues at the WTO Committees on Agriculture, SPS and TBT. When trade restrictions occur, USDA, in collaboration with other agencies such as the Office of the U.S. Trade Representative, engages bilaterally with its technical counterparts in the other country, and multilaterally through standard setting international organizations and the WTO to reach transparent, science-based solutions. When these efforts fail to resolve an issue, a case may be brought before a WTO dispute panel.

Mr. Aderholt: How is FAS notified of non-tariff trade barriers and what steps does the Agency take to resolve unfair agricultural trade practices in foreign countries?

Response: WTO Members are obligated to notify changes in sanitary, phytosanitary, and standards related measures that may affect trade, as well

as changes in tariff quotas, export subsidies and domestic support commitments to WTO Enquiry Points within the U.S. Government. USDA houses the U.S. WTO SPS and COA Enquiry Points, while the National Institute of Standards and Technology houses the TBT Inquiry Point and Notification Authority.

As with non-tariff trade barriers, FAS seeks first to prevent unfair agricultural trade practices in foreign countries. FAS trains foreign governments in the development of science-based regulatory systems, and the operation of WTO Enquiry Points for notifying trading partners of measures that could affect trade. FAS employs its worldwide network of attachés, its frequent communication with private sector stakeholders, and formal WTO notification procedures to monitor foreign trade and regulatory actions before they affect trade. FAS submits WTO comments to challenge measures that are unnecessarily trade restrictive or noncompliant with WTO obligations, and raises issues at the WTO Committee on Agriculture. USDA, in collaboration with other agencies such as the Office of the U.S. Trade Representative, engages bilaterally to address unfair trade practices when they occur, and multilaterally through the WTO. When these efforts fail to resolve an issue, a case may be brought before a WTO dispute panel.

Mr. Aderholt: What steps does FAS take proactively to reduce agricultural trade barriers?

Response: FAS trains foreign governments in the development of science-based regulatory systems, and the operation of WTO Enquiry Points for notifying trading partners of measures that could affect trade. FAS employs its worldwide network of attachés to monitor governments' domestic policy changes for trade impacts, to engage frequently with private sector stakeholders, to stay abreast of changes affecting their trade and tracks formal WTO notification procedures to monitor foreign trade and regulatory actions before they affect trade. FAS submits WTO comments to challenge proposed SPS and TBT measures that are unnecessarily trade restrictive, and raises issues at the WTO Committees on Agriculture, SPS and TBT.

Mr. Aderholt: Is USDA increasing or decreasing funding for any activities in support of this effort to reduce non-tariff trade barriers? What is the impact of any such changes to resources?

Response: The USDA budget for activities aimed at reducing non-tariff trade barriers has remained nearly steady since FY 2011, although staff numbers have declined. A small budget increase has been requested for FY 2014 in order to maintain current staffing.

Agricultural Trade Data

Mr. Aderholt: Please provide the Subcommittee with a list of the top ten agricultural exported and imported products for fiscal years 2008 through 2012 and estimated for 2013 by volume and dollars.

Response: The information is submitted for the record.

[The information follows:]

Top 10 U.S. Agricultural Exports: Value by Commodity,
FY 2008-2012 & Forecast 2013
($ in billions)

Commodity	2008	2009	2010	2011	2012	2013
VALUE						
Soybeans	$14.516	$13.815	$16.889	$20.332	$19.797	$22.2
Wheat	12.332	5.997	5.855	11.494	8.353	10.2
Corn	13.999	9.279	9.070	12.901	11.240	7.8
Fruits and vegetables, fresh	5.508	5.414	5.869	6.643	6.996	7.6
Feeds and fodders	4.821	9.982	9.818	13.987	6.900	7.5
Fruits and vegetables, processed	5.369	5.379	5.608	6.309	6.840	7.4
Tree nuts, whole and processed	3.487	3.495	4.062	5.147	6.106	7.0
Poultry and products	4.929	4.842	4.615	5.481	6.157	6.3
Pork	3.913	3.627	3.927	4.904	5.552	5.4
Beef and veal	2.683	2.688	3.220	4.555	4.770	5.0

Top 10 U.S. Agricultural Exports: Volume by Commodity,
FY 2008-2012 & Forecast 2013
(Millions metric tons)

Commodity	2008	2009	2010	2011	2012	2013
VOLUME*						
Soybeans	30.784	34.947	41.588	40.290	38.397	36.6
Wheat	32.847	22.545	25.762	34.525	26.903	28.6
Corn	60.593	47.658	49.668	45.191	38.370	24.0
Feeds and fodders	14.475	13.830	18.849	18.889	17.540	16.6
Soybean meal	8.384	7.708	10.124	8.238	8.837	8.0
Rice	3.909	3.398	4.272	3.951	3.603	3.7
Broiler meat	3.107	3.107	2.957	3.196	3.299	3.3
Cotton	2.957	2.737	2.680	3.014	2.716	2.7
Pork	1.525	1.382	1.428	1.644	1.837	1.8
Soybean oil	1.321	0.995	1.523	1.466	0.664	1.0

* Includes only products measured in metric tons.

Top 10 U.S. Agricultural Imports by Value
FY 2008-2012 & Forecast 2013
($ in billions)

Commodity	2008	2009	2010	2011	2012	2013
VALUE						
Fruits, fresh	$5.544	$6.074	$6.792	$7.125	$7.618	$8.4
Coffee beans & products	4.349	4.148	4.389	7.337	7.789	7.4
Grain products	4.603	4.521	4.885	5.384	5.749	6.2
Vegetables, fresh	4.441	4.237	5.181	5.722	5.831	6.0
Wine	4.753	4.084	4.258	4.777	5.084	5.7
Fruits, processed	3.981	3.375	3.276	4.263	4.358	5.7
Vegetable oils	4.600	3.748	3.784	5.589	5.759	5.6
Vegetables, processed	3.520	3.483	3.573	3.915	4.202	4.5
Cocoa and chocolate	3.046	3.300	4.239	4.633	4.117	4.5
Beef and Veal	2.965	2.934	2.851	3.015	3.623	4.1

Top 10 U.S. Agricultural Imports by Volume
FY 2008-2012 & Forecast 2013
(Million Metric Tons)

Commodity	2008	2009	2010	2011	2012	2013
VOLUME						
Fruits, fresh	8.668	8.478	9.101	9.266	9.599	10.5
Vegetables, fresh	4.596	4.559	5.378	5.513	5.696	5.9
Swine	10.134	6.976	5.805	5.703	5.779	5.5
Vegetable oils	3.255	3.339	3.456	3.746	3.976	4.0
Fruit juices	4.935	4.399	4.163	4.407	3.591	4.0
Vegetables, processed	3.015	2.937	2.925	3.026	3.202	3.4
Malt beer	3.389	3.121	3.112	3.159	3.287	3.3
Cattle and calves	2.563	2.040	2.251	2.146	2.331	2.0
Fruits, processed	1.447	1.364	1.408	1.481	1.502	1.8
Wine	0.835	0.933	0.972	1.002	1.202	1.3

Mr. Aderholt: Please provide the Subcommittee with a list of the top ten agricultural export and import countries for fiscal years 2008 through 2012 and estimated 2013 by volume and dollars.

Response: Data below is presented on a value basis only. No data is available for total agricultural exports and imports to countries by volume. Data is available for specific commodities but not for agricultural products as a group. This is due to the fact that many volume categories comprise the agricultural total group and cannot be aggregated because of the different units of measurement such as metric tons, gallons, and counts. The information is submitted for the record.

[The information follows:]

U.S Agricultural Exports
Value by Country
FY 2008-2012 and FY 2013 Forecast
($ in billions)

	2008	2009	2010	2011	2012	2013
COUNTRY						
China	$11.170	$11.073	$15.002	$19.875	$23.359	$22.0
Canada	16.257	15.541	16.597	18.617	20.008	21.0
Mexico	15.186	13.325	13.936	17.643	18.890	18.5
Japan	13.061	11.182	11.206	13.937	13.770	13.5
European Union-27	10.66	7.611	8.512	10.254	8.872	10.2
South Korea	5.552	3.821	4.992	6.754	6.203	6.3
Taiwan	3.509	2.889	3.175	3.609	3.093	3.6
Hong Kong	1.598	1.737	2.460	3.225	3.381	3.3
Indonesia	2.205	1.667	2.130	2.989	2.470	2.5
Philippines	1.73	1.247	1.606	2.014	2.304	2.4

U.S Agricultural Exports
Value by Region
FY 2008-2012 and FY 2013 Forecast
($ in billions)

	2008	2009	2010	2011	2012	2013
REGION						
Canada	$17.936	$15.354	$15.682	$17.946	$19.989	$22.0
Mexico	10.761	11.248	12.972	15.427	16.278	18.0
India	1.533	1.319	1.498	2.251	5.393	5.6
China	3.426	2.915	3.208	3.916	4.348	5.2
Brazil	2.598	2.551	2.644	3.458	3.791	4.0
Indonesia	2.669	1.999	2.631	3.954	3.666	3.8
Australia	2.404	2.442	2.319	2.360	2.557	3.1
Chile	1.961	2.135	2.274	2.324	2.499	2.7
New Zealand	1.74	1.779	1.624	1.925	2.172	2.6
Thailand	1.831	1.594	1.917	2.574	2.459	2.6

Free Trade Agreements

Mr. Aderholt: Please provide a summary of the current status of the Trans-Pacific Trade Agreement. What role has USDA taken in these negotiations on behalf of U.S. agricultural exports?

Response: The United States continues to negotiate the Trans-Pacific Partnership (TPP) with Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam. On April 24, 2013, USTR notified Congress of its intent to negotiate with Japan, beginning the 90-day domestic consultation period, which must be concluded before Japan can join the negotiations. Stakeholders may submit comments regarding Japan's participation in the TPP through the Federal Register through June 9. The seventeenth TPP round is taking place in Lima, Peru, May 15-24. Additional rounds are scheduled for July and September 2013 with an aim to finish the negotiations by October 2013.

From the beginning of TPP negotiations, USDA negotiators have been actively involved in aspects of the negotiations related to agriculture including market access, rules of origin, sanitary and phytosanitary measures, technical barriers to trade, regulatory coherence, competition, and trade capacity building. USDA's goal, with guidance from the U.S. industry, Congress, and other stakeholders, is to create a TPP Agreement that increases U.S. agricultural exports and supports U.S. jobs by addressing tariff and non-tariff barriers.

Mr. Aderholt: Please provide a summary of the current status of the Transatlantic Partnership Agreement. What role has USDA taken in these negotiations on behalf of U.S. agricultural exports?

Response: On March 20, 2013 the Administration notified Congress of our intent to enter into negotiations with the European Union on a Transatlantic Trade and Investment Partnership (TTIP). We are currently conducting consultations with Congress and the public to help determine our objectives and priorities for these negotiations. A Federal Register Notice requesting public comment on priorities and issues for the negotiations was published on April 1, 2013. We are now evaluating the comments submitted in response to that Notice. USDA has been very active in the preparatory work for these negotiations, developing summaries of agricultural issues for consideration by the interagency team to help develop priorities and negotiating strategies and gathering information on the issues being discussed in Europe through our Agricultural officers stationed overseas.

Mr. Aderholt: Please provide a status of the three free trade agreements with Korea, Colombia and Panama, including whether or not U.S. agriculture exports can demonstrate progress in those three countries as a result of the agreements.

Response: The U.S-Korea Free Trade Agreement (KORUS), the U.S.-Colombia and U.S.-Panama Trade Promotion Agreements (TPA) entered into force in March, May, and October 2012, respectively. Not only did U.S. agricultural exports to those countries reach $7.6 billion in FY 2012, but agricultural exports to the three countries supported over 51,600 American jobs in FY 2012.

Although these agreements are still new, U.S. exporters have seen gains in a wide range of products, ranging from bulk commodities (e.g., soybeans and wheat) to specialty crops.

Korea: U.S. agricultural exports to Korea exceeded $6 billion in FY 2012, making it our sixth largest market. Under KORUS, tariffs for two-thirds of current trade by value were immediately eliminated, increasing opportunities for a range of products including soybeans, cherries, pistachios, almonds, wine and orange juice. Many U.S. agricultural exports experienced large gains, including soybeans and soybean meal, tree nuts and fresh fruit.

Colombia: U.S. agricultural exports to Colombia topped $1 billion in FY 2012, and were 46 percent higher in May-March 2013 after the Colombia TPA went into force than for the same time period a year earlier, totaling over $1.2 billion. Specific products that have benefited include soybeans, dairy, rice, and poultry. Currently, under the U.S.-Colombia TPA, tariffs on 77 percent of all agricultural tariff lines are duty free.

Panama: U.S. agricultural exports to Panama reached almost $490 million in 2012. Currently 68 percent of tariff lines are duty free. Products that have gained include corn, rice, and chicken leg quarters.

In addition to closely monitoring the full implementation of the agreements FAS participates with USTR in regular meetings with all three trading partners. For example, a KORUS SPS meeting occurred in Washington on February 19, 2013. FAS staff regularly provide technical assistance to Colombian and Panamanian government officials in TRQ administration which has resulted in smooth TRQ implementation.

Mr. Aderholt: What resources will be devoted to support these agreements in fiscal years 2013 and 2014?

Response: FAS is USDA's lead agency to ensure trade agreements are implemented and enforced per the text of the specific agreements. FAS staff who were actively involved in negotiating these agreements were redeployed to implement the agreements (KORUS and Colombia TPA in FY 2012 and Panama TPA in FY 2013) and are now monitoring and enforcing them. This has been possible with existing resources, including drawing on our Foreign Service officers and staff in the relevant overseas posts. As with the previous year, FAS is considering proposals to provide additional support in-country to address new requirements in the most cost-effective manner. In addition, the $200 million available for the Market Access Program (MAP) provides support for the market development efforts of over 70 industry group partners known as Cooperators. The vast majority of Cooperators are using some MAP funds for activities to advance implementation of the three FTAs, considered critical to their overall market development strategies.

McGovern-Dole International Food for Education and Child Nutrition

Mr. Aderholt: Please provide the Subcommittee with an update on what USDA is doing to address concerns about the McGovern-Dole Food for Education program raised by the Government Accountability Office last year. Has USDA changed its oversight of the non-profits implementing the programs?

Response: USDA is committed to ensuring a strong culture of monitoring and evaluation within its McGovern-Dole Program oversight. USDA is using its

Monitoring and Evaluation Policy (MEP) to guide the integration and implementation of monitoring and evaluations systems into the McGovern-Dole Program. All FY 2012 and FY 2013 McGovern-Dole agreements have a Monitoring and Evaluation Plan that complies with the MEP.

USDA established a Monitoring and Evaluation Unit which is responsible for managing and providing technical assistance in performance management and evaluation of FAS programs, including food assistance programs.

USDA is using its Food Aid Information System (FAIS) to help manage and administer its food aid programs and interact with its strategic food aid partners, both within and outside the U.S. Government. FAIS has allowed USDA to track grantees' compliance with the grant agreements and improved operational efficiency, planning and coordination, analysis of effectiveness, and performance measurements. USDA continues to improve on the timeliness of the closeouts of the grants and the completion of final evaluations for each project.

Mr. Aderholt: Has USDA done anything to change performance goals for the McGovern-Dole program? If so, please explain.

Response: FAS is managing the McGovern-Dole Program by focusing on two high-level performance goals: 1) improved literacy of school-age children, and 2) increased use of health and dietary practices. The goals are part of a comprehensive results-oriented management (ROM) system begun in the FY 2012 solicitation cycle. The frameworks and the practices that lead to these goals are fully explained on the FAS website. FAS's adoption of the results-based approach is strengthening the delivery of more efficient and effective food assistance programs through a greater focus on results and accountability of taxpayer resources. This approach also provides a platform for more meaningful program evaluations and opportunities to learn which interventions work well and which ones do not.

Through this ROM system and associated initiatives, USDA expects to improve its ability to measure the impact of the McGovern-Dole Program by: 1) clarifying program strategy; 2) identifying expected results; 3) linking measurable indicators to results; and 4) mapping program objectives and results back to the Agency's strategic plan. In turn, implementing partners are expected to identify project results and report achievements of the identified results. These organizations must report twice a year as well as have a midterm and final evaluation performed.

As part of the ROM process, USDA developed program result frameworks for these goals and measurable indicators, which it shared with stakeholders. The frameworks are key tools in communicating the intent of USDA's food assistance programs both internally and externally. Food assistance program results frameworks are also used in support of the "whole-of-government" effort to coordinate across USG agencies to focus on results rather than process and activities. In addition to standard McGovern-Dole Program indicators, all implementing partners need to report on specific indicators that contribute to the Administration's Feed the Future initiative, if applicable to the project. In addition to the program and Feed the Future indicators, implementing partners may also develop custom indicators specific to their projects.

Mr. Aderholt: In fiscal years 2011 and 2012, what percentage of total resources went towards commodity expenses and what percentage went towards program implementation and administrative expenses? Has USDA determined whether or not this ratio meets the needs of the program or has the Department determined that there should be more commodity purchase and less program implementation or vice versa?

Response: The McGovern-Dole Program focuses on improving the literacy of school-aged children and increasing the use of health and dietary practices. In order to achieve these two objectives, USDA provides donations of agricultural commodities as well as financial assistance to program participants. The funds provided assist participants with the administration and implementation of program activities such as school feeding, local capacity building, infrastructure improvements, school gardens, and teacher training.

The ratio of funds used to cover the cost of commodities and freight to those funds used to administer and implement the program varies largely due to the types of commodities purchased, destination country, the operating environment of the country, and the type of program activities. Activity costs tend to rise and commodity costs generally fall as projects move towards graduation and a turnover of the project to the recipient country's government or community. In these later stages, a larger share of funding is required to provide the final technical assistance for continuing the program. The recipient countries are often providing their resources for at least a portion of the food.

In FY 2011, approximately 40 percent of the total McGovern-Dole funds were used to purchase commodities, 20 percent were used for transportation costs, and 40 percent were used to administer and implement project activities in the recipient country. In FY 2012, approximately 29 percent of the total McGovern-Dole funds were used to purchase commodities, 14 percent were used for transportation costs, and 58 percent were used to administer and implement project activities in the recipient country. Several projects in FY 2012 required a larger share of funding for technical assistance and other non-food expenses to prepare for or complete the graduation of the projects. These funding needs increased the percentage of funds for administration and implementation of project activities.

In each fiscal year, USDA reviews awards and determines that the mix of funding allocated for commodities, freight, and administrative and implementation costs is the best use of program funding to meet the needs of the program.

Climate Change

Mr. Aderholt: How much does FAS plan to spend on climate change activities in fiscal years 2013 and 2014 and how much did it spend in fiscal year 2012?

Response: FAS expenditures on climate change activities totaled $219 thousand in FY 2012, and the agency expects to spend $210 thousand per year in fiscal years 2013 and 2014. These figures include salary and travel expenses necessary to support multilateral negotiations and other bilateral and plurilateral activities related to climate change.

Trade with China and Brazil

Mr. Aderholt: The economic potential related to the strategic trade relationship with China yields significant volume and revenue for U.S. exporters, but what is USDA and the other domestic trade agencies doing to monitor Chinese trade practices to ensure a level playing field?

Response: USDA contributes to the Office of the U.S. Trade Representative's (USTR) annual China WTO Compliance Report (among other reports), a tracking tool used by the entire interagency. USDA participates in the annual bilateral U.S.-China Joint Commission on Commerce and Trade (JCCT) mid-year review with USTR, the Department of Commerce (DOC), and our Chinese counterparts, where progress on prior commitments is discussed. USDA also participates in annual U.S.-China Strategic and Economic Dialogue (S&ED) planning meetings with interagency and bilateral counterparts, where progress on prior commitments is discussed as well.

There are obvious trade issues with China, which USDA raises at every bilateral opportunity. Of particular concern is China's continued ban on U.S. beef, its import suspensions on several states due to low pathogenic avian influenza, and its asynchronous review of biotech products, which unnecessarily delays product approval. Our senior principals are engaging with their counterparts to address these issues, Secretary Vilsack has raised these issues with his counterparts at the Ministry of Agriculture and General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) in Washington, DC at the December, 2012 U.S.-China Joint Commission on Commerce and Trade meeting and Under Secretary Scuse has engaged the Chinese at the March, 2012 agricultural trade mission to China. Our strategy is to advocate for China's adoption of science-based standards and encourage the Chinese to see the benefits of trade across the entire agricultural trade portfolio, and not on individual products.

As you are aware, the United States brought an antidumping and countervailing duties (AD/CVD) dispute against China's duties imposed on U.S. broiler products. We can confirm that a WTO panel issued its draft interim report on the U.S. challenge to China's imposition of anti-dumping and countervailing duties on U.S. broiler products. Because the interim report is confidential, we cannot publicly comment on the report. USTR has already consulted with congressional committees regarding the interim report and will continue to keep them apprised.

USDA works very closely with USTR on potential trade violations affecting U.S. agriculture. We have a shared commitment to ensure that our trading partners adhere to the WTO and other trade agreements. We seek to address issues through negotiation when possible and litigation where appropriate. The Administration continues to make clear to our trading partners that we will fight to support each job here at home affected by unfair restrictions abroad. President Obama established a new trade enforcement unit - the Interagency Trade Enforcement Center (ITEC) - specifically to enhance the administration's capabilities to prioritize and aggressively challenge unfair trade practices around the world. USDA supports this effort and has provided detailees. The Administration will continue to analyze and address foreign barriers that affect U.S. agricultural products.

To get beyond seemingly intractable issues, USDA successfully proposed and implemented the first U.S.-China Agricultural Symposium, held in February,

2012. The Symposium underscored the depth of our bilateral agricultural trade relationship and established a partnership around trade and cooperation with China to create a more open, secure market for U.S. exports. At the Symposium, we signed a 5-Year Plan of Strategic Cooperation to codify our interest in a cooperative approach to issues of mutual concern. We are seeing immediate effects of this warming relationship, with the Chinese agreeing to a pilot program for expediting the review of biotech product applications. In addition, USDA and other agencies continue to be fully engaged on market access issues in various fora, including the WTO and related international standard setting bodies.

Mr. Aderholt: As the U.S. ramps up exports to Asia, is USDA increasing its staff footprint in the country and the region? If not, why not?

Response: USDA/FAS has increased its staffing footprint in Asia. FAS conducts an annual rightsizing exercise to align the number and location of staff assigned overseas with foreign policy priorities, security, and budgetary constraints. Staffing was reduced in more mature markets and moved to growing export markets such as Asia over the past decade.

Mr. Aderholt: What is USDA doing to address the ever growing body of evidence that Brazil's subsidies to its farmers, ranchers, and producers is negatively impacting U.S. exports?

Response: Additionally, FAS Attaches in Brazil monitor and report on agricultural policies of the Brazilian government. USDA works closely with USTR on potential trade violations by our trading partners, including Brazil, that adversely affect U.S. agricultural products. We have a shared objective of ensuring that our trading partners adhere to their commitments under the WTO and other trade agreements. We seek to address issues through multilateral fora such as the WTO Committee on Agriculture and through negotiation when possible and litigation where appropriate. The Administration continues to make clear to our trading partners that we will fight to support jobs here at home affected by unfair practices abroad. In 2012, President Obama established a new trade enforcement unit, Interagency Trade Enforcement Center (ITEC), to enhance the Administration's capabilities to aggressively challenge unfair trade practices around the world. USDA supports this effort and has provided detailees to ITEC. The Administration will continue to analyze and address barriers to U.S. agricultural exports and will challenge such actions when warranted.

Agricultural Policy Advisory Committee (APAC)

Mr. Aderholt: Please provide the Subcommittee with a summary of activities for the Department's involvement with the 35 member Agricultural Policy Advisory Committee (APAC) and the six Agricultural Technical Advisory Committees (ATACs), including all meeting dates, agenda items, and total resources for both fiscal years 2012 and 2013 to date.

Response: The meetings of the APAC and ATAC committees from FY 2012 to the present are summarized in the following table. The information is submitted for the record.

[The information follows:]

FY 2012	
DATE	TOPIC DISCUSSED
12/6/2011	MEETING - All Committees - Orientation for new members - Annual ethics training - TPP negotiations - TPP negotiations - Implementation of the Korea, Colombia, and Panama FTAs - Farm Bill update - WTO Ministerial - Russian accession to the WTO - Food Safety Modernization Act - WTO dispute settlement cases.
2/27/2012	CONFERENCE CALL - Processed Foods ATAC - Bilateral and multilateral issues to be discussed at the WTO committees on Sanitary and Phytosanitary Measures and Technical Barriers to Trade - TPP negotiations - Bilateral market access issues for processed products - Food Safety Modernization Act
3/6/2012	CONFERENCE CALL - Fruits & Vegetables ATAC - Bilateral and multilateral issues to be discussed at the WTO committees on Sanitary and Phytosanitary Measures and - Technical Barriers to Trade - TPP negotiations - Bilateral market access issues for fruits and vegetables - Food Safety Modernization Act
4/4/2012	MEETING - All Committees - Use of USTR's secure advisors website - TPP negotiations - USTR's new Trade Enforcement Center - FTA implementation - U.S.-EU High Level Working Group - Updates on WTO dispute settlement cases

FY 2012	
DATE	TOPIC DISCUSSED
4/27/2012	CONFERENCE CALL - Animals & Animal Products ATAC - U.S. Bovine spongiform encephalopathy (BSE) case
5/31/2012	CONFERENCE CALL - Processed Foods ATAC - Presentation on FAS Budget - Processed Foods Reporting and Analysis - Prioritization of Issues for Future Processed Food ATAC calls
7/24/2012	CONFERENCE CALL - All Committees - Trans-Pacific Partnership Trade Agreement Negotiations - WTO committees on Sanitary and Phytosanitary Measures and Technical Barriers to Trade - Bilateral market access issues for U.S. agricultural commodities
8/23/2012	CONFERENCE CALL - All Committees - Implementation of Panama's Agricultural Tariff Rate Quotas (TRQs)
9/25/2012	CONFERENCE CALL - All Committees - Update on 14th Round of Trans-Pacific Partnership Trade Agreement (TPP) Negotiations held in Leesburg, VA -WTO committees on Sanitary and Phytosanitary Measures and Technical Barriers to Trade - Bilateral market access issues for U.S. agricultural commodities

FY 2013	
DATE	TOPIC DISCUSSED
11/29/2012	- Orientation for new members - Annual ethics training - Enforcement of Trade Agreements - Updates on Korea, Colombia and Panama FTAs - Overview of Database on Foreign SPS and TBT Measures
12/4/2012	MEETING - Fruits and Vegetables ATAC - Update on TPP Negotiations (SPS Issues) - Update on Indonesia Market Access - Update on Food Safety Modernization Act (FSMA) - Technical Assistance for Specialty Crops (TASC) Update
1/31/2013	CONFERENCE CALL - All Committees - Sanitary and Phytosanitary (SPS) Chapter in the Trans-Pacific Partnership trade agreement negotiations
2/6/2013	CONFERENCE CALL - All Committees - Sanitary and Phytosanitary (SPS) Chapter in the Trans-Pacific Partnership trade agreement negotiations
2/14/2013	CONFERENCE CALL - APAC - Trans-Pacific Partnership (SPS/Cooperative Technical Consultations (CTC)
2/22/2013	CONFERENCE CALL - Grains, Feed, Oilseeds and Planting Seeds ATAC - Trans-Pacific Partnership (SPS/Cooperative Technical Consultations (CTC)
3/21/2013	CONFERENCE CALL - APAC, Animals ATAC, Processed Products ATAC - Consultations on USDA-issued Proposed Rule: Country of Origin Labeling (COOL) Program
3/22/2013	CONFERENCE CALL - Fruits and Vegetables ATAC - Trans-Pacific Partnership (SPS/Cooperative Technical Consultations (CTC)

Mr. Aderholt: Please provide a summary of accomplishments by APAC over the past two years.

Response: The APAC has provided crucial advice on topics such as: U.S. strategy for the WTO Doha Round negotiations; priorities for implementation of the free trade agreements with Korea, Colombia and Panama; objectives for the TPP negotiations; objectives for the negotiations with Russia on its accession to the WTO; objectives for the TTIP; and advice regarding the new Interagency Trade Enforcement Center and proposals for a new consolidated trade agency.

The APAC's advice and input on the negotiations and issues mentioned above is an important factor in USDA and USTR deliberations on U.S. trade policy. Two specific examples demonstrate the importance of these issues for U.S. agriculture.

As recommended by the APAC, implementing legislation for the Korea, Colombia, and Panama Trade Promotion Agreements was presented to Congress in the fall of 2011 and signed into law on October 21, 2011. These agreements eliminate tariffs on U.S. exports and are expected to expand U.S. agricultural exports by over $1.3 billion. The agreements entered into force on March 15, 2012 for Korea; May 15, 2012 for Colombia; and October 1, 2012 for Panama.

The APAC's advice was also an important factor in establishing the recommendations for the U.S.-EU High Level Working Group that recommended launching the TTIP. APAC's recommendation that any agreement must be comprehensive and deal with regulatory and non-tariff barriers as well as tariffs was incorporated into the final recommendations of the Working Group that was issued on February 11, 2013.

Food Aid and Long-term Approach to Local Sustainability

Mr. Aderholt: Please explain what USDA's long-term plans are for international food assistance. In particular, what is USDA or its sister agencies plan to increase agricultural sustainability in these under-developed countries through Food for Progress or any other programs?

Response: The primary goal for USDA's food aid programs is to ensure that activities administered through our food aid programs contribute toward sustainability and reduce the need for additional food aid over the long-term. For example, under the Food for Progress program, USDA uses proceeds of monetized commodities to support initiatives that increase rural incomes and enhance food security by improving agricultural productivity, supporting agribusiness development and expanding the availability of financial services. Under the McGovern-Dole program, our focus is to support education, child development and food security for many of the world's poorest children, with the aim of establishing programs that work toward sustainability. The sustainability of the McGovern-Dole program depends upon the respective government's willingness to assume responsibility for managing school feeding/education programs. To accomplish these goals, USDA leverages its food aid programs with other development-related activities to promote the establishment of market-driven institutions and policies, strengthen the private sector, and foster human capital development. USDA's food aid programs are also tied to the principles and strategies of the Administration's Feed the Future Initiative. Through this process and through coordination with others such as USAID, USDA ensures that food aid

programs are aligned with broader initiatives and are consistent with the country-based investment plans.

Market Access Program and the Foreign Market Development Program

Mr. Aderholt: FAS manages the $200 million program called Market Access Program designed to promote and market U.S. goods to foreign countries or regions for small and medium sized companies.

Please inform the Subcommittee of what controls are in place to make sure that this program is serving those cooperators that really need it. What process does FAS have in place to verify plans for each cooperator?

Response: Under the MAP, USDA's, Commodity Credit Corporation (CCC) enters into agreements with nonprofit trade organizations to share the costs of certain overseas marketing and promotion activities that are intended to develop, maintain or expand commercial export markets for U.S. agricultural commodities and products.

Nonprofit associations, nonprofit state regional trade groups, U.S. agricultural cooperatives and State agencies are eligible to participate in the MAP. MAP participants may implement generic and branded programs. Branded program participation is limited to small sized entity, for-profit firms. As required by statute, MAP funding is not provided directly or indirectly to large companies.

MAP participants with branded programs solicit small company applications and carefully review and verify company legitimacy and past performance. These small companies are reimbursed 50 percent of authorized expenditures and are limited to five years of activity in any one market. MAP participants and the companies certify that MAP funds supplement and do not supplant their funding. All MAP participants undergo audits conducted by FAS to verify that the organizations are in compliance with the regulations governing the use of program funds.

Mr. Aderholt: Please list any cases and summarize the circumstances of fraud, waste or abuse associated with MAP or FMD grants over the past three years.

Response: Instances of fraud, waste, or abuse associated with MAP or FMD are rare. Both programs generally operate on a reimbursable basis. This provides a significant measure of funds control since program payments are not released until after an allowed expenditure already has been made. The online reimbursement process is highly automated, with secure access features and records of all transactions that make fraud, waste, or abuse more difficult to accomplish. In addition, all program expenditures regularly undergo physical on-site reviews by FAS's compliance staff, and most program participants are subject to annual audits in accordance with the Office of Management and Budget's Circular A-133. Both MAP and FMD are audited annually as part of the CCC Financial Statements and neither program has any history of improper payments.

Nevertheless, FAS does have occasion to refer cases to the USDA OIG for criminal action, and sometimes OIG makes a further referral to DOJ for prosecution. There have been two such instances in the past three years:

In September 2012, a small business owner was convicted of wire fraud and sentenced to one year in prison followed by 3 years of supervised release, 6 months of home confinement, and 500 hours of community service. He also was ordered to pay $342,500 in restitution to the CCC, all for filing a series of false claims for MAP reimbursement through a State Regional Trade Group that participated in the program and recognized and reported the fraud.

In January 2012, FAS made a full recovery through agency administrative action of $11,940 from an individual who submitted false claims for MAP reimbursement related to travel undertaken on behalf of a program participant.

FAS maintains a close dialogue with program participants and constant monitoring of program activities on nearly a daily basis to ensure that participants are following the regulations in planning and conducting activities. The active oversight of these partnership programs by FAS marketing specialists in Washington and attachés in the field goes a long way in preventing instances of fraud, waste, or abuse associated with MAP or FMD.

Mr. Aderholt: Please inform the Subcommittee of the funds obligated under the Foreign Market Development Program from fiscal years 2009 to estimated 2013 and estimated 2014. Provide a description of recent success with this program, including any specific metrics.

Response: The table below identifies Foreign Market Development Program (FMD) obligations made between 2009 and 2013, to date. The program has not been authorized for 2014. The information is submitted for the record.

[The information follows:]

Participant	2009	2010	2011	2012	2013*
Almond Board of California	0	0	0	$337,501	$240,825
American Hardwood, Plywood, Softwood, and SFPA	$3,336,252	$3,530,482	$3,001,753	3,036,394	2,787,327
American Peanut Council	634,050	737,985	674,759	691,019	507,562
American Seed Trade Association	228,499	228,073	235,592	231,854	203,333
American Sheep Industry Association	158,091	183,479	173,194	177,526	131,810
American Soybean Association	6,653,799	7,273,160	7,135,883	6,320,709	4,145,418
Cotton Council International	4,187,329	5,052,334	4,864,937	4,815,519	3,529,886
Cranberry Marketing Committee	0	0	0	225,000	160,550
Leather Industries of America	140,165	162,157	164,147	180,069	190,149
Mohair Council of America	0	15,768	9,454	18,288	0
National Hay Association	56,625	78,325	85,988	56,583	9,177
National Renderers Association	860,410	945,818	899,268	913,154	708,762
National Sunflower Association	263,372	259,748	270,698	289,009	212,376
North American Millers Association	57,511	60,797	25,582	65,568	38,325
U.S. Dairy Export Council	640,575	752,301	639,159	648,290	526,852
U.S. Dry Bean Council	131,461	138,264	111,214	125,547	103,916
U.S. Grains Council	4,730,977	4,342,466	4,708,771	4,591,648	3,277,058
U.S. Hide, Skin and Leather Association	144,545	155,983	105,289	109,130	83,212
U.S. Livestock Genetics Export Inc.	663,100	763,923	719,393	694,236	556,832
U.S. Meat Export Federation	1,780,090	1,846,115	1,730,671	1,641,289	1,106,364
U.S. Wheat Associates	6,658,416	4,178,916	5,402,892	5,839,490	4,146,134
USA Dry Pea and Lentil Council	176,735	185,694	168,863	190,192	154,271
USA Poultry and Egg Export Council	1,468,921	1,613,144	1,424,627	1,505,756	1,171,375
USA Rice Federation/US Rice Producers	1,529,077	1,645,068	1,564,842	1,757,605	1,414,415
Administrative Costs	0	350,000	383,024	38,624	0
Reserve	0	0	0	0	9,094,071
Total	34,500,000	34,500,000	34,500,000	34,500,000	34,500,000

*FY 2013 numbers are as of April 25, 2013.

Foreign Market Development Program (FMD) Success Stories

U.S. Legume Exporters Project Over $1 Million in Sales at Gulfood: FMD provided funding for U.S. Dry Bean Council and USA Dry Pea and Lentil Council to have a joint booth at the Gulfood trade show held in Dubai in December 2012. U.S. legume exporters, which are small and medium-sized companies, had face-to-face contact with over 250 buyers during the four day show, facilitating $500,000 in immediate sales reported and exporters projected over $1 million in 12-month sales.

FMD-funded Southeast Asia Buyers Conference Results in Nearly $560 million in Sales: The 9th Southeast Asia U.S. Agricultural Cooperators Conference, implemented with $70,000 in FMD funds, resulted in over 1.2 MMT of estimated agricultural product sales, including soybeans, soybean meal, corn and wheat. A record 194 participants attended, representing 95 organizations involved in feed ingredient import and distribution, integrated food and feed operations, poultry and livestock production, oilseed crushing, port and logistics management and other agricultural-related businesses. The event was jointly organized by the U.S. Soybean Export Council, the American Soybean Association, the United Soybean Board, the U.S. Grains Council and the U.S. Wheat Associates.

FMD-Funded Technical Assistance Program Builds Demand for US Distiller's Dried Grains with Solubles (DDGS) in Taiwan: The U.S. Grains Council used FMD funds to bring a technical consultant to Taiwan, organize a survey team to the United States, conduct DDGS nutritional seminars, and publish a DDGS technical bulletin, to address the Taiwanese feed industry's questions and concerns about DDGS use. These programs have resulted in steady growth in U.S. DDGS exports to Taiwan, nearly doubling in recent years, reaching about $50 million.

Codex Alimentarius

Mr. Aderholt: Please summarize FAS' involvement with Codex Alimentarius, including any type of support and coordination within the past year.

Response: FAS personnel participate in the U.S. delegations to the majority of Codex Committee meetings, both the Commission and the various subject committees. Early interventions by FAS in the development of Codex work plans, guidelines, and recommended standards serve to assure that agricultural exporter interests are well-represented. FAS helps in keeping issues on science-based and within the human-health-science purview of Codex, and helps ensure trade-relevant factors are addressed. There are often suggestions by various nations to incorporate inappropriate considerations, such as consumer preferences, national legislation constraints, or animal welfare concerns into Codex standards. The inclusion of factors beyond the scope of Codex delays standards. Further, FAS personnel help ensure that appropriate technical and practical production methods and information is considered in Codex standards and guidelines. Early interventions are much more effective in advancing U.S. interests than attempts to modify work that has progressed to near final adoption.

FAS works in coordination with the U.S. Codex office to host workshops to engage with delegates from other countries. The workshops allow a dialogue with the delegates, an examination of technical issues, and a chance to explain the rationale for U.S. positions on pending standards. It is clear

that the workshops have prompted some nations to change previously held positions to positions that align with those of the United States. In 2012, FAS, in collaboration with the U.S. Codex Office, organized and provided experts for regional workshops held in Latin America, Asia, and Africa; conducted an African Delegate Mentoring Program in Washington D.C. and organized two Codex Committee meetings.

FAS also assists the U.S. Codex office to interact with targeted countries through the efforts of FAS overseas officers and by identifying the decision makers who determine national positions for Codex. FAS overseas officers also meet with senior foreign technical and policy level experts and Codex delegates to advocate for U.S. positions and to align critical multinational support.

FAS regularly communicates with industry to help assure that industry perspectives are considered in the development of Codex standards both at the standard development stage, and while advocating U.S. positions in Codex meetings.

Poultry Trade with India

Mr. Aderholt: Please summarize the current WTO case involving poultry trade with India. What are the circumstances and what is FAS doing to eliminate this particular non-tariff trade barrier? What is the potential size of the export market for U.S. poultry in India?

Response: Since 2006, India has banned the importation of various U.S. agricultural products, including poultry meat, eggs, and live swine. The purported basis for the ban is to prevent the entry and establishment of avian influenza (AI). This measure is inconsistent with a number of India's obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. The United States has raised concerns with India repeatedly, including at WTO meetings and in bilateral discussions, to no avail. On February 18, 2013, a WTO panel was composed to hear the dispute. Panel hearings will be held this summer. FAS has been instrumental in researching and proposing elevation of this dispute to the WTO and continues to work closely with the Office of the United States Trade Representative on this issue. FAS estimates that current trade loss as a result of India's measure is approximately $15-50 million annually, with up to $30 million worth of that loss stemming from lost poultry meat sales. Industry estimates are significantly higher. A successful outcome of the dispute with India may also lead to trade gains in other countries that are currently maintaining unscientific AI bans.

Presence in Foreign Countries

Mr. Aderholt: For the record, please provide the Committee with a table listing the countries where FAS has an office or permanent presence and the numbers of FAS employees and the number of non-FSA employees per country. Also, please specify a listing of other countries covered by the permanent office. Note any plans for expansion to future offices. Lastly, has any office closed in the past five years? If so, please provide an explanation as to why.

Response: The information is submitted for the record.

[The information follows:]

Table1: Permanent Offices, Staffing and Country Coverage

COUNTRY	AMERICAN STAFF	FSN/LES STAFF *	COUNTRY COVERAGE
Afghanistan	1	3	
Algeria	1	2	Libya
Argentina	2	5	Paraguay; Uruguay
Australia	1	3	New Zealand
Austria	0	2	
Bangladesh	0	2	
Belgium	4	7	
Bosnia/ Herzegovina	0	1	
Brazil	4	8	
Bulgaria	0	2	
Burma	0	1	
Canada	2	5	
Caribbean Basin	3	0	Anguilla; Antigua and Barbuda; Aruba; Barbados; Bermuda; British Virgin Islands; Caribbean Dutch; Cayman Islands; Curacao; Dominica; Grenada; Martinique; Montserrat; Saint Barthelemy; Saint Kitts and Nevis; Saint Lucia; Saint Martin; Saint Vincent and the Grenadines; Saint Maarten; The Bahamas; Trinidad and Tobago; Turks and Caicos Islands
Chile	1	4	
China	12	38	Mongolia
Colombia	2	5	
Costa Rica	2	5	Nicaragua; Panama
Croatia	0	1	
Czech Republic	0	2	
Dominican Republic	1	5	Haiti; Jamaica
Ecuador	0	2	
Egypt	3	5	Iraq; Israel; Lebanon; Jordan; Syria; Yemen
El Salvador	0	2	
Ethiopia	1	2	African Union; Djibouti; Eritrea; Somalia; South Sudan
France	2	3	United Kingdom; Ireland

COUNTRY	AMERICAN STAFF	FSN/LES STAFF *	COUNTRY COVERAGE
Germany	1	4	Austria; Hungary; Slovenia
Ghana	0	1	
Guatemala	2	4	Belize; El Salvador; Honduras
Honduras	0	2	
Hong Kong	1	6	Macau
Hungary	0	1	
India	4	11	Bangladesh; Sri Lanka
Indonesia	2	7	
Iraq	0	3	
Israel	0	3	
Italy	2	6	Albania; Bosnia; Croatia; Greece; Malta; UN Food Agencies (FAO, WFP, IFAD); Serbia
Jamaica	0	1	
Japan	5	14	
Jordon	0	1	
Kazakhstan	0	1	
Kenya	1	3	Burundi; Malawi; Rwanda; Tanzania; Uganda; Zambia
Korea	4	12	
Malaysia	1	3	Brunei; Papua New Guinea; Singapore
Mexico	7	15	
Morocco	1	3	Tunisia
Mozambique	0	1	
Netherlands	1	3	Belgium; Denmark, Iceland; Luxembourg; Sweden; Norway
New Zealand	0	2	
Nicaragua	0	2	
Nigeria	2	4	Benin; Cameroon; Ghana; Liberia
Pakistan	2	5	
Panama	0	2	
Peru	2	5	Bolivia; Ecuador
Philippines	2	6	
Poland	1	4	Bulgaria; Czech Republic; Estonia; Latvia; Lithuania; Slovakia
Romania	0	2	
Russia	5	12	Armenia; Belarus; Kazakhstan

COUNTRY	AMERICAN STAFF	FSN/LES STAFF *	COUNTRY COVERAGE
Saudi Arabia	1	2	
Senegal	2	3	Burkina Faso; Chad; Cote d'Ivoire; Mali; Niger; The Gambia
Serbia	0	2	
Singapore	0	2	
South Africa	3	5	Angola; Botswana; Lesotho; Madagascar; Mauritius; Mozambique; Namibia; Swaziland; Zimbabwe
Spain	1	3	Portugal
Switzerland	3	0	
Taiwan	3	9	
Thailand	2	6	Burma
Tunisia	0	2	
Turkey	2	5	Azerbaijan; Georgia; Kyrgyzstan; Tajikistan; Turkmenistan; Uzbekistan
Ukraine	1	3	Moldova
United Arab Emirates (UAE)	1	4	Bahrain; Kuwait; Oman; Qatar
United Kingdom	1	4	
Uzbekistan	0	1	
Venezuela	1	6	
Vietnam	3	8	Cambodia
Yemen	0	1	
Total	112	330	

*FSN/LES = Foreign Service National/Locally Employed Staff

Table 2: Future Office Expansion Plans FY 2014

Country	Post	American Staff	FSN/LES Staff*
Angola	Luanda		1
Bangladesh	Dhaka	1	
China	Chengdu ATO		1
China	Guangzhou ATO		1
China	Guangzhou ATO	1	
China	Wuhan ATO		1
Colombia	Bogota		2
France	Paris		1
Germany	Berlin		1
Indonesia	Jakarta		1
Indonesia	Jakarta	1	
Kenya	Nairobi	1	
Taiwan	Taipei		1
Turkey	Ankara		1
United Arab Emirates	Dubai	1	
Vietnam	Hanoi		1
TOTAL		5	12

*FSN/LES = Foreign Service National/Locally Employed Staff

Table 3: Office Closures 2008 - 2012

Country	**Post**	**Year Closed**
Philippines	Manila (ATO)	2008
Denmark	Copenhagen	2009
Ireland	Dublin	2010
Greece	Athens	2010
Germany	Bonn	2011
Sweden	Stockholm	2012
Syria	Damascus	2012

FAS conducts an annual rightsizing exercise to align the number and location of staff assigned overseas with foreign policy priorities, security, and budgetary constraints. As a result, FAS shifted staff resources from more mature European markets (Copenhagen, Denmark; Dublin, Ireland; Athens, Greece; and Bonn, Germany) to growing export markets over the past decade. There are two offices that were closed due to budgetary constraints: the Agricultural Trade Office in Manila, Philippines and the Office of Agriculture Affairs in Stockholm, Sweden. Lastly, the Office of Agricultural Affairs in Syria was closed due to security issues in country.

Department of State Costs

Mr. Aderholt: Please provide the Subcommittee with a breakdown of costs charged to FAS by the Department of State for the past five fiscal years as well as estimated charges for FY 2013 and FY 2014.

Response: The information is submitted for the record.

[The information follows:]

($ in Thousands)

State Department Reimbursable Agreements	FY 2008 Actual	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Estimated	FY 2014 Estimated
ICASS	$12,232	$12,630	$12,609	$15,501	$16,478	$19,539	$21,805
Other Misc. Reimbursable Agreements	1,468	1,565	1,650	1,943	2,015	1,710	1,907
CSCS*	7,073	9,545	9,684	8,905	7,379	6,047	3,767
Total	$20,773	$23,740	$23,943	$26,349	$25,872	$27,296	$27,479

* Note: As per Congressional direction, other agencies' CSCS contributions are reduced in amounts equal to those reductions applied to the Department of State's CSCS contribution. Therefore, beginning in FY 2012 the Consolidated Appropriations Act (2012) reduced the Department of State's CSCS contribution. A similar reduction occurred in FY 2013. CSCS charges include direct and reimbursable costs to FAS.

Mr. Aderholt: Please provide the Subcommittee with the IT costs for the past three years and current year costs per charges from the State Department.

Response: The information is submitted for the record.

[The information follows:]

State Department charges for IT costs for the past three years and current year are as follows

($ in Thousands)

FY 2010	FY 2011	FY 2012	FY 2013
$2,513	$2,814	$2,418	$2,513

All charges by State Department for IT services are governed by a Memorandum of Agreement between both USDA and Department of State.

Cochran and Borlaug Fellowship Programs

Mr. Aderholt: Please provide a five-year history of funding for the Cochran and Borlaug Fellowship programs to include actual and estimated levels for fiscal years 2013 and 2014.

Response: The information is submitted for the record.

[The information follows:]

Cochran Fellowship Program
FAS Appropriation Funding for Fiscal Year 2010 through 2014
($ in Thousands)

FAS Appropriated Funding:	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Estimate	FY 2014 Estimate
Direct	$5,000	$5,000	$5,000	$5,000	$5,000
Carry-Over*	$0	3,587	6,449	6,944	0
Total FAS Appropriated	$5,000	$8,587	$11,449	$11,944	$5,000

*FAS Appropriation carry-over funds from prior fiscal years (tracked separately beginning FY11).

Norman E. Borlaug International Agricultural Science and Technology Fellowship Program (Borlaug Fellowship Program)
FAS Appropriation Funding for Fiscal Year 2010 through 2014
($ in Thousands)

FAS Appropriated Funding	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Estimate	FY 2014 Estimate
Direct	$1,967	$2,000	$3,961	$1,500	$1,500

Bill Emerson Humanitarian Trust

Mr. Aderholt: Please explain to the Subcommittee the possible scenarios that would prompt the Administration to shift resources out of the Bill Emerson Humanitarian Trust. Has the Administration considered such transfers over the past three years? If not, why not in light of a number of emergency situations around the world and limited resources necessary to address starvation and malnutrition in those countries or regions?

Response: The Bill Emerson Humanitarian Trust (BEHT) is available to provide food aid resources to avert an emergency, respond to an emergency, or recover and rehabilitate from an emergency. A release is triggered when the USAID Administrator determines that P.L. 480 Title II funding for emergency needs is inadequate to meet those needs in any fiscal year. Approximately $311 million in cash is available in the BEHT. The Administration will consider using BEHT resources for any emergency situation where a quick response is needed and existing Food for Peace Title II or International Disaster Assistance resources are not sufficient. Potential causes of the emergencies include floods, droughts, and earthquakes.

Transfers of Funds

Mr. Aderholt: Did the agency transfer or reimburse any funds to the OCIO or CCE in fiscal year 2012? If so, when, what for, and in what amount?

Response: FAS transferred approximately $9 million to OCIO in FY 2012. The information is provided for the record.

[The information follows:]

FY 2012 Activity ($ in Thousands)	Amount
Computer desktop and network Operations & Maintenance	$5,850
Enterprise Data Center services	1,465
Network modernization services	1,115
Enterprise Software as a Service (SaaS) AgLearn, USDA connect etc.	294
Department eGov Initiatives	133
Telecomm Customer Services Center	121
Enterprise Authentication services (HSPD-12, e-Auth)	102
Total	$9,080

Mr. Aderholt: What is USDA doing to monitor or control the costs charged to the Department from the State Department for their overseas services?

Response: USDA/FAS actively participates on interagency working groups both in Washington and overseas. USDA/FAS devotes staff time to vigorously monitor and mitigate ICASS costs. In Washington, FAS is a member of the ICASS Executive Board, the ICASS Working Group, and is a member of various inter-agency working groups that tackle policy, budgetary, and IT related issues. Overseas our USDA/Foreign Service Officers are voting members on the Post ICASS Council and the Budget Committee which verifies and approves the annual post budget for all agencies. Moreover, USDA/FAS conducts exhaustive and detailed reviews of all State Department billings to ensure the agency has been accurately invoiced. Any inaccuracies are disputed immediately and persistently until corrected invoices are received. In addition, USDA/FAS does leverage its existing infrastructure in Washington to support overseas operations in areas such as travel, financial management, procurement, and the payment of local vendors and Foreign Officers' entitlements. Overall, the shifting of services out of ICASS to our domestic agency as deemed appropriate and doable by management has resulted in significant savings to USDA/FAS.

OIG Audits and Evaluations

Mr. Aderholt: Please provide a status of any FAS actions to come to management agreement on findings or recommendations made by OIG audits over the past two years.

Response: Over the past 2 years OIG has issued one audit report with recommendations for FAS, dated March 28, 2013 ("Effectiveness of FAS' Recent Efforts to Implement Measurable Strategies Aligned to the Department's Trade Promotion and Policy Goals," OIG Audit Report 50601-0001-22). The report was issued with management decisions already achieved on four of the five recommendations. FAS is working with OIG and is confident that a management decision on the remaining recommendation, which involves validation of a performance measure used to report the economic impact of agricultural

exports, will be achieved prior to the September 28, 2013, deadline for doing so.

Employee Job Satisfaction

Mr. Aderholt: FAS continues to score in the lowest quartile for the annual "Best Places to Work" survey. What does the Agency attribute to these low scores to and what is the Agency doing to improve the overall scores and the corresponding job satisfaction?

Response: FAS Leadership has been briefed and presented an Executive Summary of the results of the 2012 Federal Employee Viewpoint Survey and the Best Places To Work Report. The low 'scores' have been assessed and are a result of insufficient communications from leadership to their employees, the impact of lower budgets on staffing, career growth and general morale of employees, and the lack of employee engagement. FAS Leadership has commenced several actions to address these improvement opportunities. This includes:

- Communication - Creation of the Administrator's Corner (blog) on the Agency SharePoint as a regular form of communicating to employees regarding significant events or timely information that help employees identify with the mission; and the increase of Administrator 'Town Hall' meetings.
- Budget - Increased funding for employee training and development activities including formal training programs, the development of competency-based Career Guides for Mission Critical Occupations representing over 81% of the FAS career population, and implementation of the 360 Leadership Assessment Program to augment leadership succession and improve effectiveness of Agency Leaders.
- Engagement - Ensuring employee participation through the Labor Management Forum projects, such as expanding Telework participation, providing input to Recognition & Awards policy and events; and involving employees in decisions that impact their work.
- Formation of the Human Capital Sub Committee as an integral part of the Agency Enterprise Governance. This group of leaders addresses long term training needs, employee issues that impact morale, employee participation in cross Agency developmental programs, and other major matters that can increase employee communications and morale. In addition, all recommendations from the Human Capital Sub Committee are presented to the Management Council for review and final disposition.

QUESTIONS SUBMITTED BY CONGRESSMAN ALAN NUNNELEE

Collaboration with Other Departments

On December 10, the Food Safety Inspection Service issued a notice, "Hazard Analysis and Critical Control Points (HAACP) Plan Reassessment for Not-Ready-To-Eat-Comminuted Poultry Products and Related Agency Verification Procedures." I understand that FSIS has decided to postpone sampling of mechanically separated poultry until it can consider stakeholder comments on the new rules, but poultry producers are seriously concerned that if this rule moves forward, it could mean a halt in exports of this product and ultimately millions in lost revenue. More importantly this potentially leads to a loss of an important protein source to those who import the product, and for U.S. poultry workers, this means possible jobs at risk. I understand that you are not the FSIS, but Administrator Heinen's testimony commentary on the incredible $1 billion in poultry products to Mexico last year caught my

attention. Did FSIS discuss with Foreign Ag. Service the international trade implications of these new rules before publishing the notice? Has Foreign Agriculture Service evaluated the economic implications of this proposed rule? Do you believe that there would be any retaliation from those countries that currently import the majority of mechanically separated poultry from the United States to be used in ready-to-cook poultry products? With the Administration's goal to increase exports, can you tell me specifically how many pounds of mechanically separated poultry will not be allowed for export and what this change in the export market will do to the poultry in the United States? In general, when departments within and outside of USDA propose rules that could potentially negatively affect agriculture trade, is there an effort to discuss with your office or collaborate with your office?

Response: After the 2011 Salmonella multi-state foodborne illness outbreak associated with ground turkey, FSIS undertook a thorough review of how ground turkey and other similar products are made to improve food safety. As a part of the lessons learned from this outbreak, FSIS issued a Federal Register notice (http://www.fsis.usda.gov/wps/wcm/connect/0dffacbe-45e8-43ea-8b65-3b7100e19acb/2012-0007.pdf?MOD=AJPERES) stating that establishments producing raw ground or comminuted chicken or turkey product need to reassess HACCP plans for these products in response to outbreaks. FSIS also announced that it intended to begin sampling raw comminuted turkey or chicken products, in addition to ground product, for Salmonella. While the Agency has started sampling and testing this product, it has not established any new performance standards or requirements for these products. Raw comminuted or ground chicken or turkey product intended for export is subject to Agency sampling and testing for Salmonella, but can still be exported. This is true for all classes of raw product subject to FSIS sampling and testing for Salmonella. Because FSIS did not establish any new performance standards and did not change policies or procedures for product intended for export, FSIS did not discuss international trade implications. However, FSIS did notify WTO of this Federal Register notice.

No country has taken action against these products at this time although we understand the industry's concerns about the potential impact on trade if this action is misunderstood by trading partners. Since the announcement of this action, FAS has assisted industry in exploring alternatives that could minimize the potential for negative responses by foreign governments.

Questions Submitted by Mr. Farr

National Agriculture Imagery Program

Mr. Farr: For the last 11 years, the National Agriculture Imagery Program has annually delivered aerial imagery to serve the mapping and analytical needs of federal, state, and local community agencies across the nation. With sequestration in place what is the strategy for funding this Program for 2013, to insure the provision of consistent, current aerial imagery necessary to manage critical natural resource assets? Additionally, what are your plans for FY14?

Response: The information is provided for the record. Coupled with funding received from partner organizations, funding from FY 2013 and FY 2014 will allow FSA to fly approximately 1/3 of the country.

[The information follows:]

NAIP Funding Summary - Amounts in Thousands ($000)

Funding Source	FY 2011 Actual	FY 2012 Actual	FY 2013 Plan	FY 2014 President's Budget
S&E				$10,141
Advances & Reimbursement (NAIP Partnerships) a/	$4,830	$5,400	$2,995	5,400
CCC Section 4	11,641	11,747	9,624	
Total, FSA Funding	16,471	17,147	12,619	15,541

a/ NAIP Partnerships include 3 Federal Agencies (US Forest Service, Natural Resources Conservation Service & Department of the Interior).

Questions Submitted by Mr. Bishop

Beginning Farmer Loans

Mr. Bishop: Beginning Farmer Loans - Mr. Garcia, according to your testimony, in FY 2012, 66 percent of FSA's direct lending activity or just over $1.1 billion went to beginning farmers! FSA also assisted beginning farmers with an additional $638 million in credit through loan guarantees! I must say that's a pretty impressive figure. Was this level of funding a direct result of the Secretary's initiative to expand the number of beginning farmers last year or was this consistent with the previous year?

Response: Over the past several years FSA has been increasing assistance to beginning farmers. The funding set-asides Congress has established for beginning farmers have assisted in this effort, particularly in the direct loan programs, where 75 percent of ownership and 50 percent of operating funds are reserved for beginning farmers. However, the Secretary's initiative re-focused our efforts to target this traditionally underserved group. FSA assisted 16,043 beginning farmers in FY 2012 as compared with 14,823 in FY 2011.

Mr. Bishop: How does USDA define a "beginning farmer?"

Response: FSA Farm Loan Program requirements and funding reservations are tied to the term "qualified beginning farmer or rancher" which is defined in statute (7. U.S.C. 1991(a)(11)). To meet the definition, an applicant must have operated a farm or ranch for 10 years or less, be materially involved and provide day-to-day labor and management of the operation, for real estate loans only- own land no more than 30 percent of the median farm size in the county, and lack financial resources to farm on a viable scale without FSA assistance. If applying as an entity, all individuals in the entity must meet the definition.

Mr. Bishop: Can you tell the Subcommittee how many loans or transactions this $1.7 billion represents?

Response: FSA made or guaranteed 16,043 loans to beginning farmers in FY 2012.

Mr. Bishop How many new or "beginning farmers" were actually approved for loans with the $1.7 billion?

Response: FSA made or guaranteed loans to close to 16,043 beginning farmers. Some of these applicants will receive multiple loans, for example an operating loan and an ownership loan, which results in fewer than 16,043 separate farmers; however this would not be typical.

Mr. Bishop: What was the "average" age of the loan recipients?

Response: FSA does not capture this information.

Mr. Bishop: How many beginning minority farmers were approved for loans with the $1.7 billion?

Response: FSA made or guaranteed 2,782 loans totaling $286.6 million to SDA beginning farmer applicants in 2012. This includes both women and minorities.

Mr. Bishop: How many beginning women farmers were approved for loans with the $1.7 billion?

Response: FSA made or guaranteed 2,782 loans totaling $286.6 million to SDA beginning farmer applicants in 2012. This includes both woman and minorities.

Mr. Bishop: In your opinion, are all of these "beginning farmers" actually new farmers, or, are many the descendants or relatives of the current/former owner of the farms involved in the transaction?

Response: Some of these beginning farmers are relatives or descendants of established farm operators, but we are not able to identify how many. It is important to note that under the statutory eligibility criteria, all of these beginning farmers are unable to obtain commercial credit, and if they are part of an entity, all entity members must be beginning farmers and be unable to obtain commercial credit.

Mr. Bishop: Does FSA currently maintain data related to direct or guaranteed loans to beginning farmers which were owned/controlled by close relatives?

Response: FSA does not collect this information.

FRIDAY, APRIL 26, 2013.

FOOD AND DRUG ADMINISTRATION

WITNESSES

MARGARET A. HAMBURG, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAMES TYLER, CHIEF FINANCIAL OFFICER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

NORRIS W. COCHRAN, DEPUTY ASSISTANT SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. ADERHOLT. Good morning. I would like to welcome everyone to the subcommittee today.

And I would like to welcome especially Dr. Margaret Hamburg, Commissioner for Food and Drug Administration. Joining the Commissioner today is Mr. Norris Cochran, the Deputy Assistant Secretary for Budget of the U.S. Department of Health and Human Services, and Jay Tyler, FDA's Chief Financial Officer.

Welcome to all three of you.

The work that you and your colleagues at FDA perform touches the lives of every American, and we appreciate the dedicated service that each of you perform on a day-to-day basis. With that said, there are many challenges that face FDA. Compounding pharmacies, drug shortages, foodborne illnesses, dietary supplements are just some of those challenges. From where I sit, I see another challenge, and that is the pace at which FDA moves guidance, rules, and regulations through the process.

In addition to the budget request, I want to focus today on this bureaucracy that just can't seem to produce crucial guidance, even though the science is evident. For example, USDA's dietary guidance for Americans on seafood consumption for women who are pregnant have been in place since January of 2011. However, for the past 2 years, this subcommittee has repeatedly asked the FDA to finalize its seafood consumption guidance, with no indication of closure, because the issue is tied up in bureaucratic infighting at the Department of Health and Human Services. This type of delayed response causes frustration with Congress as well as the millions of women who need answers on this and other important matters.

Turning to the budget, I don't quite understand why the budget was submitted so late, given the fact that the basis for the request was the fiscal year 2013 continuing resolution that was signed into law on September the 28th, 2012. The result is a simple repeat of last year's budget. This budget could have been submitted much earlier, and there would have been more clarity regarding the President's request than there are currently.

On Monday of this week, we asked the Food and Drug Administration to provide something as simple as a table that shows the proposed changes between the final fiscal year 2013 enacted levels and the fiscal year 2014 budget request level. Other agencies within the subcommittee's jurisdiction provided that to the committee more than 2 weeks ago without us even asking them for it. Unfortunately, we just got the information from the FDA well after the sun went down last night. This is basic budgetary information that FDA should have provided to the subcommittee without asking, and FDA should provide it upon request without delay.

Overall, FDA is requesting $4.7 billion for fiscal year 2014, of which $2.6 billion is in discretionary budgetary authority and $2.1 billion is in user fees. Once again, FDA is requesting new user fee authority for food imports and food facility registration and inspection. These particular fees total $226 million. These fees do not appear to enjoy the same level of industry support as the prescription drug or medical device industries gave to their programs, because the food industry believes this to be a food safety tax.

It seems that FDA has failed to communicate to the industry what, if any, performance measures FDA would use in managing this program. These fees are not currently authorized, and the chance of Congress authorizing this, I would say, would be very slim.

With that, I would like to turn it over to the gentleman from California, our ranking member, Mr. Farr.

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

I also welcome the Commissioner here and want to thank her very much for coming out to the Salinas Valley to see how fresh produce is grown and produced right in the field.

We are still talking about your visit and how you compared the fact that you had to dress up in a suit and a hair net and gloves in order to go into the fields, it was like going into an operating room. That is how we are trying to keep our fields very healthy and clean.

Mr. Chairman, I think we have all criticized the administration for a late budget, but we also need to criticize ourselves. Congress never even produced a budget. We haven't had a bill out of this committee since 2012, and before that, the only time we had had it was in 2010. So, you know, the President is supposed to base his budget on what Congress approves the year before. I hope we can remedy that.

I would also just suggest that I think we in this committee ought to give the FDA the flexibility, the authority to use the user fees. These user fees are being paid by the private sector to get a job done, and they can't get the job done because we have unintended consequences of budget cuts and sequestration. This is money that is in the bank, it is sitting there, and we ought to give it to FDA to use, as we have done for other agencies. We did it for our parks to allow them to keep the fees and use them. Look at the way we qualify to run for Congress. You have to pay a fee at the local registrar, and they get to keep that fee for running the elections department, and so on.

This is a fee that has been collected. The private sector is going to get really frustrated, really discouraged that the government

isn't being a fair partner. And I think, you know, if you believe in private enterprise, they are coming up with paying these fees because they want answers to their questions, and we ought to allow the Department to use the fees they are paying for that purpose.

So I look forward to this hearing, and I think that is something we ought to try to work on as a committee.

Mr. ADERHOLT. Thank you, Mr. Farr.

Mr. ADERHOLT. We are fortunate to have the full committee chairman, Mr. Rogers, with us today, and I would like to recognize him for any opening remarks he may have.

Mr. ROGERS. Thank you, Chairman, for recognizing me.

Good morning——

Dr. HAMBURG. Good morning.

Mr. ROGERS [continuing]. Commissioner, and thank you for being with us today to discuss the fiscal 2014 budget request for FDA.

In other subcommittee hearings, I have already lamented the fact that this budget request is woefully late and won't get our Nation back on solid financial footing. But we will persevere.

Before I comment on your budget, let me hasten to thank you for FDA's recent decision that prohibits generic crushable OxyContin from coming to market without abuse-deterrent technologies. Unfortunately, drugs misused are a recipe for disaster. And advocates across the country salute you for your leadership in shepherding this landmark decision on generic painkillers. Thank you.

As you know, the abuse of prescription drugs, particularly opioid pain pills, is our Nation's fastest-growing drug threat. So great, in fact, that your colleagues at the Centers for Disease Control have called this crisis an epidemic.

Just as FDA must responsibly address other epidemics like H1N1 and public health threats like meningitis from tainted steroid injections, you must also closely examine drugs entering or on the market, including the prescribing patterns and potential abuse. Last week's decision by your agency will surely save lives, and I hope it is a sign of things to come as it relates to our Nation's very serious pain pill addiction.

Undoubtedly, the FDA is a critical partner in getting this multifaceted health, law enforcement, patient access, and education issue under control. I am anxious to hear from you today about how we can build on this success story and what other steps FDA can take to beat back on the abuse of prescription medications, like rescheduling our most widely prescribed and abused painkillers—hydrocodone combination drugs—and limiting the indication for prescribing these powerful opioids to severe pain only.

Now to your budget, Commissioner. The FDA is seeking nearly $4.7 billion, which is $622 million above the fiscal 2013 level. I should note, however, that this request assumes that sequestration for fiscal 2014 is undone—far from a given, considering the President's unwillingness to truly engage in discussions to address our real cost drivers without talking more about taxes.

Toward that end, this budget assumes the inclusion of six new user fees, including one for registration of food facilities, a fee likely to be passed on to consumers. As you can imagine, this committee and the general public has little appetite for food fees.

I am sure we will discuss this issue at length, as well as your recent comments about the effects of sequestration on food inspections and the recent court order for FDA to move forward on the implementation of the Food Safety Modernization Act.

So we look forward to hearing from you this morning.

Dr. HAMBURG. Thank you.

Mr. ADERHOLT. Thank you, Chairman Rogers.

Mr. ADERHOLT. Just bear in mind, we have votes today. I don't expect votes to be called for close to another hour, so we should get well into the hearing and make a big dent into the hearing. And we will just see how long we go. Sometimes the floor schedule is very unpredictable, so it may be even later before we have votes.

So, with that, your, of course, statement is entered into the record, but at this time we would like to recognize you for your opening statement and comments before we go into the questioning aspect of the hearing.

Dr. HAMBURG. Well, thank you very much. And good morning, Chairman Aderholt, Ranking Member Farr, and certainly Chairman Rogers, and all the members of the subcommittee.

[The information follows:]

TESTIMONY OF MARGARET HAMBURG, MD

COMMISSIONER OF FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

U.S. HOUSE APPROPRIATIONS SUBCOMMITTEE ON

AGRICULTURE, RURAL DEVELOPMENT,

FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

April 26, 2013

Good morning Chairman Aderholt, Ranking Member Farr and members of the Subcommittee. I appreciate the opportunity to discuss the Food and Drug Administrations (FDA) priorities and provide an overview of the Fiscal Year (FY) 2014 budget request. I would also like to thank the Subcommittee for its past investments in FDA, which have helped us meet the demands of our broad and increasingly complex mission.

I. FDA plays a vital role in the health of our citizens and our regulated industries

Congress has given FDA responsibility for a vast range of products that are central to the health and well-being of every American. From spinach and frozen dinners, to vaccinations that save millions of children's lives, to new medicines for the treatment of major killers like cancer and heart disease, Americans rely on products overseen by FDA every single day. A short list of what FDA oversees includes:

1. The safety of most of America's food supply;
2. The safety and effectiveness of drugs, biologics, vaccines, and medical devices;
3. The safety of the blood supply;
4. The development of medical countermeasures to address chemical, biological, radiological, and nuclear threats, and infectious diseases;
5. The safety of products that emit radiation;
6. The quality of mammography facilities services;
7. The safety of dietary supplements and cosmetics;
8. The nutritional quality of infant formula;
9. The safety of animal food and feed as well as the safety and effectiveness of drugs for use in livestock, pets, and other animals;
10. And most recently, FDA has been charged with reducing harm from tobacco use.

The products we oversee are capable of producing great benefits: sustaining human life, reducing suffering, treating previously untreatable diseases, and extending lives. FDA's recent approval of the first drug to treat one of the causes of cystic fibrosis, as well as the first bionic eye system for a rare genetic condition, illustrate the ability of these products to transform lives.

Without proper oversight, however, many of these products are also capable of causing great harm. We need only look at the recent outbreaks of foodborne illnesses from peanut butter or the newest report of counterfeit cancer drugs being imported into the US to understand those risks.

FDA has a dual responsibility to the public health—to make safe and effective products available to Americans as quickly as possible, while at the same time protecting our citizens from those products that injure or kill. Our citizens' health depends on both.

We also recognize that the producers of our nation's food and medical products are vital to the health of our economy—and a strong FDA is vital to their health as well. Our history shows that when there is public trust in FDA's oversight, our industries flourish. Conversely, when food and medical products cause serious harm, the result is often severe economic damage across the industry involved—to offenders and non-offenders alike.

II. FDA carries out its far-reaching responsibilities with few taxpayer dollars

FDA is a true bargain among Federal agencies. Added together, the products we regulate represent more than 20 cents of every consumer dollar spent on products in the U.S. Americans each pay about $8 a year for FDA's appropriations, which is substantially less than the amount Americans spend each year on snack chips alone.

And putting money into FDA is a smart investment. For about two cents a day, Americans get an extraordinary array of public health benefits, including: (1) life-saving medicines approved as fast or faster than anywhere in the world, (2) confidence in the medical products they rely on daily, and (3) a food supply that is among the safest in the world. But maintaining this level of performance for the American public, especially related to food safety, demands a fully-funded FDA.

Although FDA continues to be an effective and efficient investment, our job has become increasingly demanding. We are in the midst of dramatic technological and market-based changes in the way that foods, drugs, biologics, and devices are produced—from personalized medicine and nanotechnology to the globalization of our food and medical product supplies. Congress has also continued to pass new laws and expand our responsibilities. While we welcome these new responsibilities, they don't always come with added resources. These changes force us to stretch our limited resources, while finding ways to ensure the safety of a

global supply chain. Our scientists must also adapt to, and even drive, new science and technology so that we can accelerate medical product innovation rather than impede it.

Let me say a few words about the impact of globalization, which I believe to be among our greatest current challenges. Not that long ago, FDA's job was to oversee a largely domestic market of food and medical product suppliers. Most of the facilities in which these products were stored and manufactured were within our borders and relatively easy to inspect and oversee. Most of our producers and manufacturers were accustomed to operating under the rules of a modern regulatory system and most lived up to our high standards.

We have now entered a brave new world—a world in which, very soon, the majority of our food and medical products will come in whole or in part from foreign countries. In the last ten years, the number of imported shipments of FDA-regulated products has skyrocketed – in 2012, approximately 28 million shipments of imported food and medical products crossed our borders. That includes 50% of our fresh fruits and 20% of our fresh vegetables, around 80% of our seafood, and 40% of drugs on our shelves. Eighty percent of the manufacturers of active drug ingredients are located outside the U.S., and more than half of medical devices are imported. Most of the increase in imports is coming from China and India, countries with limited regulatory oversight. Many other imports are from developing nations with even less regulation.

The vast increase in imported foods raises the risk of contamination and illness. Of the imported produce and seafood refused entry at the border, 70-85% is for potentially dangerous violations, including the presence of disease-causing organisms and chemical contamination.

The global marketplace also increases the threat of deliberate adulteration, fraud, and counterfeiting. Criminals exploit how hard it is to inspect and track products through the global supply chain. Chinese suppliers of heparin, a critical drug to prevent blood clots, substituted a lower-cost, adulterated raw ingredient in their shipments to U.S. drug makers, causing deaths and severe allergic reactions. Chinese suppliers of wheat gluten substituted melamine, an ingredient used in making plastic, which was toxic when it was used in U.S. pet food and dairy products. The contaminated food sickened and killed pets across the U. S. and put many people at risk.

The global supply chain itself is becoming increasingly complex. Each product may pass through a number of foreign links in the chain, and each additional link increases the risks to

American consumers. Consider canned tuna. Once primarily canned in the U.S., tuna processing and canning is now outsourced to foreign facilities, and tuna often takes a circuitous journey through processors and canners in Southeast Asia, Africa, and/or Latin America, before it is ultimately shipped to the U.S. for distribution to our grocery store shelves.

The world has changed and our historical regulatory approaches and tools—such as hoping to intercept products at our borders—are outdated and often inadequate. Border inspections will remain important but they cannot guarantee the safety of even a small fraction of our 24 million food and medical imports a year. Globalization demands a major change in the way FDA fulfills its mission. If we are to continue to promise Americans a safe food and drug supply, FDA must continue to transform itself—from a primarily domestic agency to one that uses innovative global strategies to secure a vast global supply chain. Although challenges lie ahead, we have already made strides toward this goal using the resources you have provided.

III. We are delivering results that help Americans every day

A. Implementing Major New Laws.

We are partners with Congress in implementing the policies in three major new laws and several smaller ones that add to FDA's responsibilities in advancing the health of Americans.

1. The Food and Drug Administration Safety and Innovation Act (FDASIA). With the passage of FDASIA last year, Congress granted us important new authorities, reauthorized human drug and device user fees, and authorized new user fees for generic human drugs and biosimilars. These authorities and fees are intended to increase the speed and predictability of medical product reviews, better protect the drug supply chain, reduce drug shortages, and speed the review of more affordable versions of drugs that are essential in holding down health care costs. We are working hard to implement FDASIA and achieve these important goals.

Drug approvals. We continue to run a state-of-the-art drug approval process that brings important new drugs to Americans quickly and safely. In 2012, FDA approved 39 novel medicines, and the great majority were approved in the U.S. before any other country in the world. The drugs included 13 treatments for cancer patients, 13 orphan drugs, and the first brain imaging agent to help rule out Alzheimer's Disease. Recognizing the need to bring safe, life-saving drugs to Americans as quickly as possible, FDA approved some of them in as little as 3½ months.

Medical Device Approvals. Over the past decade, important indicators of the efficiency of the FDA's medical device review program, including the average length of review and the size of the backlog of overdue applications, had steadily worsened. Since 2011, FDA has worked intensively to turn this around. Almost every major indicator has now reversed: review times are getting shorter and backlogs are shrinking. This important turnaround will allow the industry to bring safe and effective devices to market more quickly and at lower cost.

Drug Safety. FDA has also used your investments to improve our oversight of the safety of marketed drugs. The new Mini-Sentinel system allows us to quickly assess potential drug safety problems using data from over 130 million patients. FDA used Mini-Sentinel to assess reports that a new blood thinner, Pradaxa, was causing more bleeding than similar drugs. The results gave reassurance that bleeding rates were not higher with Pradaxa than with the other drugs.

Drug Shortages. FDA prevented 282 drug shortages in 2012—87 more than in 2011. Early notification to FDA of potential shortages has made a huge difference in our efforts. In 2012, we cut the number of new shortages by more than half (117 v. 251).

Affordable drugs. FDA is working to provide Americans with better, quicker access to affordable generic drugs and is also implementing an abbreviated pathway for approval of biological products shown to be "biosimilar to" or "interchangeable" with an FDA-approved biological product. Biosimilars are products that are similar to approved biologics, and while biologics are among the most important drugs Americans use today, they are also the most complex and expensive. We are developing a science-based process for bringing safe and effective biosimilar and interchangeable products to market, which should increase competition and create substantial savings for patients, healthcare providers, and insurers.

2. The FDA Food Safety Modernization Act (FSMA). Even though the U.S. food supply for humans and animals is among the safest in the world, the current rate of foodborne illness remains too high—according to CDC estimates, roughly one in six Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases each year, leading researchers to estimate a cost of more than $75 billion due to medical expenses and lost productivity. This does not include costs to the food industry or public health agencies. These are preventable human and economic costs, and they reflect an outdated food safety system. FSMA, the most sweeping reform of our food safety laws in more than 70 years, creates a modern food

safety system that shifts our traditional focus—responding to contamination after it occurs—to preventing it before it happens. This new prevention strategy involves all participants in the food system, domestic and foreign, government, industry, and consumers, doing their part to minimize the likelihood of harmful contamination.

FDA is working on regulations on the kinds of risk-based measures food producers and importers should put in place to reduce the risk of contamination. We take pride in our release earlier this year of two proposed rules that set science-based standards for the prevention of foodborne illnesses – one on safe growing and handling practices for produce and another on prevention practices in facilities that process, handle, and store food. Before drafting the proposed rules, FDA conducted extensive outreach with farmers, manufacturers, consumer groups, state and local officials, and the research community. We have just completed three public meetings across the country to get additional input from stakeholders.

The proposed rules are built on existing voluntary industry guidelines and recognized best practices for food safety. Many producers already follow these guidelines, so compliance will be less of a burden. For those who need to add new food safety practices to their operations, FDA, in collaboration with USDA, will offer technical assistance and guidance.

FDA is committed to working with industry members to provide the support they need, especially the smallest businesses. We know that our rules and oversight practices must be responsive to the diversity of operations covered by FSMA, be risk-based and flexible, and address small business concerns. That's why we've included a number of exemptions for small businesses, including one for farms. The produce rule would also exempt low-risk products, like potatoes that are rarely consumed raw, or that will be further processed with a step that kills bacteria—like vegetables that will be canned. We've also proposed that small farms and other small business be given extra time to come into compliance with both rules.

3. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act gives FDA responsibility to reduce death and disease caused by tobacco and to lessen tobacco use, especially the initiation of smoking, by children and teens. This program is entirely supported by tobacco industry user fees. Since enactment, FDA has worked to enforce a ban on cigarettes with candy and fruit flavors, to make them less appealing to kids; prohibit claims like "light" or "mild" that misleadingly imply products are safer; and

enforce new smokeless tobacco warnings. FDA has also joined with States and Territories to enforce laws against under-age sales. We have conducted over 131,000 retail inspections and sent over 6,800 Warning Letters and 420 Civil Money Penalty complaints to retailers.

4. Other New Authorities

FDA is also implementing other recently enacted laws. Last month Congress passed the Pandemic and All-Hazards Preparedness Reauthorization Act, strengthening FDA's authority to prepare for chemical, biological, radiological, and nuclear threats, as well as infectious disease emergencies like pandemic flu, and to support rapid deployment of medical countermeasures. FDA is also carrying out new requirements in the Affordable Care Act, including provisions on biosimilars and nutrition information on menus.

B. Safeguarding the Global Supply Chain

Using the public's investments, the agency is working to transform itself into a public health agency capable of preserving the safety of our food and medical products in a complex global marketplace. We are developing better enforcement and regulatory tools, encouraging greater industry responsibility, increasing transparency and accountability in the supply chain, and increasing collaboration with international regulatory counterparts and other third parties.

1. Foreign posts. To enhance our ability to oversee import safety, we now have 12 permanent FDA overseas posts in key locations around the world: three in China, two in India, three in Latin America, two in Europe, one in the Middle East, and one in South Africa.

2. Foreign inspections. FDA conducted over 2,700 foreign inspections in FY 2012, the largest number ever, exceeding last year by 23%. We are on track to surpass that record this year.

3. Border screening. To make the most of our limited border inspection resources, FDA developed PREDICT, a sophisticated computer screening system that uses intelligence from many sources—such as intrinsic product risks, past inspection results, and information about such threats as extreme weather that could spoil a shipment—to flag the riskiest imports before they arrive. This allows FDA to focus its border resources on those imports that are most likely to pose a danger, and at the same time easing entry of low risk products. PREDICT has helped stop many contaminated products at the border. Recently, PREDICT flagged a large shipment of cucumbers from the Dominican Republic, which were contaminated by *Salmonella*. PREDICT has also identified products with illegal pesticides, heavy metal contamination, filth, and

decomposition, as well as substandard medical devices and improperly canned food.

FDA also developed mobile handheld devices that allow our investigators to immediately identify products that may be counterfeit or adulterated. The counterfeit detection device uses light waves to detect irregularities in the chemical composition or labeling of a drug, while the chemical detection (IMS) device identifies inappropriate chemical compounds in a product. The IMS recently identified an unlawful prescription drug—one taken off the market because it can cause heart attacks and strokes – in a large number of imported dietary supplements for weight loss. We hope to fund the development and use of more such mobile handheld devices.

4. Collaboration with other nations. To address the vast number of imports successfully, we must build a global public health safety net by partnering with other nations. FDA has signed over 120 international arrangements with foreign counterparts to create mechanisms for information sharing and collaboration. We are actively using information from, and conducting joint inspections with, trusted foreign counterparts, and engaging in harmonization efforts on foods and medical products. For example, we have signed an arrangement with Brazil, Canada and Australia to implement a Medical Device Single Audit pilot program under which a medical device inspection done by one regulator can be relied on by other regulatory agencies. Such programs can cut duplicative requirements for industry and allow us to better allocate our resources.

C. Supporting Biomedical Innovation

The U.S. food and biomedical industries are among the most successful and respected in the world and FDA plays a key role in that. FDA is sometimes viewed as a barrier to the economic success and innovation of both industries, but that does not take into account the benefits FDA regulation brings them. Public confidence in a strong FDA fosters consumer trust in the safety, effectiveness and quality of the products we regulate. This, in turn, helps producers build their markets. For example, as FDA became the model for science-based drug approval around the world, its high standards spurred decades of medical advances and turned the U.S. pharmaceutical industry into the world leader in innovative medicines.

As you know, I have made it a priority to help U.S. biomedical companies maintain their status as world leaders in innovation. It is well known that advances in biomedical research are not being translated into real world products as swiftly and surely as we all would hope. The

time and costs of developing new drugs has been increasing. Yet despite increases in research and development, the pipeline of new, innovative drugs remains disturbingly limited. Serious public health needs, such as treatments for autism and Alzheimer's disease, are not yet being met, despite years of research and investment. And many drugs are not revealed to be unsafe or ineffective until the last stages of development, wasting valuable time and resources. Through its regulatory science programs, FDA is committed to helping to develop new knowledge and tools that can help translate basic scientific discoveries and approaches into life-saving medicines, and reducing the time, complexity, and cost of drug and device development.

Investment in FDA allows our scientists to support innovation through a range of activities, including:

(1) The Innovation Pathway, which cuts the time and cost of developing and reviewing breakthrough device technologies—the first to benefit from the Pathway was a robotic arm controlled by a microchip in the brains of patients with spinal cord injuries or amputations;

(2) Greater use of genetic data to advance personalized medicine, especially in cancer therapies;

(3) New scientific tools and partnerships to learn earlier in development whether a drug or device will work and be safe, saving time and money now wasted on late-stage product failures;

(4) More guidance to industry early in technology development to help bring important new products, like the artificial pancreas, to market more quickly; and

(5) More collaboration with companies earlier in development. When companies come to us for help early in the process of testing their products, experience shows that they can shave up to five years off their development time. That's a dramatic shortening of the path to market.

D. Stretching Budget Dollars

We have also made belt-tightening a priority. We have consolidated our information technology infrastructure and administrative functions across FDA, and put in place controls to cut the cost of travel, training and conferences. We are avoiding additional rent costs by making better use of existing office space through tele-work and office-sharing, and we are reviewing contracts to cut service and product duplication.

IV. Current Budget Requests

The budget includes $4.7 billion, an $821 million increase from FY 2012. Of this requested increase, user fees account for 94% ($770 million). Mindful of the need to reduce

spending, we seek a reduced budget authority in several areas, including a $15.4 million decrease for human drug, biologic, and medical device programs. We are also asking for a small number of increases, which are necessary to meet our growing duties and preserve the safety of our food and medical products:

1. An additional $43 million to carry out our responsibilities under FSMA and to modernize our food safety system. These resources will go to building prevention-based food and animal food and feed safety systems, to reduce the toll of foodborne illnesses.

2. An additional $10 million, above FY 2012, for overseeing the safety of goods from China. This increase will add 16 new inspectors in China, who can conduct more inspections and train Chinese counterparts, strengthening our ability to prevent safety problems before products reach the U.S.

3. An additional $3.5 million, above FY 2012, to improve the development timelines and success rates for medical countermeasures intended to protect against chemical, biological, radiological and nuclear threats and new infectious diseases. The top priorities for these funds include care for U.S. soldiers suffering from traumatic brain injury, treatment of acute radiation syndrome, and supporting rapid deployment of critical medical countermeasures in emergency situations.

4. An additional $17.7 million to permit us to equip and obtain certification for four already-constructed buildings, including two labs, on the White Oak campus, so that they may begin carrying out research to support biomedical advances. Without these funds, the labs cannot be used and the $300 million cost of constructing them will have been wasted. Moreover, we will need to continue to pay rent for the old space occupied by FDA staff.

Under agreements negotiated with industry, we seek an increase in current law user fees of $500 million to support our drug, device, animal drug, animal food and feed, color additive, export, and tobacco product programs. We also seek $269 million in proposed user fees, including $225 million for food facility registration and inspection, and imports, $31 million for animal drug application fees that are up for reauthorization this year, $19 million to strengthen our oversight of cosmetic safety, and $15 million for reinspection of medical product facilities.

I know that some of you have expressed concern that proposed user fees for food producers will impose unexpected burdens, especially on small producers. Please be assured that

food-related user fees, if authorized, will be developed in close cooperation with stakeholders.

V. Conclusion

FDA's oversight of our food and medical products supply is indispensable to the health and well-being of every American. We carry out our broad public health responsibilities effectively and with few taxpayer dollars--even as those responsibilities are expanding as a result of new legislation, technological advances, and a globalized marketplace. Our FY 2014 budget targets our spending efficiently, on programs that are essential to providing Americans with the safe foods and effective medical products they expect. I look forward to answering your questions today and to working with you in the coming year.

I do want to congratulate you, Congressman Aderholt, on your new position as chairman.

And I also do want to thank the subcommittee for your past investments in FDA, which have helped reduce the gap between our budget and the demands of our increasingly complex mission.

Congress has given FDA the responsibility for a vast range of products that are central to the health, safety, and wellbeing of every American. From spinach and breakfast cereals, to vaccinations that save millions of children's lives, to new medicines to treat killers like cancer and heart disease, Americans rely on products overseen by the FDA every single day.

We also recognize that those who produce our Nation's food and medical products are vital components of the U.S. economy, as is a strong FDA. History shows that when the public trusts FDA's oversight of the products we regulate, these industries flourish. Conversely, when products cause serious harm, it can result in severe economic damage across the industry involved, to offenders and nonoffenders alike.

I want to mention some of our measurable accomplishments this past year. In 2012, FDA approved 39 novel medicines, the highest number in over a decade. And the majority of these drugs were approved in the United States before anywhere else in the world, some in as little as 3½ months. The number of drug shortages were cut in half compared to 2011. We successfully turned around a decade of lengthening medical device reviews and backlogs. Working together with 45 State and territorial partners, we have conducted more than 158,000 inspections of tobacco retailers to ensure that they are not selling cigarettes or smokeless tobacco products to minors. And we have published our first two food safety proposed rules as part of the implementation of the historic Food Safety Modernization Act.

And I might add that FDA is a smart investment and a bargain. Consider that the products we regulate represent more than 20 cents of every dollar that consumers spend on products in the United States. But if you look at our budget, in terms of the BA or public dollars, every American effectively pays only about $8 a year for FDA services.

And while FDA continues to oversee a multitude of products vitally significant to all of us, our job has become increasingly demanding.

First, we are in the midst of dramatic changes in the way that foods, drugs, biologics, and devices are produced and reach the American public. We are witnessing revolutionary advances in science and technology that hold such promise to improve health and prevent disease, yet also bring new scientific and regulatory complexities. And we are facing the globalization of our food and medical product supplies, demonstrated by a quadrupling of imports over the past decade.

FSMA

Second, Congress has continued to expand our responsibilities with new laws, including FSMA, the most sweeping reform of our food safety laws in some 70 years; the Family Smoking Prevention and Tobacco Control Act, the landmark legislation giving FDA the

responsibility to regulate tobacco products; and, most recently, the passage of the FDA Safety and Innovation Act, FDASIA, which, among other things, creates two new user fees to speed the review of more affordable versions of drugs, essential to holding down healthcare costs, and new regulatory strategies to increase our efficiency and effectiveness.

As we look at our fiscal year 2014 budget needs, we must respond to the demands of complex and increasing responsibilities while recognizing the realities of a constrained economic environment. Thus, we must focus on a set of key mission-critical programs and activities and leverage limited resources to the greatest degree possible.

The President's proposed fiscal year 2014 budget request is for over $4.6 billion, which includes $2.5 billion in budget authority and $2.1 billion in user fees. This represents an $821 million increase over fiscal year 2012, $52 million of which is budget authority and $769 million in user fees, including two new user fee proposals for food safety and cosmetics.

A central component of the budget request, as noted, supports our efforts to implement FSMA and create a modern food safety system based on prevention rather than responding after a problem occurs. FDA is committed to working with industry and our partners at all levels of government to put in place the necessary risk-based, flexible system that recognizes and respects the varying needs of different components of the food enterprise.

I want to thank you for the $40 million in one-time, no-year money that was part of the recent CR, which will help us to continue our outreach and activities. For fiscal year 2014, our budget request is $43 million and $225 million in proposed user fees for food facility registration, inspection, and imports.

FOOD SAFETY

As you know, Congress has long endorsed the use of fees to help support government agency work, especially work that meets specific industry needs as well as benefiting the American public. A broad coalition of industry groups supported enactment of FSMA because they knew they would benefit from a food safety system that works effectively to prevent food safety problems and strengthens consumer confidence in the food supply.

We cannot build this modern food safety system, including the new mandates for import oversight, without the funding laid out in the President's budget. We look forward to dialogue with Congress and all of our stakeholders to shape a fee proposal that is fair, workable, and advances both industry and public interests.

In addition, we must respond to and harness modern science to enhance the pipeline of new and better, safer medicines and vaccines. We are asking for $18 million to continue our efforts to consolidate FDA scientists and other professionals in the White Oak campus, including requirements to outfit FDA's three bioscience labs and other facilities. Without these funds, the labs cannot be used and the $300 million cost of constructing them will be wasted.

We are eager to continue this and other important work. I believe our fiscal year 2014 budget efficiently targets our needs, focusing on programs that are essential to providing Americans with

safe food and effective medical products that they expect and deserve. I look forward to answering your questions today and working with you in the coming year.

Thank you very much.

Mr. ADERHOLT. Thank you, Dr. Hamburg, for your testimony and, again, for being here this morning.

Let's jump right on in to the budget request for fiscal year 2014. Your testimony says that you are asking for an additional $10 million, which is above the fiscal year 2012, for overseeing safety of products from China and that you will add 16 new inspectors in China.

The question is, is that the same $10 million that was provided in the current CR for those activities?

Dr. HAMBURG. Yes. And I apologize for the confusion with the budget. This process has been a complex one this year with the work on developing fiscal year 2014 going forward, as there was uncertainty about funding levels for fiscal year 2013.

But we are asking for a continuation of that $10 million to continue our efforts to oversee food and drug safety in China, imports from China. So we are asking for a continuation of the base that was now established with an addition of $10 million in the fiscal year 2013 budget, not an additional $10 million on top of that.

Mr. ADERHOLT. There is $3.5 million in the request, again, above the fiscal year 2012 for medical countermeasures.

Dr. HAMBURG. Uh-huh.

Mr. ADERHOLT. Did the committee already provide this funding as part of fiscal year 2013?

Dr. HAMBURG. Again, that is a continuation of the base. We do need that additional $3.5 million. We needed that $3.5 million in fiscal year 2013 to really round out the program that we need to implement this important area, to advance medical countermeasures availability for the American public. We need to continue that money in the base in fiscal year 2014.

Mr. ADERHOLT. Okay.

FSMA

According to your testimony, FDA is seeking an additional $43 million to carry out responsibilities under the Food Safety Modernization Act, which you referred to in your opening comments. The fiscal year 2013 CR provided FDA with an additional $40 million for food safety. Does this $40 million request replace the one-time $40 million for food safety that was provided in the current CR?

Dr. HAMBURG. Well, I think in fiscal year 2013 the addition of $40 million is vitally important. We want to continue that in the base. And if that would be to occur, that there would be $40 million and we could get an additional $3 million to make $43 million in fiscal year 2014, that would be terrific.

I should note that the $40 million in fiscal year 2013 was one-time, no-year money, and that is important in terms of our ability to use it effectively. Because we do need those resources, but because they came late in the budget cycle, we would have a hard time spending all of it within the fiscal year time frame. But we do need and are counting on those resources.

WHITE OAK

Mr. ADERHOLT. You had mentioned the White Oak facility, also, in your opening comments. FDA is seeking $17.7 million for the White Oak facility.

Again, this committee provided these funds as part of the fiscal year 2013 CR, continuing resolution. Furthermore, fiscal year 2013 requests for these funds were described as a one-time request that would complete the $300 million investment at White Oak.

Again, is this the same $17.7 million that was provided in fiscal year 2013? Because the reading of the budget justification looks like the money is for the same thing that was asked for and received in fiscal year 2013.

Dr. HAMBURG. Unlike the other two issues we just discussed, this would actually be a continuing need, an additional need in fiscal year 2014. There are further requirements for fully outfitting the laboratory, training the individuals, making sure that we have certification, adding critical components to make the laboratory work, such as the loading docks for delivery and pickup of materials, hazardous material handling services, et cetera.

So those are actually additional needs on top of what was in the fiscal year 2013 funding.

Mr. ADERHOLT. Okay. Yeah, let me just clarify. It looks like from the request that it is for the same thing, so we need some additional justification——

Dr. HAMBURG. We would be very pleased——

Mr. ADERHOLT [continuing]. To provide that——

Dr. HAMBURG [continuing]. To work with you and your staff to clarify. And, again, I apologize for the confusions that may have arisen in the budget process.

[The information follows:]

The White Oak funding request is a continuing need, maintaining the $17.7 million as a base in FY 2013 and providing additional funds in fiscal year '14. The FY 2013 enacted funds provides resources to make the Life Sciences complex operational. The FY 2014 request funds further requirements to fully outfit the laboratories, make sure that we have all necessary certifications, and add critical components to make the laboratories work such as the loading docks for delivery and pick up of materials. The fiscal year '14 requests are additional needs on top of what was in the fiscal year '13 funding. Sustaining the $17.7M provided in the fiscal year '13 appropriation will allow FDA to fund these additional FY 14 needs.

Mr. ADERHOLT. Okay.

Let me recognize Mr. Farr.

USER FEES

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

I want to follow up on the comment I made about the fee structure. You are collecting fees, but you are not allowed to spend them. What kind of a backlog do you have with not being able to spend those fees?

Dr. HAMBURG. Well, you know, of course, we are just beginning to implement the sequestration cuts, but it creates a very serious concern for us.

We carefully negotiated with industry around a set of critical program goals and priority areas for work and performance measures to track our progress toward achieving those goals. And with-

out the full funding that was evaluated as necessary to achieve those goals, we obviously will fall behind. And it will have implications for a number of important activities, in terms of medical product reviews, training and recruitment of critical staff——

Mr. FARR. What will that do to the private sector who is seeking the approvals?

Dr. HAMBURG. Well, I think it is troubling to them and to us that there were agreements made, including starting two critical new user fee programs in generics and biologics that will make a real difference to the American people, and those moneys are being collected from industry, but they are going into a bank, in essence, Treasury Department, I guess. And they can't be used to support our programs and activities; at the same time, they can't be used to offset the debt, as I understand it.

So I think it is a troubling situation that compromises our ability to move forward in critical areas of mutual importance to industry and FDA and, of course, to all of our stakeholders that depend on our products.

Mr. FARR. Mr. Chairman, I would hope that we might be able to look at that, just like we are looking at giving some flexibility to air traffic controllers, like we gave flexibility to the Department of Defense, plus a lot more money to the Department of Defense. And we ought to give the flexibility in these fee structures to the FDA to be used for the purposes for which they are collected.

Let me ask you about the countermeasures that the chairman asked you about. It is 3 years since you began the countermeasure initiative, and Congress is always looking for ways to measure the success of these Federal programs.

Has the FDA approved any drugs, biologics, or diagnostics to treat chemical, biological, radiological, or nuclear threats since establishing the MCMI?

Dr. HAMBURG. Yes, we actually have made enormous progress going forward in some key areas of activity. We have had a number of important new drug approvals: antibiotics for the treatment and prophylaxis of plague; a monoclonal antibody to treat inhalational anthrax and to prevent it under certain circumstances; a botulism antitoxin, which can make a real difference both in response to a potential biological threat and also naturally occurring disease; a number of important influenza diagnostics to help us address the potential of a pandemic threat as well as seasonal flu.

We have also readied a number of products for use in an emergency. They are not fully approved but can be used as part of an emergency use authorization when there is a public health crisis, including a drug to treat smallpox and a smallpox vaccine. So these are very important advances.

And with respect to the three new drug approvals that I mentioned, they have actually all included a pediatric indication, which has been a serious gap in some of the public health preparedness and medical countermeasure availability opportunities in the past.

So it is an area of, I think, real progress that will make a difference to the American people.

Mr. FARR. My question was going to be geared toward children, and you have answered that. I am pleased to see that we are mov-

ing forward with that, and hopefully we can strongly support you in that.

One of the questions that comes up is the backlog on sunscreen. My brother-in-law, a surfer, very active guy who got melanoma and died in our house from melanoma, and we went through all the suffering that families go through. It just shocks me that we haven't done any new sunscreen approvals for a number of years, decades.

I hear there are eight pending sunscreen applications, and none of them have yet been approved, none of them. So what is taking so long?

Dr. HAMBURG. Well, we have made some forward progress on issues of labeling and some other aspects of assessing safety and indications for an appropriate use of sunscreens.

This issue that you describe is a priority for us, and, you know, we are trying to move forward with respect to both availability and safety of sunscreen products and their ingredients.

With respect to the individual applications that you are mentioning, I actually am not aware of the particulars, but I am happy to follow up with you.

Mr. FARR. Do you think something will be done this year?

Dr. HAMBURG. You know, I really don't want to speak to that since I don't know the specifics, but, as I said, I would like to follow up with you.

But this is an area—sunscreens are regulated under the monograph framework. And the sunscreen monograph is, you know, one of the highest priorities. And a process is in place to try to move forward, I know, with respect to the overall regulation of sunscreens and to enable us to really apply the best possible science with respect to safety and ingredients and also issues around using data that has been collected in other settings, as well, including overseas.

But we will follow up with your office.

[The information follows:]

The "sunscreen applications" to which you refer are time and extent applications (TEAs) that ask FDA to include eight new sunscreen active ingredients in the Over-the-Counter (OTC) Drug Review, also known as the OTC drug monograph system. In brief, TEA reviews are regulatory proceedings that are inherently complex, and must compete for resources and priority with other OTC monograph reviews and proceedings, among other FDA activities. Additionally, FDA is currently evaluating important scientific questions relating to OTC sunscreen ingredients. Because of the public health importance of OTC sunscreens, FDA is actively working to complete our review of these TEA ingredients, and expects to take action on them in the near future. We are committed to finding ways to facilitate the marketing of additional OTC sunscreen products, but must assure their safety, effectiveness, and overall risk-benefit profile.

To elaborate, the pace of FDA's ongoing review of the sunscreen TEAs is best understood in the context of the overall OTC drug monograph system, of which the TEA process is a part. In brief, the Food, Drug, and Cosmetic Act (FD&C) Act requires FDA review and approval of a new drug application (NDA) for all new drugs before they may be marketed in the U.S. To avoid "new drug" status as defined in the FD&C Act, a drug must be generally recognized as safe and effective (the GRAS/E standard), and must also have been marketed to a material extent and for a material time under the conditions described in its labeling (the material time and extent standard). The OTC Drug Review is a multi-step notice-and-comment rulemaking procedure that was established in 1972 to review the safety and effectiveness of OTC drugs then or previously marketed in the U.S. (which were presumed to satisfy the material time and extent standard), and to provide a regulatory mechanism (the OTC monograph system) allowing OTC drug products that were found to be GRAS/E to be marketed under an applicable OTC monograph rather than product-specific NDAs. OTC drug monographs are FDA regulations that describe conditions, including specified active ingredients, for marketing various categories of OTC drugs (such as sunscreens).

The TEA process (21 CFR § 330.14) was established in 2002 to provide a pathway to OTC monograph status for additional active ingredients and other conditions not marketed in the U.S. for OTC use prior to the establishment of the OTC Drug Review, by enabling sponsors to establish that a condition satisfies the material time and extent requirement based on historic marketing data other than the date of U.S. market entry. This is done by submitting a TEA containing the required marketing data, which is reviewed by FDA to determine whether or not the condition is eligible to be considered for inclusion in an OTC monograph (eligibility determination).

FDA has issued eligibility determinations for all TEAs submitted to date, and all 8 sunscreen TEAs were found eligible to continue to the next stage of the TEA process, the GRAS/E determination, which is now ongoing. TEA ingredients and other conditions must satisfy the same GRAS/E standard and evidentiary requirements that apply to other active ingredients and

conditions under the general OTC monograph process. And, consistent with the general monograph process, ingredients found eligible for review under TEA applications are subject to multi-step notice and comment rulemaking procedures before they may be included in a final OTC drug monograph.

As the preceding background indicates, the process for establishing and expanding OTC drug monographs can be lengthy and resource intensive. It has been particularly challenging for OTC sunscreens due to evolving scientific information and changing patterns in OTC sunscreen use. In the 1970s, sunscreens were used primarily on a seasonal basis, to prevent sunburn among consumers with the fairest skin coloration, and sunscreen active ingredients were not thought to penetrate beyond the skin surface. Today, sunscreens are used routinely by a large percentage of the population and in large amounts covering a much greater body surface area, with the result that the extent and duration of consumers' exposure to sunscreen ingredients is orders of magnitude greater than it was in the 1970s. There is also increasing evidence that some sunscreen ingredients can be absorbed through the skin, leading to systemic exposures to these agents that was not previously anticipated or evaluated. These shifts in sunscreen usage, together with advances in scientific understanding and safety evaluation methods, have given rise to new questions about what information is needed and available to support general recognition of safety and effectiveness for both currently marketed sunscreens and ingredients seeking inclusion in the monograph via the TEA process.

Within FDA, there has been an active examination of these important scientific questions, one result of which was significant new rulemaking in 2011 that focused primarily on updated efficacy testing and related labeling issues. We also are engaged in an ongoing internal evaluation of current sunscreen safety issues and evidentiary standards, which is directly informing our evaluation of all sunscreen active ingredients, including the eight TEA ingredients.

Mr. ADERHOLT. Mr. Rogers.

OXYCONTIN

Mr. ROGERS. Thank you, Mr. Chairman.

Commissioner Hamburg, as we discussed last week on the phone and other times, I am thrilled by the FDA's decision to keep crushable generic OxyContin off the market. Young people, especially, were crushing those time-released pills, the 12-hour pill, crushing it, injecting it, and getting the immediate high from the 12-hour dose all at once. So I salute you for that. That will keep very dangerous drugs off of the street and out of our kids' hands.

From a legal perspective, FDA determined that the reformulated OxyContin, the noncrushable one, did, in fact, possess abuse-deterrent characteristics and that the original crushable formulation was indeed removed for reasons of "safety or effectiveness," end of quote.

Dr. HAMBURG. Uh-huh.

Mr. ROGERS. Now, that decision dealt with OxyContin, the Purdue Pharma product. How many other drug manufacturers currently have applications for abuse-deterrent formulations?

Dr. HAMBURG. You know, there is another product that is being looked at in that context, not in terms of a specific new application but in terms of whether or not it, in fact, meets the criteria for abuse deterrence.

This is an important area, and one of our hopes is that we can better incentivize industry to work with us to develop models of abuse deterrence, to strengthen the existing approaches, such as the one used by Purdue in their product, but also develop new approaches, because we think this needs to be dynamic, as unfortunately abusers will no doubt figure out ways to overcome some of the abuse-deterrent strategies.

So we put out a guidance, as I think you know, about how we think about criteria for meaningful abuse deterrence, and we are continuing to really try to work with industry to encourage more innovation in this area. We would like to see more product applications before us.

Mr. ROGERS. What standards will you apply in deciding whether these drugs will be approved and labeled for abuse deterrence?

[The information follows:]

As explained in the draft guidance entitled *Evaluation and Labeling of Abuse-Deterrent Opioids* (issued in January 2013), FDA generally will approve labeling describing a product's purportedly abuse-deterrent properties if, based on its review of all the available data, FDA concludes that those properties can be expected to, or actually do, result in a significant reduction in the product's abuse potential. If that standard is met, then the relevant data, together with a clear and accurate characterization of those data, should be included in product labeling. The draft guidance discusses the four categories of abuse potential studies FDA will examine to make its assessment, as well as examples of language that may be appropriate for inclusion in product labeling based on those data. FDA has received comments and will hold a public meeting on this draft guidance planned for September 30 to October 1, 2013. After that FDA will develop a final guidance.

Dr. HAMBURG. Well, it is outlined in the guidance. And I regret to say there are four criteria, as I recall, but I don't think I can reproduce them for you here.

But the critical issue is whether, in fact, it can be demonstrated that they do what they say they do, that, in fact, they behave in ways that will significantly reduce the ability to crush and inhale or crush, melt, or otherwise liquify for injection these products. And we need to sort of see it scientifically in the laboratory context and also, you know, some evidence in terms of actual clinical experience.

Mr. ROGERS. Well, we want to be sure that the same standards are applied to generics and others as was applied to OxyContin.

Dr. HAMBURG. Absolutely.

Mr. ROGERS. And I am sure you are agreeable with that.

Dr. HAMBURG. I am.

Can I just underscore, though, it is also very important that just because a company claims it is abuse-deterrent, it doesn't mean it is. So it is really in everybody's best interest that we try to have standards so that we can really achieve the goal. We don't want the standards to be so high that nobody can actually meet them.

Mr. ROGERS. Right.

Dr. HAMBURG. We want to incentivize industry to work on these kind of products.

Mr. ROGERS. Well, you are doing good work in this regard, because the Centers for Disease Control calls prescription drug abuse an epidemic. It is killing more people than car wrecks, especially young people. So your decisions so far, I think, will save lives.

Let me ask you quickly about rescheduling hydrocodone combination drugs. In late January, the FDA Drug Safety and Risk Management Advisory Committee voted almost two to one to tighten restrictions for prescribing hydrocodone combination drugs. You don't have to follow their recommendation, but I am trying to figure out whether or not you will. I hope you do.

Emergency room visits involving hydrocodone rose from 38,000 in 2004 to 115,000 in 2010. These drugs are often taken in combination with other drugs and/or alcohol, one of the most popular being what is called the holy trinity, a combination of hydrocodone with a sedative like Valium and a muscle relaxant.

The current Schedule III classification for hydrocodone projects a false sense among some patients and doctors that Vicodin or Lortab are less potent or less habit-forming and, therefore, less dangerous than oxycodone painkillers, which are Schedule II.

Prescriptions for Schedule II drugs can't be called in. You need to see a doctor to get a new prescription for each refill after 90 days, no automatic refill. As a result, while almost every opioid painkiller is considered a Schedule II drug and more carefully regulated, the most abused narcotic, hydrocodone, is missing from that list.

So we have made pleas by letter to you. And I am wondering when you will decide this issue and where you think it is going.

Dr. HAMBURG. Well, it is an ongoing process, as you know. We did have an advisory committee, and, of course, you know, important information was discussed and they made a recommendation to us. We are looking at the information presented in that committee and other information that has come in to us from a range of stakeholders with, you know, frankly, differing perspectives on this issue, and trying to address the important issue of balance of

access to critical medicines for legitimate medical needs and, you know, the potential, as you note, for abuse and misuse.

We will be making a recommendation soon. I can't really speak to the direction that we are going or the specifics of timing. But I can assure you, Congressman Rogers, that when a decision is made, as I did with the other abuse-deterrent issue, I will reach out to you and let you know.

Mr. ROGERS. Well, I thank you. And I thank you for reaching out to me when you made the ruling on OxyContin.

Finally, Mr. Chairman, on the matter of the labeling of the opioid narcotics, which up until now has said can be used for moderate to severe pain, I think it has misled doctors and patients that it is not as addictive a drug as it really is. And we have been pleading with FDA, I have for now 10 years, to restrict the labeling on OxyContin drugs and similar to just severe pain, which it was intended for, I think, in the first place.

It is a great drug, a 12-hour release, for people who have horrible pain, terminally ill patients. But it has been thrown out there for toe aches and toothaches and everything else, misleading people that it is not as habit-forming and difficult to kick as it really is.

Can you tell me when we might get some sort of indication of what may happen on changing the labeling to strike "moderate"?

Dr. HAMBURG. Well, again, Congressman, as you know, we are in a process of consideration of these important issues and what is the appropriate management of acute and chronic pain with respect to this class of drugs. And we had a public meeting to hear presentations and get expert and public comment on these issues. We are reviewing that.

We take the issue very, very seriously. We believe that FDA labeling and indications for use is an important component of what needs to be, of course, a multifaceted strategy to address this really critical and urgent public health problem. And we, you know, are actively engaged.

I want to commend you for the leadership that you have taken on this issue and others, in terms of really making sure that adequate attention is paid and there is a sense of urgency. We do feel that and are working hard to really address it in a meaningful, scientifically based way.

Mr. ROGERS. Well, it shouldn't be a very difficult decision. I can't imagine why we would want to keep "moderate pain" labeling for such a dangerous drug that has proven a killer around the country.

Congressman Frank Wolf and I, 10 years ago, came up to FDA and testified about this very issue of removing "moderate" on the label, which invites doctors and patients to use it for less than severe pain, and nothing happened. That was 10 years ago. So we have been sort of a lone wolf out there in the forest crying for help, but now we have some help. We are not alone anymore.

A citizens' petition submitted to the FDA this summer, clinicians, researchers, health officials, all of them asking FDA to change the way opioid narcotics may be prescribed. They argue that, with the proper labels on prescription painkillers, physicians would be more aware of the safety concerns and effectiveness of certain opioids before unnecessarily prescribing highly addictive narcotics to patients for minor pain.

So there is a growing consensus, I think, out there to do this and do it now.

Dr. HAMBURG. Well, we have heard you and your concerns, and we take them very seriously, and those of other stakeholders as well.

As you know, we have taken steps with respect to some aspects of the labeling of opioids, the REMS that have been applied to the class of opioid drugs; voluntary requirements, as part of that, on physician education, which I think is absolutely key.

We are hoping that there will be legislation that will actually include mandatory training as part of the DEA licensing for physicians who use these products because they are so powerful, both in effective treatment when indicated but also the potential for abuse.

And we will be coming forward with a specific response to your question very soon.

Mr. ROGERS. Well, I thank you. Thank you for being here.

Dr. HAMBURG. Thank you.

Mr. ROGERS. I yield back.

Mr. ADERHOLT. Thank you, Mr. Rogers.

We have been joined by the ranking member of the full Appropriations Committee, Mrs. Lowey.

And I will recognize you for any opening statement and also any questions that you may have at this time.

Mrs. LOWEY. Thank you, Mr. Chairman.

And welcome, Commissioner Hamburg. We are indeed fortunate to have a person of your caliber in this position. Thank you very much.

This week, there has been a lot of attention paid to the damaging effects of the sequester on the FAA and commercial air travel. While flight delays are an inconvenience and represent real economic losses to individuals, families, and businesses in New York and across the country, we can't ignore the real and dangerous effects of the sequester in other areas of our budget, especially when they have a profound consequence for public health.

From frozen TV dinners to medical countermeasures, to addressing nuclear threats, to new drugs that treat major causes of death like cancer and heart disease, the American people rely on FDA and its expertise to review and approve products they use every single day.

The repercussions of congressional inaction to replace the sequester are clear at the FDA. The agency will undertake 2,100 fewer inspections, which is at an 18 percent decline compared to last year. The implementation of the 2011 Food Safety Modernization Act will be further delayed, meaning we can continue to expect an estimated cost of $75 billion annually in lost productivity and medical expenses. And new drugs that reduce pain and sustain life will take longer to review and approve, robbing sick Americans of improved quality of life and more time with their loved ones.

By cutting services and decreasing investments critical to our economic competitiveness, these across-the-board budget cuts are having a severe impact across all sectors of our economy. We must replace reckless, indiscriminate cuts with a renewed focus on jobs, economic growth, and a balanced fiscal package that creates long-term deficit reduction.

And I just want to say, I look forward to a day soon when Chairman Rogers and I can work together in a bipartisan way and really address the serious issues as a result of sequestration, bring about regular order and do a budget that makes sense for the American people. We know that the discretionary budget is at its lowest level in the last 45 years as a percent of GDP. That is unacceptable.

So I guess I made my message clear. Let me ask you a few questions.

CELIAC DISEASE

First of all, millions of Americans with celiac disease or gluten intolerance have been waiting for the FDA to finalize a standard for gluten-free labeling. Of course, it took me 5 years to get bipartisan support for just labels on food, which is food allergies, celiac disease, et cetera.

GLUTEN-FREE LABELING

In 2004, the Food Allergen Labeling and Consumer Protection Act that I authored became law. One of the provisions required the FDA to create a gluten-free labeling standard by August 2008. Nearly 5 years past the deadline and 9 years since the law was signed, I am still waiting for the administration to finalize the rule.

I know that the rulemaking process is complicated. FDA must work with OMB and others. But when will a rule be finalized which will give those with celiac disease the peace of mind that the foods they purchase are truly gluten-free?

By the way, no matter who I speak to, everyone seems to be going on a gluten-free diet. So it would be really helpful if we could be assured that what is declared gluten-free really is gluten-free.

Dr. HAMBURG. Well, you are right, this is a really important problem. And it does turn out, as we learn more about the nature of celiac disease and also broader nutritional concerns, that a gluten-free diet is benefiting more and more Americans. And it is critical that people have that information about the nature of their products and what is gluten-free.

I had hoped I might have been able at a hearing at this moment in time to have been able to speak to the rule actually having been issued. It is in the final stages of administrative review, and I really do believe that you will see it soon. And as I promised Congressman Rogers on another matter, the first call I make will be to you.

Mrs. LOWEY. I hope it is soon. I think it is really very important.

DRUG COMPOUNDING

Another area that I have been particularly concerned with, as we all have, is drug compounding. The safety of products sold by compound pharmacies, particularly following last year's deadly meningitis outbreak, is a serious concern.

In an effort to crack down on unsafe facilities, the FDA has recently conducted a number of inspections of these pharmacies. Could you share with us your findings?

Dr. HAMBURG. Yes. Well, we did recently undertake a fairly aggressive effort to do about 31 surveillance inspections of facilities that we considered potentially high-risk because they were making

sterile injectable products. And we knew about them either because of past problems because of States telling us that they thought they should be on the high-risk list or, in some cases, what we learned, you know, from public and the media. And we also did another set of for-cause inspections in relation to reports that we were getting of actual concerns about products.

I would have to say that those inspections were very concerning, because we did find real sterility concerns at many of the sites. I would underscore that these are facilities that, for the most part, aren't required to register with the FDA because they are compounding pharmacies, so they are not routinely inspected by us. But when we went in and looked at their standards for sterile processing, there were very real reasons for concern.

We actually undertook a number of recalls of products that we thought represented a more imminent risk. And we certainly believe that it underscores the importance of a stronger, clearer regulatory and legal framework for oversight of these kinds of facilities.

I think it is also really striking that, even in light of recent events, we had real trouble with a number of these inspections going in, having our authorities questioned. In two cases, we actually had to go to the courts to get administrative warrants so that we could do the full inspections and have access to the records that we needed to both assess what they were making and their business practices and really understand the risk.

So we have indicated a very serious and urgent desire to work with Congress to create new, stronger, clearer legislation to provide the oversight of these facilities that I think the American people deserve and expect.

Mrs. LOWEY. Well, I certainly hope, Mr. Chairman, we can continue to work together to resolve this huge challenge.

I have been told in talking with some people, since last year's deadly outbreak, there have been recalls, reports of additional serious infections, cases of reported blindness, loss of the eye associated with the use of repackaged Avastin for off-label treatment of wet age-related macular degeneration.

So, as a clinician, I would assume you would agree that certain areas of the body, such as the eye, the brain, the spinal column, are least able to defend against infections and, thus, that any repackaged or compounded products which are injected into these areas, if they have compromised sterility, have a higher likelihood of causing injury or even death.

So I would hope—and I will conclude, Mr. Chairman—that the FDA would consider prioritizing its oversight, while we are working on regulations, and enforcement activities to focus on those compounded or repackaged products that pose the most significant risk patients based on such risk factors.

And would all patients benefit from a single quality standard relating to sterile injectables?

Dr. HAMBURG. We definitely believe that there needs to be clear, explicit standards for sterile practices that apply in a uniform way.

In terms of FDA regulatory oversight, we think we can provide the greatest benefit in terms of where the risks are by really addressing, as you note, sterile injectable products. Those facilities that are making sterile injectables in advance of or without a pre-

scription and selling across State lines, we think, represent the category that really presents the highest risk to the American public, though we think that, you know, clearly, any sterile product should be made in accordance with sterile procedures.

Mrs. LOWEY. Well, thank you, Mr. Chairman. It seems so obvious, it is shocking to me that this is a such a huge issue out there. And it is costing people their eyes, in some cases their life, and enormous expenses in trying to treat it.

Thank you very much.

And thank you, Mr. Chairman.

Mr. ADERHOLT. Thank you, Ms. Lowey.

Mr. Yoder.

Mr. YODER. Thank you, Mr. Chairman.

Commissioner, thanks for being here today.

BUDGET REDUCTIONS

You know, as we have this discussion about how to properly handle the sequester and how to resolve the budget reductions that you are facing, you know, it is interesting to note that the Federal Government continues to grow at pretty significant rates. This year, the Federal Government will have more tax dollars from the American people than at any other time in history. Yet we are still running record deficits.

And so I think we all know that, as you endeavor to try to figure out how to do more with less, and you are getting greater and greater requirements put upon you based upon implementation of the Obama healthcare bill, new laws passed by Congress—those are additional requirements that your agency didn't have some time ago—that that is what the private sector has had to deal with.

And so, I know you get that. But just in context, while we have this debate and think about how we have to handle these reductions, for most of the American people, they have had to deal with much more than this. Folks have lost their jobs. They have had, you know, hours cut, salaries cut. I talked to a constituent yesterday who is having her hours cut because her employer doesn't want to have her have over 30 hours to qualify under the healthcare bill.

And so, huge problems in the economy, some of which have been created by policies that have been pursued by Congress over the past few years that increase mandates on businesses, increase the cost of doing business. And I want to talk about a couple in particular of those, and then I have a few questions for you.

One of the impacts on the economy have been billions of dollars in unfunded mandates, trillion in taxes, the healthcare law. We just raised taxes on January 1. And so, if those burdens weren't enough, we now have Federal food labeling mandates, which I know your agency is engaged in, on local grocers and convenience store owners. All of this is obviously, of course, bad for the economy, job creation, drives up the cost of doing business.

FOOD LABELING

And so, I know one of the mandates on the FDA was to try to help those requirements coming from the healthcare law have the most affordable way to be implemented. And so I guess I would ask, where are we on those food labeling requirements? Are we

working hand-in-hand with our grocers and convenience store owners to ensure that these healthcare mandates that are required by law to come down the pike that you have to create rules for can be done in the most cost-beneficial manner as possible?

And do we know what the impact is in terms of the outputs that these convenience store and grocery store owners are going to have to pay?

Dr. HAMBURG. Well, the healthcare reform act did include menu labeling, as you note, for chains of 20 or more and also for vending machines when there are 20 or more by the same owner. And we have been doing rulemaking on that, and it has been an extended process with proposed rules, you know, notice and comment. And we are now working through all of the comments that we have gotten in that process to put forward the final rule.

One of the challenges of this, you know, to be frank, has been really defining what is a restaurant-like establishment. You know, what a restaurant is seems very straightforward, and I initially thought that implementing this was going to be, you know, one of the easier tasks before the FDA, but it has been actually enormously complicated. And, you know, some of the issues about convenience stores, box stores, movie theaters, different kinds of facilities that sell prepared food have all been, you know, part of the discussions and considerations.

And we have attempted to look at both the public health impact and, of course, you know, the economic analyses required to look at the requirements for implementation, trying not to make an excessively burdensome rule but one that will have meaning and reflect the spirit of the legislation.

So we will be, by the end of the calendar year, I think, putting out the final rule on menu labeling.

Mr. YODER. Do we know what the cost to comply is? I have seen some reports saying that it would be up to a billion dollars on grocers and convenience stores, and I have seen reports showing less. Does your agency have an idea of what this will cost these——

Dr. HAMBURG. Well, the final——

Mr. YODER [continuing]. Small-business owners? And how can the FDA help reduce those costs?

Dr. HAMBURG. Well, I think there have been various estimates out there, as people have sort of thought about different models for how the contours might be defined in terms of the broad array of restaurant-like establishments.

You know, the final determinations have not been made in terms of which kinds of facilities will be in and which won't be. But we are looking at economic analyses as well as public health implications with respect to the overall consideration of the appropriate regulatory——

Mr. YODER. And I have one question regarding the PDUFA user fees. When those fees are sequestered, do those fees go back to the paying entities, or are they allowed to be spent at a later date by the FDA? Is this a delay in expenditures, or is it actually a cut? And if it is a cut, then do the fees go back to the paying entities?

Dr. HAMBURG. You know, I think that is a question that is still being resolved at higher levels than I. The user fees are being sub-

ject to the same levels of cut in sequester as budget authority dollars. Those fees are still being collected from industry——

Mr. YODER. Right.

Dr. HAMBURG [continuing]. But they are not going to support the FDA programs that were negotiated with industry as part of the collection of those user fees.

Do you want to speak to——

Mr. COCHRAN. I guess the only other thing I would have to add is that FDA and the user fees, with regard to sequestration, follows guidance under OMB. And our understanding is that those dollars are held basically in FDA's account, and the only way that FDA would have the authority to spend them would be if Congress took action to effectively reappropriate them.

Mr. YODER. So, essentially, the money is still there. It is not necessarily a cut, it is a delay in spending; that FDA may get those dollars at a later if Congress gave them that permission.

And I have to yield back.

Dr. HAMBURG. I don't know that for sure, but that would be——

Mr. ADERHOLT. Ms. DeLauro.

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

And welcome, Commissioner. Thank you for the great job that you do with an amazing portfolio, which includes foods, drugs, devices, tobacco. It really is pretty extraordinary.

And to that, I want to make a note about user fees, if I can quickly, so I can get to my questions. The FDA budget without user fees is $2.5 billion for 2014. Contrast, the request for NASA is $17 billion for 2014. Move back to 2013, you got $2.3 billion, NASA got $17 billion. It is 7.3 times larger than the FDA.

Again, review the portfolio of this agency and what it does. We are not talking about hardware. We are not talking about—we are talking about life and death at the Food and Drug Administration. If we are serious, let us provide the FDA with the budget authority that it needs commensurate with the job that it does. And let's start, in fact, putting our money and our dollars where our mouths are. And I would rather have budget authority than user fees any day of the week and am willing to vote to give this agency the money it needs to get there.

Before I start the questions, I am glad to hear that the FDA has moved forward on reclassifying tanning beds to their appropriate risk category, and long overdue. We will wait to see where we are.

I hope to see, as the author of the—I would just say to my colleague, I authored the menu labeling rule, and it became part of the ACA, and it was to include movie theaters, chains—we are talking about chains—chain grocery stores, and all similar retail establishments.

I just want you to know—and this is about the movie industry, who claims that they are not in the food business. I take pictures when I go. This is chicken tenders, a chicken tender combo, hot dog and fries, cheese fries, a curly fry cone, mozzarella sticks, and funnel cake. We are not talking popcorn and soda any longer at movie theaters. We are talking about hot and cheesy and a kid's pack here, pretzel bites. Go to the movie theater, take pictures, and find out what business our movie theaters are in these days.

So this is a key part of their marketing and their profit. And they ought to be required to label in the same way that the Restaurant Association agreed—and we worked very, very closely with the Restaurant Association to agree to put the calories up on the board.

Dr. Hamburg, let me talk about—the question I really want to ask here is, the Trans-Pacific Partnership, that trade agreement, those negotiations are under way. I understand that some segments of the food industry are strongly advocating for a binding dispute resolution. What are your perspectives for making the SPS provisions subject to binding dispute settlement?

Dr. HAMBURG. Well, as you know, these are ongoing discussions and involve very important issues. We are a partner across government in these discussions. Our role is obviously to make sure that important issues of public health and public safety are adequately addressed in the agreements that are ultimately reached.

We do think that there is a very clear role for incorporating technical consultative cooperation as part of a dispute resolution mechanism. Our concern, of course, is that we want decisions about the safety of imported products, the appropriateness of bringing certain kinds of products in for the American people, that those questions are adjudicated with the right subject-matter experts based on the best possible science and knowledge about the public health and medical implications.

And so I think the issue of, you know, whether it is a binding dispute mechanism is one that needs further discussion and exploration. Because we would never want to be in a position where critical decisions would be locked into that might not reflect the best possible science, the subject-matter expertise necessary to best serve the health of the American people. And, you know, one needs to really think through what are the unintended consequences of various approaches that could be undertaken.

Ms. DELAURO. There is a danger, in my view, about the integrity of the standards that are imperative to consumers and confidence in our food safety. I will just say the substance, ranging from the inspection process to specific microbiological standards, our zero tolerance for some of the most dangerous pathogens, can be put in harm's way if we move in this direction.

I will continue to follow this with you. And I am hopeful. And maybe at another point, I want to know about your seat at the table in those trade negotiations and the weight of your voice in that effort.

Thank you, Mr. Chairman.

Mr. ADERHOLT. Thank you.

And let me just say, we are going to try to stay to the 5-minute rule as close as possible because votes are coming up.

So, at this time, I would like to recognize Mr. Valadao.

FOLIC ACID PETITION

Mr. VALADAO. Thank you, Mr. Chair, Commissioner.

Hispanic women are 20 percent more likely to have a child with neural tube defect, a devastating birth defect that can be permanently disabling or deadly. Up to 70 percent of these defects can be prevented if women of childbearing age had adequate levels of

folic acid, B vitamin, before and in early pregnancy. For over a decade, our Nation has mandated that folic acid be added to enriched cereal grain products. Unfortunately, this does not include corn masa flour, a staple of many Hispanic women's diets.

I understand that a petition was filed with the FDA over a year ago that proposes to allow the addition of folic acid to corn masa flour in products such as corn tortillas and tacos. What is the status of FDA's review of this petition?

And I would urge you to ensure an expedient and reasonable review of the petition and be mindful that neural tube defects continue to occur while the FDA deliberates.

Dr. HAMBURG. This is a very important public health issue, and I have, you know, been briefed on it and am aware of the citizens' petition.

I am not up to speed on the timing of that review, and, if I may, I would like to get back to you with the specific information on that. But it is certainly an issue that is on our radar screen and being worked on. And I will give you some more specific information, if I may.

Mr. VALADAO. All right. Thank you.

Mr. ADERHOLT. Ms. Pingree.

Ms. PINGREE. Thank you, Mr. Chair.

Thank you very much for being with us here today. It has been fascinating to hear the wide-ranging level of information that you have to cover. And I know there is a tremendous amount of responsibility that rests with your Agency. So thank you so much for your very hard work.

I hear about the FDA from my constituents in a variety of ways. And I just want to take on one of the issues right now that you have talked a little bit about, and that is the Food Safety Modernization Act and the rule implementation that you are going through.

I want to start by saying we all want our food to be safe, and every day we hear about a concern that people have about making sure our food is safe. I represent a lot of farmers, and I know I can say that I have never met a farmer who does not take very seriously their responsibility to produce good, safe food for consumers.

I also want to commend my colleague, Rosa DeLauro. I know she worked so carefully to produce a bill that produced and ensured food safety for consumers. So I know that she also, from the consumer side, has been working extremely hard, as so many other Members of Congress have.

During the debate on the Food Safety Modernization Act, Congress had a healthy discussion about one-size-fits-all regulations and how best to assess where risk actually comes from. I was encouraged the other day in the Senate hearings when Senator Tester was successful in reminding everyone that he had included a provision in the final food safety bill that works toward making regulations more workable for small and midsize farms involved in low-risk supply chains. And while I am encouraged that that is in there, I remain very concerned about the impact of the final rules on diversified small food producers.

Unfortunately, for my first 4 years in Congress, I have heard almost nothing from the farmers in my district but fear, frustration,

confusion about how the food safety rules are going to be implemented. They want to know how the rules will impact them and how they will fit into the system. They are very concerned about the cost and administrative burden that it will put on them and whether or not they will be able to stay in business.

I have often talked frequently in front of this committee about the growing role of local foods and agriculture and how people are very interested in buying food from small retail outlets, from local foods, from CSAs, farmers markets.

So I just want to make sure—and I know you have a lot of work left to do, and this is kind of long, but it is a deep concern of mine. I really want to make sure that you are looking at diversified operations, that you have those farmers in mind as you work to improve the proposed rule, and that you are scaling the regulation to the size of the farm and the amount of risk.

The fact that different supply chains pose different levels of risk in our food supply must be part of the guiding principle that the FDA works with. I don't think that we want something that looks like a repeat of what happened with HACCP in the meat-processing rule a long time ago, which had the unintended consequence of shutting down hundreds of small meat processors, because they could no longer afford to do business. And it, in my opinion, hasn't provided the consumer with necessarily all safe or all perfect food.

Some of the FDA estimates have said that the cost to comply with this proposed produce rule for farms with less than $250,000 of annual revenue will face over $22,000 in compliance costs. For many farmers who are just getting a start or are starting to grow or small farmers in my district, that is their profit for the year.

So I hope you are looking carefully at how these rules will be imposed, really understanding some of the aggregation, food hubs, things that the Department of Agriculture on the one hand is promoting and we are finding great success with, and making sure that, as you look through how these rules are implemented, that there isn't an onerous burden and, in fact, it makes our food safer, but doesn't cut out the small and medium-size farmer.

PROPOSED RULES—FSMA

Dr. HAMBURG. Well, I could give you a very quick answer to a very important question, which is that we are very mindful, we take this very seriously.

We have tried, as we were shaping the proposed rules, to really do a lot of outreach, meet with the diverse grower community and actually, you know, go on to many of these different kinds of farms to get a better understanding of their issues and concerns.

Of course, the original Food Safety Modernization Act did have the Tester amendment that excluded certain size farms and with limited distribution areas altogether. But as we think about the rules going forward and, of course, as we get feedback on the proposed rules that are out there for comment, you know, we are very much recognizing this set of issues.

I think no matter who is growing and producing the food, you know, at the end of the day, everybody wants safe food. But we do need to recognize that the approaches need to be tailored to unique and differing needs, including both some of the approaches and also

the phase-in to enable and support farmers who are trying to make a living and trying to produce safe, high-quality food.

Ms. PINGREE. Well, thank you very much. I am out of time, but I just want to say I am looking forward to working closely with the FDA. This is, as I said, an issue that I have heard probably as much about as anything else since I have been in Congress from the farmers and food processors in my area. And I hope we can continue to have a conversation about this. Thank you.

Thanks, Mr. Chair.

Mr. ADERHOLT. Mr. Fortenberry.

Mr. FORTENBERRY. Thank you, Mr. Chairman.

Thank you, Dr. Hamburg, for appearing today.

Is our imported food safe?

IMPORTED FOOD SAFETY

Dr. HAMBURG. You know, we are very fortunate in this country to have one of the safest food supplies in the world, but as the world has become more globalized, the volume of imported food has increased dramatically, and many of the foods that are being imported into this country are coming from places with much less sophisticated regulatory oversight and are commodities that are vulnerable intrinsically.

And, you know, I did see a survey recently that showed that 61 percent of the American people are very concerned about the safety of imported food, and it is a concern that I share.

And we are really making aggressive efforts at the FDA to respond to the growing volume of food safety imports, doing it in a number of different ways. But we feel that we have to strengthen oversight of these products in order to assure that the food Americans get in the grocery store and in other settings is as safe as it can possibly be, whether it comes from an imported source or a domestic source.

Mr. FORTENBERRY. This is an interesting article, in The New York Times last year, "China's Corrupt Food Chain," talking about how there is a significant lack of business ethics as well as distrust among Chinese people of their own food supply.

Now, I don't know what the percent of food that we import comes from China. On medical devices, another category, I think you have pointed out that 80 percent of it comes from either China or India. So I don't know how that correlates to food imports——

Dr. HAMBURG. Right.

Mr. FORTENBERRY [continuing]. But I assume it is a significant percentage. And then 80 percent of our seafood is coming from overseas. And, again, I don't know how that correlates to China. But the larger generality here is that, given the aggressive expansion of food imports, there is real reason to be concerned here.

CHINA FOOD SAFETY

Dr. HAMBURG. Yes. And, you know, we are very focused on a set of critical products and our working relationships with critical regions of the world that are importing products to us.

China is a major partner in our efforts to improve food safety. We now have——

Mr. FORTENBERRY. Well, could you unpack that statement? Explain what that means, precisely.

Dr. HAMBURG. It means that we do get a large volume of products, food and medical products, from China, including active pharmaceutical ingredients in drugs used here. It means that we do need to really have a robust regulatory framework to address concerns, both known, existing concerns and also ones that we can anticipate possibly in the future.

We now have three offices in China—Beijing, Shanghai, and Guangzhou—to strengthen our ability to be on the ground working with both industry and regulators in China——

Mr. FORTENBERRY. What percent of the——

Dr. HAMBURG [continuing]. Doing more inspections. We have asked——

Mr. FORTENBERRY. What percent do we inspect?

Dr. HAMBURG. The percentage of facilities overseas that we are able to actually inspect is not very large. I don't know what the number is.

We are doing many more foreign inspections than we have ever done in the past, but we are not going to be able to inspect our way out of the realities of the modern world and the challenges that we face. We also have to put in place new systems that involve new cooperative arrangements with regulatory authorities, more sharing of information, sharing of the workload in terms of inspections. We need more sophisticated screening methodologies that are based on risk. And we need industry to work with us to put in place the kinds of supply chain protections that are——

Mr. FORTENBERRY. My time is running short. I am sorry to interrupt you. But does the American taxpayer subsidize the inspection of food imports? In other words, what is the mechanism here by which those are paid for?

Dr. HAMBURG. Our inspectional program, whether it is domestic or imported, comes out of our budget. We in this budget are asking for user fees to also help to support some of our important import oversight activities and inspection activities. But, yes, our activities, whether domestic or international, for food safety come from our available budget.

Mr. FORTENBERRY. Thank you, Mr. Chairman.

Thank you.

Mr. ADERHOLT. Mr. Bishop.

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

And thank you very much, Dr. Hamburg, for being here with your team.

ANTIBIOTICS LIVESTOCK

I have some questions I would like to explore with regard to antibiotics and livestock and poultry. I have consistently tried to look out for industry as well as the consumer and try to balance when it comes to regulations. And my thoughts have always been that regulations should be based in sound science, that they should be subjected to a cost-benefit analysis, and they should make common sense.

And I appreciate very much, and this committee does, the FDA's efforts to examine the sales data of antibiotics. But some are say-

ing that the data that you are collecting is flawed because of two things: One is that the data includes antibiotics that may be used on non-livestock species, and also because the data includes tracking ionophores.

IONOPHORES

Given that the mode of action for ionophores is extremely different from that of antibiotics and that, to the best of my knowledge, the use of ionophores in livestock does not pose any risk to humans, why does the FDA still classify ionophores as antibiotics?

And I am going to ask my second question since we are running short on time. The fact that you monitor antimicrobial resistance and you keep track of trends in both the grocery store and on the farm, we have heard that the NARM program is currently undergoing some changes. And so I would like for you, after you answer the first question, to share with us why the program is being changed, what changes you are proposing, and particularly what changes with regard to home farm monitoring.

Dr. HAMBURG. Well, you have asked a lot of questions embedded in one and on very important public health issues.

The problem with antibiotic resistance for both humans and animals is a very serious one, and we need to protect our ability to have antibiotics that really work against important infections.

The use of antibiotics in animal populations is certainly a contributor, a major contributor, to some of the resistance that we have seen evolve over the years. And, you know, we are making very concerted efforts both to really understand the nature and scope of the problem and to address it.

Importantly, you know, we are taking actions, as I am sure you know, to really achieve judicious use of the antibiotics that we have in both animal and human populations, but, with respect to animal husbandry, to make sure that antibiotics are not inappropriately used for growth promotion but are used to treat infections——

Mr. BISHOP. I appreciate that very much.

Dr. HAMBURG [continuing]. Under the guidance of veterinarians.

We do feel that our NARM system is very important, but that leaves——

Mr. BISHOP. Excuse me. Before you get to the NARM system, the part of ionophores, which are different from antibiotics and which, from my understanding, has not proven to contribute to any resistance in humans.

Dr. HAMBURG. You know, I think that I can give you the best possible answer if we get back to you as part of the record, because I am not directly familiar with the data on ionophores.

Mr. BISHOP. Okay. And make sure that when you do get back, that it is based in sound science.

Dr. HAMBURG. Well, I will do my best. That is a guiding principle.

[The information follows:]

FDA clasifies ionophores as "antimicrobials" because they are used to treat infections in animals caused by certain non-bacterial microorganisms called coccidia. Section 512(1)(3) of the Federal Food and Drug and Cosmetic Act requires sponsors of antimicrobial new animal drugs to submit to FDA on an annual basis a report specifying "the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals." This section also requires FDA to

publicly report annual summaries of this antimicrobial sales and distribution data, which includes ionophores.

But with respect to NARMS, you know, we are looking at it. We put out an ANPRM to get input from the public and stakeholders about how we could, you know, really effect some enhancements to our data collection systems to better inform our decision-making and make sure that we have good, solid data.

Mr. BISHOP. Thank you for that answer.

But I was struck to find out that it appears that FDA is categorizing as antibiotics ionophores, which are quite different and have a different way of working in terms of being mixed with the feed for our livestock and our poultry. And, of course, that, again, as a proposed regulation—and I understand that you are looking at the anti-resistance developments—could have a great impact on the meat industry and the poultry industry as they process and grow the food that we eat.

And, of course, it has to be balanced, but when you regulate, make sure that it is based in sound science, that it is subjected to a cost-benefit analysis, and that it makes good common sense.

Thank you.

Mr. ADERHOLT. Mr. Nunnelee.

Mr. NUNNELEE. Thank you, Mr. Chairman.

Dr. Hamburg, thank you for being here.

USER FEES—PHARMACEUTICALS

Mr. Yoder had asked questions about the user fees paid for approval and analysis of pharmaceuticals. I will summarize what I thought I heard the answer is, that the users are still paying those fees, but some of them are being set aside in some kind of expense account that is not being used to evaluate the drugs. Is that right?

Dr. HAMBURG. Yeah. I mean, let me be clear, this is not an FDA policy. This is a decision or a determination based on the way in which the user fee dollars are appropriated, that they are treated like budget authority dollars.

In terms of the impact on FDA, you are absolutely right. The user fees are being collected from the industries that we negotiated for those fees with, but they are not available for us to use as we stand up the new user fee programs or as we implement the ongoing ones. Of course, we have access to some of the user fees, but the total dollars available is being cut at the same level as the budget authority with respect to sequester.

Mr. NUNNELEE. All right, so what effect on approving potentially lifesaving drugs is this expense account that is sitting over to the side having on the FDA?

Dr. HAMBURG. Well, you know, of course, we are going to try to do as much as we can with what we have to achieve the important goals of these user fee programs. However, the dollar amounts in the user fee agreements reflected a very careful calculation of what were the critical needs, what were the goals, what would it take to achieve them. And when those dollars are cut, it means that we aren't going to be able to fully achieve the goals and the performance targets that were set in conjunction with industry in the user fee process.

So we are worried that it will slow our ability to put out important guidances, to review applications that come before us, to do a set of important new hires, to stand up new programs and expand others, to improve business processes, to make our regulatory pathways more effective and efficient, and, importantly, to continue to do some of the work to develop the new regulatory tools that will make our regulatory system, you know, really appropriate for the sophistication and complexity of the products that are coming before us.

And the other thing is that we know that the system works better when we can work more closely with the companies, the sponsors of the products to identify what kinds of data are going to be needed, the kinds of studies that would be most important for them to do, and have ongoing communication. And this will certainly limit the staff and flexibility to engage in those activities.

Mr. NUNNELEE. You said this is not of FDA's making. And in response to Mr. Yoder's question, you said, this was made at a higher level than I. Who made the decision?

Dr. HAMBURG. Well, I might turn to my colleague from the Department of Health and Human Services, who is a budget expert, but I believe it——

Mr. COCHRAN. Yeah, so the implementation or the execution of the sequester government-wide is determined or led by the Office of Management and Budget. And so the counsel at OMB has determined what the appropriate application of that sequester would be for user fees in this fiscal year.

Mr. NUNNELEE. So a lawyer at the Office of Management and Budget made the decision that we are going to take money that has already been paid, set it aside, and not do anything with it. And your testimony is that it is slowing the approval of potentially lifesaving drugs.

Dr. HAMBURG. My testimony is that we are concerned that the user fees were negotiated and specified with respect to a set of program activities and what they would cost to achieve, and if we have cuts in the available dollars, it will likely have meaningful impacts.

Mr. COCHRAN. If I could just add, I think OMB's view is that this isn't an elective decision. This is their interpretation of the statute as it stands.

Mr. NUNNELEE. All right.

Thank you, Mr. Chair.

Mr. ADERHOLT. Okay. We are approaching a vote, and in consideration of—we have a series of votes. We will be on the floor for quite some time, so I don't anticipate that we could get back before 30 to 40 minutes. So we are going to wrap up.

Several of us do have questions that we want to submit for the record, but we would ask, considering that we are going ahead and adjourning early, so that you are not left out here, and so that we can consolidate our schedules as well, that we could get expedited answers to these questions that will be for the record?

Mr. ADERHOLT. But I think Ms. DeLauro has another question before we adjourn.

Ms. DELAURO. Thank you very much, Mr. Chairman. I appreciate your indulgence.

Just for the record, because my colleague, Mrs. Lowey, dealt with the compounded drugs and medical products, I would just very much like to have a—get back to me, you know, directly to my office about the authorities that you need, the specific authorities that you need in order to be able to address this issue. And I would ask you to take a look at the safe legislation that has been introduced in this area to tell us whether or not it helps to meet your concerns in how we can really mitigate against what is happening there.

Food safety. The CDC is investigating an outbreak of salmonella, 18 States. That is associated with imported cucumbers. It takes up to 3 years to fully train a food safety inspector. FDA is not going to meet the target for foreign inspections this year or next, with only 1,200 planned inspections. 2016, FDA is supposed to inspect 19,000 foreign facilities.

Tell us, if you are to meet FSMA's requirements for domestic and foreign inspections, will the FDA need more inspectors? If it does, when do they need to be hired? What does this budget do to meet the requirement?

[The information follows:]

FSMA directs FDA to substantially increase its domestic and foreign inspection frequencies. To implement FSMA effectively and efficiently, FDA must modernize the way it conducts inspections and other compliance activities. The FY 2014 President's Budget would be a significant step in the funding of this long term effort.

For domestic inspections, the agency plans to inspect more than 23,000 facilities per year in the coming years, either by an FDA inspector or by a contracted state inspector. At that rate, all high risk facilities will be inspected within the first 3 years after FSMA's enactment (about 7,400 per year), and all non-high risk within the first 7 years after FSMA's enactment.

For foreign inspections, FDA has increased its coverage to 1,000 foreign inspections in FY 2011 and 1,200 foreign inspections in FY 2012. Conducting the 19,200 foreign inspections eventually called for by FSMA would require hundreds of millions of dollars in new funding. If the agency receives additional funding for food safety, the agency would need to allocate this among various FSMA and other food safety programs.

In addition to increased numbers of foreign inspections, the FSMA tool kit sharpens private sector accountability for import safety, leverages private sector resources, and takes advantage of what foreign governments can do to elevate assurances that imported food meets new prevention-oriented standards. FDA is committed to implementing its new import mandate in a comprehensive and balanced way.

The President's FY 2014 budget requests an additional $43 million in budget authority as well as authority to generate $225 million in user fee revenue to implement FSMA. If provided, those revenues would fund a number of critical projects such as improving and expanding FDA's domestic inspectional effort, with a focus on re-training FDA inspectors and its state and local public health partners to the new prevention standards. In addition, the funds would facilitate the implementation of the new import food safety system, including oversight of the new Foreign Supplier Verification Program, improved border screening with better risk data and assessments of incoming imports, improved foreign government capacity to assure the safety of their food exports, and more foreign inspections by FDA inspectors.

And then what I would like—again, I would like you to submit—I want you to answer those questions, but I would like you to submit for the record, also directly to my office, a detailed breakdown of your food inspection personnel, noting the number of personnel for domestic inspections and the number for international inspection.

Thank you.

[The information follows:]

To respond to your question, we are providing the following document which details the breakdown of FDA foods inspection personnel. Please note, these numbers are the Full-Time Equivalent hours only for the inspections. This does not include support FTE, or FTE related to other Foods activities such as investigations, domestic or import sample collections or analysis, field exams/tests, import field exams or other operations. This also does not include inspections conducted through state contracts or partnerships.

FDA FOODS INSPECTION PERSONNEL

Food Inspection Personnel *	FY2012 Estimate	FY2012 Actuals	FY2013 Estimate	FY2014 Estimate
Domestic	331	323	348	348
Foreign	44	56	44	44
Total	375	379	392	392

Dr. HAMBURG. Okay. Well, just a quick answer to your question, and then we will get back to you with more detail. But I do want to underscore that, actually, last year, we did meet our FSMA target for—in fact, exceeded it, I believe, for foreign inspections. But, of course, the numbers, as you know, in the legislation ramp up very quickly.

Ms. DELAURO. 19,000 for 2016.

Dr. HAMBURG. And I do think that, you know, as we think about the real world that we live in and what is going to be required, we need to think about not just the role of inspections but other important activities as part of our overall program, many of which are reflected in new authorities in the Food Safety Modernization Act in terms of information-sharing, strengthening regulatory capacity in other countries, doing training, technical assistance.

The Foreign Supplier Verification Program and third-party audit is going to be very, very important, as well, to our overall program that will address food safety. And, of course, the new rules, the produce safety and the preventive controls will apply whether you are a domestic or a foreign manufacturer or grower.

So I think there are a number of things beyond inspections alone that will help to strengthen the security of the supply chain in our food imports.

Ms. DELAURO. I would only add, Commissioner, that, in fact, if there is going to be a Trans-Pacific Partnership agreement, that the influx of imported seafood from Vietnam, from Thailand and Malaysia will be extraordinary. As my colleague, Mr. Fortenberry, pointed out, 80 percent of our seafood now comes—it is imported. And we know, we know now, the rate of contamination and the import alerts that have occurred. That will make your job harder.

We need to know on this committee what is required to ensure the public health of this country domestically, internationally, and

how overwhelmed your agency may be if this committee doesn't do something about the resources that it supplies to you.

Thank you very, very much, Mr. Chairman.

Mr. ADERHOLT. Thank you, Ms. DeLauro.

Again, this wraps up our last hearing for the budget for fiscal year 2014. I want to thank all the staff on both sides of the aisle for their work during this hearing process.

And, again, we thank you for being here and look forward to——

Dr. HAMBURG. Thank you.

Mr. ADERHOLT [continuing]. Working with you as we proceed on with the fiscal year 2014 budget.

Thank you.

Dr. HAMBURG. Thank you.

FOOD AND DRUG ADMINISTRATION
COMMISSIONER
QUESTIONS FOR THE RECORD
HOUSE AGRICULTURE APPROPRIATIONS SUBCOMMITTEE HEARING
APRIL 26, 2013

QUESTIONS SUBMITTED BY CHAIRMAN ROBERT ADERHOLT
Food Safety Inspections

1. Mr. Aderholt: Commissioner Hamburg, both you and the White House have said that sequestration could result in 2,100 fewer inspections that FDA could conduct at domestic and foreign food facilities that manufacture food products. I read in a March 1st Associated Press story that you said that the 2,100 number was an estimate, and it was reported yesterday that you said the number is 2,100. Is that your final answer?

   Response: Though we no longer expect to have a 2,100 reduction in inspections due to sequestration, we did not intend to imply that we would have no reductions in inspections. We are working on mitigating the inspection reductions to the greatest extent practicable to protect the public health, but we are still in the early stages of executing our budget under sequestration.

2. Mr. Aderholt: Please tell the Committee how many fewer inspections FDA will conduct at domestic and foreign food manufacturing facilities, and please break that down by domestic versus foreign?

   Response: FDA is doing everything possible to mitigate any reduction in inspections in order to protect the public health; however FDA may need to conduct fewer domestic and foreign facility inspections of firms that manufacture food products to verify that foods meet safety standards. We are in the process of shifting our resources to ensure completion of the most critical inspections. In regards to our foreign food manufacturer inspections, we plan to conduct 1,200 inspections during FY 2013, and remain on track in achieving that goal. ORA also plans to conduct 10,326 domestic food manufacture inspections in FY 2013.

3. Mr. Aderholt: The White House press release on this says that these reductions could increase the number and severity of safety incidents, and the public could suffer more foodborne illness, such as the recent salmonella in peanut butter outbreak and the E. coli illnesses linked to organic spinach. When the salmonella in peanut butter and the E. coli in organic spinach outbreaks occurred was FDA operating under sequestration?

   Response: No, FDA was not operating under sequestration at the time of those unfortunate foodborne illness outbreaks.

4. Mr. Aderholt: Dr. Hamburg, you have also said that the agency won't have to furlough workers. Do you stand by that statement?

Response: Yes, we stand by the statement that FDA does not anticipate any furlough of our workforce.

5. Mr. Aderholt: If the FDA does not plan to furlough workers, please describe in detail the specific cost-cutting items that will account for the savings to avoid furloughs?

   Response: FDA has implemented hiring controls for all Centers and Offices and is closely monitoring payroll costs to ensure payroll is not exceeded. In many cases, recruitment actions are on hold or have been eliminated completely. To date, approximately 100 critical positions have been identified that will not be filled or recruited for while under sequestration. All FDA Centers and Offices are scrutinizing their operating budgets to reduce travel, training, conference attendance and other administrative costs. Travel and training requests are only being considered if mission critical. Virtual training and meeting attendance via web cast or video teleconferencing methods are being used more frequently to reduce travel costs. Numerous invitations for FDA scientists to speak at scientific conferences that are designed to enhance collaboration and exchange scientific knowledge have been declined. FDA's Office of Acquisitions and Grants Services has been working with each FDA Center and Office to scrutinize planned contract actions in order to maximize the use of current year funds and identify specific grants and contracts that will either have funding reduced or not be funded at all.

6. Mr. Aderholt: Your testimony says that "FDA conducted over 2,700 foreign inspections in FY 2012, the largest number ever, exceeding last year by 23%. We are on track to surpass that record this year". How does this square against your statement in the press yesterday that FDA will conduct 2,100 fewer inspections this year?

   As indicated in the Program Activity Data (PAD) tables provided in the Field Activities section of the FY 2014 Congressional Justification (CJ), the *2,758 foreign inspections are a sum of foreign inspections from all field activity in all program areas.

   Please note that in the PAD tables, FDA has indicated no inspection reductions for FY 2014 and plans to maintain inspection activities at the FY 2013 levels.

   *FY 2012 Foods=1,347; Cosmetics=10; Drugs=813; Biologics=50; ADF=85; Devices=453

7. Mr. Aderholt: You recently requested a transfer of $8.9 from the Center for Food Safety and Applied Nutrition and food safety field activities and from the Center for Veterinary Medicine to the Office of Commissioner. In light of sequestration, and the reduction in inspections that you have talked about, wouldn't it be better if you came back to the committee and asked to transfer those funds back to those programs so that you wouldn't have to reduce inspections?

   Response: In 2009, FDA established the Office of Foods to oversee the Center for Veterinary Medicine (CVM) and the Center for Food Safety and Applied Nutrition

(CFSAN) and assure the best use of resources across the food program. With the passage of the FDA Food Safety Modernization Act of 2011 (FSMA), the agency was required to focus on implementing risk-based resource allocation and decision making systems across the agency's Food and Feed programs. FDA completed an in-depth study of how to most effectively and efficiently integrate the programs and activities of the FDA Foods and Veterinary Medicine Programs, resulting in FDA completing a re-organization and reprogramming action in 2012. In order to fully integrate the Food and Feed responsibilities under FSMA, the agency established the Office of Foods and Veterinary Medicine (OFVM). This reprogramming resulted in improved efficiencies by consolidating Executive Secretariat and Communication responsibilities from the centers in to OFVM and formally establishing the Coordinated Outbreak Response & Evaluation (CORE) organization to improve the management of foodborne illness outbreaks. The transfer of $8.9 million from CFSAN, CVM, and ORA only included movement of the operation funding for these activities from their old organizations to OFVM.

Additionally, we draw a distinction between the Office of the Commissioner - the staff and activities that directly support the Commissioner - and the staff in the Directorate. The Directorate staff levels were established in 2012 to manage and integrate the resources of all of the Centers and their field components. These resources are devoted to coordinating the programs of the Agency. The resources involved with this reorganization were less than 1 percent of the total program resources managed, and were added directly to support the Directorate. Finally, the transfer of these funds has had no impact on FDA's ability to complete food safety inspections.

8. Mr. Aderholt: What was FDA's FY 13 request for discretionary funding for food safety activities in the center and the field?
9. Mr. Aderholt: What is FDA's total discretionary FY 2013 resource level for the Center for Food Safety and Applied Nutrition and Field Activities for food safety, not including user fees, but including the $36.9 one-time appropriation, and the $7.7 million that was transferred from center and field activities to the Office of Commissioner?
10. Mr. Aderholt: At $841.4 in FY 2013 discretionary food safety resources, is FDA $13.8 million below the FY 13 budget request of $855.2 million?
11. Mr. Aderholt: Is a $13.8 million reduction a 1.6 percent reduction below the $855.2 million budget request for center and field activities?
12. Mr. Aderholt: Why is FDA reducing inspections of foreign and domestic food facilities by 18 percent and not 1.6 percent?

Response: This response addresses questions 8-12. FDA's total FY 2013 request for food safety was $1.42 billion, of which $1.14 billion was requested in discretionary budget authority. The request included $855 million in budget authority for the Center for Food Safety and Applied Nutrition (CFSAN) and related field activities. (This total would have been $847 million after taking out the Office of Foods transfer.)

The FY 2013 appropriation for CFSAN was $266 million. However, that amount was subject to sequestration and two rescissions within the appropriation bill language. The final amount for CFSAN after sequestration, rescission, and OFVM reprogramming was $246 million. This is approximately $15 million below the FY 2013 President's Budget

request. Similarly, the field was appropriated $580 million in FY 2013; however, given similar reductions, the final amount was $551 million in budget authority. The field budget authority is approximately $43 million below the FY 2013 request.

FDA is currently updating the spending plan for the additional $37 million in one-time Food Safety Modernization Act of 2011 (FMSA) funding that was included in the FY 2013 appropriations. We plan to inform the Committee of our final plans soon.

Though we no longer expect to have a 2,100 reduction in inspections due to sequestration, we did not intend to imply that we would have no reductions in inspections. We are working on mitigating the inspection reductions to the greatest extent practicable to protect the public health, but we are still in the early stages of executing our budget under sequestration.

13. Mr. Aderholt: The cumulative effect of the FY 2013 across-the-board cuts and sequestration is 7.5 percent. Why are you reducing inspections of foreign and domestic food facilities by 18 percent?

Response: FDA's total FY 2013 request for food safety was $1.425 billion, of which $1.150 billion was requested in discretionary budget authority. The request included $863 million in budget authority for the Center for Food Safety and Applied Nutrition (CFSAN) and related field activities. In addition, the initiative included $109 million in budget authority for the Center for Veterinary Medicine (CVM) and related field activities. The remaining budget authority would have supported a portion of the National Center for Toxicological Research, the Office of Foods and Veterinary Medicine (OFVM), the Office of the Commissioner (OC), GSA rent payments, and other rent and rent related activities.

The FY 2013 appropriation for CFSAN was $273 million. However, that amount was subject to sequestration and two rescissions within the appropriation bill language. The final amount for CFSAN after sequestration, rescission, and OFVM reprogramming was $246 million. This is approximately $18 million below the FY 2013 President's Budget request. Similarly, the field was appropriated $580 million in FY 2013; however, given similar reductions, the final amount was $551 million in budget authority. The field budget authority is approximately $48 million below the FY 2013 request.

FDA is currently updating the spending plan for the additional $37 million in one-time Food Safety Modernization Act of 2011 (FMSA) funding that was included in the FY 2013 appropriations. We plan to inform the Committee of our final plans soon.

Though we no longer expect to have a 2,100 reduction in inspections due to sequestration, we did not intend to imply that we would have no reductions in inspections. We are working on mitigating the inspection reductions to the greatest extent practicable to protect the public health, but we are still in the early stages of executing our budget under sequestration.

FDA Budget Request

14. Mr. Aderholt: Your budget request now reflects some $167 million in base adjustments. Please explain to the Committee what that means, and when will the subcommittee receive detailed explanations of how FDA would use this funding by center?

Response: FDA is working on providing the subcommittee with a revised Fiscal Year 2014 table identifying adjustments from the Fiscal Year 2013 Enacted budget and should have that information to you shortly.

Seafood Consumption Advisory

15. Mr. Aderholt: Commissioner Hamburg, I am concerned that the FDA has not updated its advice to pregnant women on seafood consumption despite significant new science that has found that Omega 3s are critical to fetal brain and eye development. When was the last time that FDA updated its advice to pregnant women on seafood consumption?

Response: FDA first issued fish consumption advice relating to methylmercury in 1994. The advice was updated in 2001 and again in 2004. The 2004 advice was issued jointly by the Food and Drug Administration and the Environmental Protection Agency. Its purpose was to protect against the possibility of neurodevelopmental harm to the fetus and to infants from methylmercury as a result of their mother's consumption of fish and to protect young children from the possibility of neurodevelopmental harm from methylmercury as a result of their own consumption of fish. Since then, studies published in the scientific literature indicate that, under certain circumstances, fish consumption by pregnant women and young children may actually improve neurodevelopment. The Dietary Guidelines for Americans 2010, the government's nutritional recommendations issued every five years by the Departments of Health and Human Services and Agriculture, have already taken this development into account by recommending that pregnant and nursing women eat at least 8 and as much as 12 ounces per week of fish lower in mercury. The 2004 FDA/EPA advice does not contain this consumption target nor does it mention a potential neurodevelopmental benefit from fish since the evidence for it did not exist in 2004. We are devoting a significant effort to update the advice and to complete a quantitative assessment of the net effects of fish consumption during pregnancy on neurodevelopment in order to have a sound analytical underpinning for that advice. Updating the fish consumption advice relating to methylmercury continues to be a top priority for FDA, and the Agency continues to work diligently on this issue.

16. Mr. Aderholt: It has been over two years since HHS and USDA released new dietary guidelines that found "the benefits of consuming seafood far outweigh the risks, even for pregnant women" and recommends a quadrupling of current seafood consumption rates. Congress has received commitments from you and Secretary Sebelius that the advice would be completed in 2011 and then in 2012. It is now 2013 and pregnant women continue to rely on outdated FDA advice that has resulted in significant declines in seafood consumption to the detriment of unborn children while the HHS Agencies

appear to be involved in bureaucratic squabbling. The American people, and especially pregnant women, are owed this advice now. Please tell the Committee what the current status is of this document?

Response: We are making every effort to complete that process. Updating the fish consumption advice relating to methylmercury continues to be a top priority for FDA, and the Agency continues to work diligently on this issue.

17. Mr. Aderholt: As I said in my opening statement, this is an area where the bureaucracy is slowing down the release of crucial science-based guidance, I think the time has come for you to personally engage with Secretary Sebelius in the final discussions to resolve any remaining roadblocks to issuing new FDA seafood advice. Can you commit to issuing final seafood advice this fiscal year?

Response: We have devoted a significant effort to update the advice and to complete a quantitative assessment of the net effects of fish consumption during pregnancy on neurodevelopment in order to have a sound analytical underpinning for that advice. We are making every effort to complete that process. The Agency cannot provide a guarantee that it will be completed by any specific date since clearance involves decisions and time frames beyond the FDA's control, but please be assured that your concerns will be appropriately conveyed.

Food Safety Modernization Act
Rules Related to Food Processing and Produce Safety

18. FDA states that the proposals were drafted following outreach to industry, consumer communities, the global communities, and others over the last two years, including 3 public meetings. The comment period was scheduled to close May 16, 2013, but in response to industry requests for more time, FDA has extended the comment period for the two proposals an additional 120 days.

19. Mr. Aderholt: Your budget requests a significant increase for implementation of the Food Safety Modernization Act. There are concerns that the approach FDA is taking to implement this law is complex, burdensome and not cost-effective. Is it FDA's intention to require all produce growers to register their farms with the Agency when perhaps there is a more efficient way to track these products through produce marketers or processors?

Response: Produce farming activities that would be regulated under the proposed produce safety rule do not trigger the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). We did not include a farm registration requirement in the proposed rule. However, we are requesting comment about whether we should require, in a final rule, that covered farms register with FDA. We are not aware of a nationwide database of farms, nor an accumulation of statewide databases, that would enable us to identify the names and locations of all entities subject to the proposed regulation. This would enable us to better provide outreach and technical

assistance to covered farms. In addition, while inspection is intended to be only a relatively minor part of our overall compliance effort, we anticipate performing inspections for enforcement purposes. We would use the covered farm registration information to create a database that we would use to allocate inspection resources. We are also interested in the existence of databases that could help us identify covered farms in the absence of a registration system, and in the appropriate data elements that should be collected in a registration system, should we decide to set up such a system.

20. Mr. Aderholt: This Subcommittee has cautioned FDA before that a "one size fits all" approach to implementing the food safety law will simply not work. With various commodities and growing climates and practices across the country, FDA must assess the risk and focus precious resources on those determined to be higher risk commodities. Is FDA determining which commodities are more at risk versus those that pose less of a food safety risk?

    Response: Yes, FDA is proposing to adopt an approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting the lowest-risk produce. We conducted a qualitative assessment of risk (QAR) of hazards related to produce production and harvesting. The QAR indicated that produce commodities are potentially subject to similar microbiological hazard pathways: Commodities can potentially become contaminated from, for example, direct contact with contaminated water or soil amendments. Therefore, we are proposing to adopt a regulatory approach for minimizing potential risks associated with those hazards. This focus on microbiological hazard pathways also led us to propose not covering certain produce that we have determined present the lowest risk. Specifically, the Produce Safety Standards proposed rule would not apply to produce that is (1) rarely consumed raw, (2) produced for personal or on-farm consumption, or (3) (with certain documentation) destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern. FDA believes this approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting the lowest-risk produce, would provide the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk.

21. Mr. Aderholt: Will the Agency focus resources on those higher risk commodities, which is a more effective use of funds?

    Response: Yes, FDA intends to focus its resources on commodities produced using higher risk agricultural practices. The proposed rule reflects our thinking that identifying the higher-risk agricultural practices and setting standards in which the stringency of the requirement tracks the risk of the chosen practices is appropriate from a public health risk mitigation standpoint and would also provide an incentive for farmers to move to lower-risk practices where such options are available.

22. Mr. Aderholt: Agriculture producers operate on very thin margins and face competitive markets both domestically and internationally. What assurances can you offer growers

that FDA will be able to require foreign producers to meet equivalent food safety standards?

Response: FDA is responsible for ensuring the safety of all domestic and imported fruits and vegetables consumed in the United States. The Produce Safety Standards proposed rule would apply to both domestic and imported produce. FDA intends to ensure compliance with the safety standards for imported produce primarily through the foreign supplier verification program (FSVP), which, when established, will help ensure the safety of foods imported into the U.S. by making importers accountable for verifying that the food they import is produced using processes and procedures that achieve the same level of public health protection for imported food as required of domestic growers and processors under FSMA's new standards for produce safety and preventive controls. FDA intends to publish the FSVP proposed rule soon. FDA also intends to provide outreach and technical assistance to foreign governments and other regulatory partners to help ensure understanding of and compliance with produce safety standards.

23. Mr. Aderholt: Given the complexity of the issues surrounding the proposed rules, do you believe it is appropriate to rush through these regulations?

Response: While we agree that the issues are complex, we do not believe we are rushing through the rulemakings. For Preventive Controls for Human Food proposed rule, FDA has a history of other similar rulemakings, such as its seafood and juice HACCP rules. FDA had also previously done a study on modernizing its Current Good Manufacturing Practices regulation. With regard to the Produce Safety Standards proposed rule, FDA issued a Good Agricultural Practices guidance document in 1998 and subsequently issued commodity-specific guidances for leafy greens, tomatoes, and melons. Prior to the release of the proposed rules, we engaged in significant public outreach, including public meetings and farm tours. Since the release of the proposed rules, we have had three public meetings and numerous regional meetings and have provided a 240-day comment period on each rule.

FDA is committed to understanding the concerns of stakeholders as we implement a new preventive controls framework for food. We intend to work with the regulated industry to address their concerns as we finalize the regulations, and to continue the dialogue after the rules are finalized as we develop guidance documents to help industry meet the regulatory requirements. In addition, we are proposing staggered compliance dates for the rulemaking so that small and very small businesses have additional time to comply.

24. Mr. Aderholt: I am concerned though since FDA says it worked closely with the industry over the last two years that long before the comment period is scheduled to end on these two rules that industry has asked for, and received, a 120 day extension. How closely did FDA work with industry to ensure the implementation of the proposed rules?

Response: FDA has conducted extensive outreach to the produce industry, the consumer community, other government agencies and the international community to obtain input and perspective on the proposed rules required by FSMA. For the Produce Safety Standards proposed rule, technical experts, scientists, and other staff from FDA and

USDA went on the road to meet with growers as well as produce industry groups, public policy groups, State agricultural departments, and public health departments in 13 States. That input and perspective helped shape the proposed regulations in ways that helped ensure the proposed rules are practical and flexible, as well as effective.

The proposed rules on Preventive Controls for Human Food and the Produce Safety Standards are large, complex, and inter-related documents, each with an accompanying risk assessment and a significant number of references. The Agency granted the extension of the comment period based on formal, written requests from many interested persons and groups that indicated more time was needed to review supporting documentation and respond fully to FDA's specific requests for data and information, and to allow potential respondents to thoroughly evaluate and address pertinent issues in the two proposed rules.

FDA Oversight of Food and Medical Products

25. Mr. Aderholt: The testimony says that "Not that long ago, FDA's job was to oversee a largely domestic market of food and medical product suppliers. Most of the facilities in which these products were stored and manufactured were within our borders and relatively easy to inspect and oversee." Provide some context to that statement. Does this mean that there were fewer food-related or drug related outbreaks when most of the suppliers were within our borders?

Response: It is difficult, if not impossible to know if there were fewer outbreaks when most suppliers were within our borders, as so much has changed along with the global supply chain. What we do know is that about 15 percent of the U.S. food supply is imported, including about 80 percent of our seafood, 40-50 percent of fruits, and 10-20 percent vegetables, all of which are foods associated with foodborne illnesses. In addition, new types of food are being imported from a large number of countries and suppliers and those foods often have more complex supply chains. These factors could potentially contribute to food-related illness outbreaks. It is difficult for FDA to monitor compliance of the increasing number of imported products through its traditional border operations. What is needed is an approach that builds in multiple layers of prevention throughout the supply with our border operations as the final, but not primary, checkpoint on safety.

With respect to drug related illnesses, regulating sites that operate in different countries present additional challenges. Language, cultural, and logistical issues are significant obstacles to efficient and effective oversight compared with U.S. facilities. More complicated supply chains—multiple wholesalers and brokers—also add to the challenge of regulating foreign manufacturing operations. FDA has made efforts to bridge the gap to facilitate better compliance globally.

The testimony was not attempting to address the question of whether there were fewer food-related or drug-related outbreaks when most of the suppliers were within our borders. What we can address is the increase in imports. Approximately 40 percent of finished drugs in the U.S. come from overseas and more than 50 percent of all medical

devices used in the U.S. are imported. Currently, imports of medical products have grown rapidly, at approximately 13 percent per year, from 2004 through 2011.

Bisphenol A (BPA): Use in Food Contact Application

26. FDA issued a draft assessment concluding that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses in 2008. In 2010, FDA issued an interim update that said, "FDA's current assessment is that BPA is safe at the very low levels that occur in some foods. This assessment is based on review by FDA scientists of hundreds of studies including the latest findings from new studies initiated by the agency."

27. Mr. Aderholt: When will FDA be providing a clear and substantive position on BPA to the public?
Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for adverse effects of BPA. These studies will be helpful in interpreting exploratory research studies on BPA that have become available in the past few years and which have raised certain concerns. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. Once the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media. Pending no unforeseen delays to the completion of the studies, an update to the safety assessment may be available as early as mid-2014. An additional long term study has recently started at the NCTR. Data from that study may be available starting in 2015 at which time the Agency could consider if an additional safety update would be needed based on these data.

28. Mr. Aderholt: When will the basis of FDA's current assessment as to the safety of BPA, along with the review of studies by FDA scientists, be made available to the public?

Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for adverse effects of BPA. These studies will be helpful in interpreting exploratory research studies on BPA that have become available in the past few years and which have raised certain concerns. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. Once the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media. Pending no unforeseen delays to the completion of the studies, an update to the safety assessment may be available as early as mid-2014. An additional long term study has recently started at the NCTR. Data from that study may be available starting in 2015 at which time the Agency could consider if an additional safety update would be needed based on these data.

29. FDA's website lists a number of studies the FDA has conducted on the safety of BPA. According to the website: "The results from these new studies so far support FDA's assessment that the use of BPA in food packaging and containers is safe."
30. Mr. Aderholt: Other than briefly describing these studies on the website, how does FDA intend to inform the public of the results of these new studies? Please inform the Subcommittee of the next steps FDA intends to take to disseminate this important information to the public at large.

    Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for adverse effects of BPA. These studies will be helpful in interpreting exploratory research studies on BPA that have become available in the past few years and which have raised certain concerns. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. Once the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media. Pending no unforeseen delays to the completion of the studies, an update to the safety assessment may be available as early as mid-2014. An additional long term study has recently started at the NCTR. Data from that study may be available starting in 2015 at which time the Agency could consider if an additional safety update would be needed based on these data.

    The preliminary results from the studies conducted at the NCTR continue to support FDA's assessment that the low levels of BPA exposure from the current approved uses of BPA in food packaging and containers are safe. One of the most notable finding is that primates, including humans of all ages, efficiently and effectively metabolize or detoxify ingested BPA. This is in contrast to rodents, the species used in most toxicological studies, which have age-dependent and lower metabolic capabilities with respect to BPA.

    Recent NCTR research also found that the level of the active form of BPA passed from expectant mothers to their unborn children, following oral exposure, was lower than our sensitive analytical methods could detect. NCTR is currently integrating the results of these studies with data from monkey, mouse, rat, and human studies in scientific literature to develop physiologically based pharmacokinetic (PBPK) models. These mathematical models will aid in extrapolation of the internal doses of BPA associated with toxicity in laboratory animals to humans and will help reduce uncertainties in the assessment of health risks posed by BPA to human populations.

    FDA has also conducted a rigorous large scale toxicological rodent subchronic study with the goal of addressing the potential for low dose effects related to the previously identified endpoints including brain, behavior, and prostate gland and the substantial uncertainties identified with respect to many previously published exploratory studies. The final component of the study is expected to be completed very soon. However, the preliminary results do not suggest a safety concern and continue to support FDA's previous statements.

NCTR has also started a two year toxicological study in collaboration with the National Institutes of Health's National Institute of Environmental Health Sciences through the National Toxicology Program. The study is unique in that additional animals and tissues will be provided to NIEHS academic researchers to analyze additional scientific interests. FDA expects to further update its safety assessment accordingly following the completion of this NCTR study.

With regard to the recent French food safety authority's (ANSES) risk assessment, ANSES assessment did not fully incorporate relevant science recently published by FDA's NCTR and others. In addition, FDA has concerns about certain underlying assumptions and criteria in assessing the quality, relevance, and evidence based ranking of available studies and data.

The cited statement from the Dr. Oz show is consistent with FDA's current position on BPA. When we next update FDA's website on BPA, we will also make clear our current position on BPA.

31. Mr. Aderholt: Provide the Subcommittee with a summary report on the findings of the recent FDA studies, and what these findings conclude as to the safety of BPA in food packaging.

Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for adverse effects of BPA. These studies will be helpful in interpreting exploratory research studies on BPA that have become available in the past few years and which have raised certain concerns. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. Once the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media. Pending no unforeseen delays to the completion of the studies, an update to the safety assessment may be available as early as mid-2014. An additional long term study has recently started at the NCTR. Data from that study may be available starting in 2015 at which time the Agency could consider if an additional safety update would be needed based on these data.

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The cited statement from the Dr. Oz show is consistent with FDA's current position on BPA. When we next update FDA's website on BPA, we will also make clear our current position on BPA.

32. Mr. Aderholt: A few weeks ago, the French food safety agency (ANSES) issued an opinion on the risks associated with BPA to human health. I would ask that FDA review this report and provide the Subcommittee with FDA's views as to the opinion's approach and conclusions.

    Response: With regard to the recent French food safety authority's (ANSES) risk assessment, ANSES assessment did not fully incorporate relevant science recently published by FDA's NCTR and others. In addition, FDA has concerns about certain underlying assumptions and criteria in assessing the quality, relevance, and evidence based ranking of available studies and data.

33. In January of this year, in response to the Dr. Oz television show on the subject of BPA, FDA released the following statement on BPA according to the show's website:
34. "The FDA has performed extensive research and has reviewed hundreds of studies about the possible health risks associated with BPA and at this time does not believe the scientific evidence suggests that the very low levels of human exposure to BPA through

the diet are unsafe. While the agency continues to address questions and potential concerns raised by certain studies, the FDA believes that the weight of the current research and evidence support the safety of BPA for use in food containers or packaging. Additional research is underway, including in-depth studies designed to answer key safety questions and to clarify any uncertainties. The FDA will take these studies into account as it continues to study the safety of BPA."

35. Mr. Aderholt: Is this FDA's current position on BPA?

    Response: The cited statement from the Dr. Oz show is consistent with FDA's current position on BPA. When we next update FDA's website on BPA, we will also make clear our current position on BPA.

36. Mr. Aderholt: If this is FDA's current position on BPA, why haven't you included this clear statement in its recent update of the BPA information on your website?

    Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for adverse effects of BPA. These studies will be helpful in interpreting exploratory research studies on BPA that have become available in the past few years and which have raised certain concerns. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. Once the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media. Pending no unforeseen delays to the completion of the studies, an update to the safety assessment may be available as early as mid-2014. An additional long term study has recently started at the NCTR. Data from that study may be available starting in 2015 at which time the Agency could consider if an additional safety update would be needed based on these data.

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The cited statement from the Dr. Oz show is consistent with FDA's current position on BPA. When we next update FDA's website on BPA, we will also make clear our current position on BPA.

Tobacco Harm Reduction

37. Mr. Aderholt: What actions has the FDA taken related to advancing harm reduction and the concept of a continuum of risk?

Response: FDA uses a public health standard when taking actions based on the regulatory authority for tobacco products. When evaluating whether a regulatory action is appropriate for the protection of public health under the standard, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) instructs FDA to consider the impact on both users and non-users, including initiation and cessation. This is a new regulatory standard and substantially different than that used by other FDA Centers that review drugs and medical devices for safety and effectiveness. FDA regulation of tobacco products is aimed at reducing the population harm that results from the use of tobacco products.

In March 2012, FDA issued draft guidance entitled, "Guidance for Industry: Modified Risk Tobacco Product Applications" for public comment. This draft guidance provides details for those who seek authorization to market a tobacco product as modified or lower risk including how to organize and submit a modified risk tobacco product - or MRTP - application, what scientific studies and analyses should be submitted, and what information should be collected through post-market surveillance and studies.

The modified risk tobacco product provisions of the Tobacco Control Act may be valuable tools in the effort to protect public health by reducing the morbidity and mortality associated with tobacco use, particularly if tobacco product manufacturers take advantage of these provisions by making bold, innovative product changes that substantially reduce, or even eliminate altogether, either the toxicity or addictiveness of tobacco products, or both.

FDA is also funding research on reduced nicotine cigarettes, smokeless tobacco products and the diversity of tobacco products including new and emerging tobacco products to inform the advancement of harm reduction at both the individual and population level.

38. Mr. Aderholt: You have stressed the importance of innovation with respect to the products FDA regulates. Does the FDA's focus on innovation include tobacco products?

Response: Tobacco products are fundamentally different from other products FDA regulates because regulated tobacco products - cigarettes, cigarette tobacco, smokeless tobacco, roll-your-own tobacco - have no health benefits and have known harms and risks associated with their use.

Tobacco companies have recently introduced newer forms of tobacco products. These changes in the marketplace need to be carefully considered given the public health standard. To that end, FDA is funding research to better understand these newer products with regard to their relative risks compared to other tobacco products at both the individual and population level. It is critically important to evaluate these products not only in terms of the relative health risks to individuals, but the increased or decreased likelihood that nonusers will start using the product, tobacco users who would otherwise stop using tobacco products will switch to the new product, tobacco user who may continue tobacco use in combination with one or more new tobacco products, and former users will begin using the new product.

Section 907 of the FD&C Act also gives the FDA authority to establish tobacco product standards. FDA believes that this is an important tool to encourage innovation by tobacco product manufacturers to replace currently marketed products with less harmful products.

39. Mr. Aderholt: How does the Agency's focus on innovation related to the concept of tobacco-related harm reduction?

Response: The modified risk tobacco product provisions of the Tobacco Control Act may be valuable tools in the effort to promote public health by reducing the morbidity and mortality associated with tobacco use, particularly if tobacco product manufacturers come forward with applications that demonstrate substantial reductions in the toxicity of tobacco products.

FDA takes Section 918 of the Family Smoking Prevention and Tobacco Control Act seriously, especially with respect to regulating, promoting, and encouraging the

development of innovative products and treatments to promote total abstinence from tobacco use, reductions in consumption of tobacco, and reductions in the harm associated with continued tobacco use. FDA submitted its Section 918 report to Congress on April 22, 2013.

Also, on April 1, 2013, FDA issued a response to a citizen petition asking the Agency to take various actions related to over-the-counter - or OTC - nicotine replacement therapy – or NRT - products, which are currently approved as aids to smoking cessation. FDA also issued a Notice of Findings based on its own review of the available literature and data on the safety of OTC NRT products. Based on that review, FDA concluded that certain statements set forth in the approved labeling of OTC NRT products, including statements related to duration of use and concomitant use with other nicotine-containing products, can be modified. FDA intends to allow the modification of these statements based on sponsor submissions as set forth in a Notice of Findings.

40. Mr. Aderholt: As you know, the Family Smoking Prevention and Tobacco Control Act defines a product approval pathway for modified risk tobacco products (MRTPs). What has the FDA done to encourage the development of MRTPs by tobacco product manufacturers?

Response: In March 2012, FDA issued draft guidance entitled, "Draft Guidance for Industry: Modified Risk Tobacco Product Applications" for public comment. This draft guidance provides details for those who seek authorization to market a tobacco product as either modified risk or reduced exposure, including how to organize and submit an MRTP application, what scientific studies and analyses should be submitted, and what information should be collected through post-market surveillance and studies.

FDA held a public workshop in August 2011 to discuss how companies might meet the requirements for modified risk tobacco product applications described in the Tobacco Control Act.

FDA commissioned the Institute of Medicine to provide recommendations on the Scientific Standards for Studies on Modified Risk Tobacco Products. This project was completed in 2012.

FDA has met nine times with individual tobacco product manufacturers to provide feedback on their possible MRTP study protocols.

In addition, FDA convened a meeting of the Tobacco Product Scientific Advisory Committee on April 30, 2013, to solicit input from TPSAC and the public, including tobacco manufacturers, on the process for referring Modified Risk Tobacco Product Applications to TPSAC as per section 911(f)(1) and (2) of the FD&C Act. The draft guidance was presented, as well as the anticipated process within FDA for the journey of a modified-risk tobacco product application.

Industry-funded research

41. Mr. Aderholt: What is FDA's position as it relates to industry-funded or industry-conducted research?

    Response: To be sent in 2nd batch

42. Mr. Aderholt: Do you agree the industry has a role to play in conducting research related to its products and submitting the data to FDA for its evaluation?

    Response: Both industry-funded and industry-conducted research generally play an important role in product development. For example, sponsors, including industry, are responsible for providing the information needed to for FDA's pre-market review. The role of industry in such research can be major given their long term work in research and development of the products and the information they obtain during that process, often from multiple studies and sources. Industry supported research is often augmented through the engagement of practicing clinicians, academic institutions, and other experts. Results from this research is then presented to the FDA, which considers it along with any other relevant information, in its review. As part of any required product review, FDA also assesses the quality, reliability, integrity and analysis of the data it receives, whatever the source and particularly for studies key to a pre-market approval. At times, industry-conducted research also allows FDA to qualify novel tools and methods for use in product development and regulatory review.

43. Mr. Aderholt: Isn't FDA the final arbiter of all industry-submitted data or scientific analyses?

    Response: Yes, as described above. Industry supported research is often fundamental both in developing products and in providing evidence for review of the applicable product. For certain products, post-approval, industry may also conduct post-marketing studies to further assess the product safety or effectiveness.

Reagan-Udall Foundation

44. Mr. Aderholt: Please provide the Committee with an update on what FDA is doing in partnership with the Reagan-Udall Foundation. Why should taxpayer dollars be spent on this?

    Response: The Reagan-Udall Foundation (RUF) is coordinating the following public-private partnerships, targeting regulatory science issues identified by FDA as high priority public health needs. In each case, the resources, data, expertise, and perspective of diverse stakeholders (e.g., public health, patient groups, companies, academia) are needed. In each case, RUF undertakes the heavy administrative load inherent in developing the partnership and serving as a neutral convener.

    • Innovation in Tuberculosis Drug Regimens. RUF is working with the Gates Foundation and others to accelerate the development of more effective tuberculosis (TB)

regimens. RUF is organizing international TB stakeholders with diverse perspectives to develop better methods for testing promising TB drug candidates in combination. This work will accelerate development of more effective therapies for TB, and the methods developed will be applicable to improve treatment for other diseases where multi-drug regimens are common, such as cancer.

• Advancement of Personalized Medicine: Safer Cancer Chemotherapy. RUF is working with the Komen Foundation and others to analyze health outcomes data from a variety of sources, to identify predictors of cardiac toxicity associated with breast cancer treatments. If successful, this approach could be a model for enhancing the safety of other classes of drug.

• The Innovation in Medical Evidence Development and Surveillance (IMEDS). Electronic health care data are complex and diverse, making it difficult to gather useful information. RUF is developing a public-private partnership to bring the latest advances in information technology to bear on the development of analytic techniques for mining electronic health care data, to generate better evidence on the safety and efficacy of regulated products in post-market settings. Methods developed through IMEDS will increase the accuracy and timeliness of post-market information available to patients and physicians.

The RUF website includes detailed information on each of these projects.

Pathway to Global Product Safety and Quality

45. Mr. Aderholt: Provide the Committee with an update of activities that have occurred during the past year regarding the Pathway initiative, including efforts to conduct more risk assessments and information sharing.

Response: The Pathway model involves an increased emphasis on risk analytics, as well as a focus on building global data systems and networks that allow for regular, systematic information exchange between our foreign and domestic regulatory partners.

With respect to information sharing, FDA has made strides this year. With the Pan American Health Organization, we launched the Regional Platform on Access and Innovation for Health Technologies (PRAIS), an information hub to facilitate regulatory medical product data sharing in the Americas, a regional model of a data sharing system and network that can be expanded globally.

We implemented broad information sharing with the Canadian Food Inspection Agency and Health Canada that enabled FDA to conduct border-to-border meetings to discuss import procedures, share information on import issues, and improve enforcement.

We sponsored and launched a World Health Organization (WHO) multi-regional platform for monitoring sub-standard, spurious, falsely-labeled, falsified and counterfeit

(SSFFC) medical products as a tool to improve data sources and collection methodologies globally. With the WHO, we also launched Food Safety Collaboration (FOSSCOLLAB), a new data-sharing and information global platform to guide risk assessment and decision-making in food safety.

We initiated the implementation of a Laboratory Information Management System (LIMS) to facilitate and enhance electronic data capture, storage and analysis, and, in the future, the sharing of data between FDA and domestic and international regulatory partners.

With respect to risk assessment, we deployed the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) in all 16 import districts and continue to roll it out to all district offices to target the highest risk products for entry review, while we also continue to improve PREDICT's utility through partnership with the Centers.

We developed technological tools to increase efficiencies and information access, such as the Counterfeit Detector (Version 3) rapid screening tool and the Egg Farm Inspection Prototype System.

46. Mr. Aderholt: Has the FDA completed its evaluation of an action plan for the initiative? What is the current status of the action plan? Please provide a copy of that plan for the record. If FDA has not completed the plan, when does the FDA plan to complete it?

Response: FDA is implementing the global operating model laid out in the Pathway to Global Product Safety and Quality (Pathway initiative). This has required incorporating partnering with other regulators, enhanced intelligence, information sharing, data-driven risk analytics, leveraging the efforts of public and private third parties, and the smart allocation of resources into strategic planning efforts as well as daily operations. To implement this new model, FDA's largest Directorate, the Office of Global Regulatory Operations and Policy, developed a cross-cutting Strategic Framework.

The Strategic Framework provides a cohesive strategy for the Directorate's Office of Regulatory Affairs (ORA) and Office of International Programs (OIP) to address the challenges FDA faces related to modernization, globalization, and the implementation of new legislative mandates. ORA and OIP have developed Strategy Maps for their organizations which connect directly to the Directorate's framework. Through these Strategy Maps and associated strategic and operational plans, ORA and OIP are aligning their organizations to focus on the activities and actions to accomplish the Pathway initiative.

Full implementation of the Pathway initiative required continuing to transform FDA from a domestic agency into a global public health enterprise where our new operating model is embedded into all of our work, becomes the new way of doing business, and is timeless. Although this effort will take many years, since the publication of the Pathway report, we've built upon our relationships with our foreign counterparts to enhance

information-sharing; collaborated with trusted partners; and put global data systems in place to inform decision-making.

47. Mr. Aderholt: Provide an update on the strategies FDA is utilizing to handle the growth in imported products? Please be specific.

Response: FDA is ensuring robust import, foreign inspection programs are in place and is enhancing the use of risk analytics. In FY 2012, FDA conducted 2,758 foreign inspections, more than any previously conducted. We have implemented PREDICT and are using portable handheld devices such as the Counterfeit Detector-3 at the border and International Mail Facilities to detect undeclared Active Pharmaceutical Ingredients, contaminants, and counterfeit pharmaceutical dosage forms and packaging as they are offered for entry. We also continue to utilize traditional enforcement tools such as Import Alerts.

We are increasing collaborations and information-sharing activities with federal and foreign partners. For example, we are helping to strengthen the regulatory capacities of other countries and ensuring that FDA standards are well understood and applied. These efforts enable convergence of regulatory standards and foster best practices, increasing the likelihood that products will be FDA-compliant when they reach our shores. FDA is implementing model inspection programs with our foreign counterparts, allowing FDA to reduce duplicate inspections of the same facilities they inspect and better target inspections in high-risk areas. The Agency has developed a new approach to regulatory cooperation known as systems recognition designed to recognize food safety systems that are comparable to the U.S. system. FDA recently recognized New Zealand's food safety system as comparable to our own. We continue to utilize our 12 Foreign Posts to build FDA's knowledge based about the global regulatory landscape.

A pilot known as the Secure Supply Chain pilot, developed with U.S. Customs and Border Protection, will facilitate the importation of approved pharmaceutical products from firms that also have met the requirements of the Customs Trade Partnership Against Terrorism program. And the Agency deployed the Import Trade Auxiliary Communication System which allows the submission of electronic import entry documentation to facilitate trade.

48. Mr. Aderholt: FDA has been exploring the broader use of confidentiality commitments to allow for greater information sharing. Last year, FDA reported having commitments with 44 foreign counterpart agencies in 21 countries and with 4 units of the World Health Organization. Has FDA secured more confidentiality commitments and with what countries does FDA have these arrangements?

Response: Since May 2012, FDA has secured six new confidentiality commitments. The Agency now has these arrangements with: Australia--The Australian Government Department of Health And Ageing; Czech Republic--The Czech Republic's State Institute for Drug Control; France--The French Directorate General for Food; Ireland--The Food Safety Authority of Ireland; Spain--The Spanish Food Safety and Nutrition Agency; and Switzerland--The Swiss Federal Office of Public Health.

49. Mr. Aderholt: Provide the Committee with an update on the use of third-party audits.

Response: ORA is working with two Centers on the use of third-party audits – the Center for Devices and Radiological Health (CDRH) and the Center for Food Safety and Applied Nutrition (CFSAN).

ORA and CDRH continue to collaborate to develop a pilot program intended to provide FDA with the capability of receiving third-party audit reports on medical device manufacturers. The objective of the pilot is to provide FDA with additional information related to the compliance status of manufacturers, thus expanding FDA's knowledge of regulated industry when ORA and CDRH are identifying manufacturers for routine surveillance inspections. This program will lead to greater regulatory and consumer confidence in the medical device supply chain and facilitate safe and effective medical device products for the U.S. market.

In addition, FDA published guidance allowing manufacturers to submit third-party reports of inspections conducted under International Organization for Standardization (ISO) 13485:2003. The medical device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program is a way in which FDA may leverage audits performed by other International Medical Device Regulators Forum (IMDRF) regulators and their accredited third parties in order to assist the agency in setting risk-based inspectional priorities for medical devices. To date, 19 inspection reports have been accepted by FDA under this program.

Furthermore, pursuant to the FDA Food Safety Modernization Act (FSMA), FDA is working towards developing an Accredited Third Party Certification Program. Under the program, FDA will recognize accreditation bodies to accredit certification bodies to conduct rigorous and independent food safety audits of foreign food facilities and, where appropriate, to issue food and facility certifications. These certifications may be used to facilitate the entry of imports under the Voluntary Qualified Importer Program or when certification is required for admission of a food FDA determines poses a safety risk. These privately conducted audits will not replace FDA inspections, but rather will provide additional tools to ensure FDA makes the best, most efficient use of both public and private resources in the oversight of a safe food supply.

50. Mr. Aderholt: How specifically has FDA engaged the Chinese government to facilitate more information sharing, ensure product safety and quality, and conduct other related activities?

Response: Some specific examples of our engagement with the Chinese authorities include:

Between 2010 and 2012, FDA held a series of workshops on good clinical practices for Chinese inspectors who inspect sites that conduct trials to support the development of pharmaceuticals. FDA's training helped the China Food and Drug Administration

(CFDA) to establish its national clinical research inspectorate and develop a cadre of 30 inspectors who will train the next generation of Chinese inspectors in this key area.

At the request of CFDA, FDA's China Office and Office of Criminal Investigations (OCI) worked with U.S. internet-hosting companies to shut down 16 Chinese-language websites that illegally sold unapproved medical products through servers located in the United States.

In 2012, CFDA provided to FDA's China Office a list of Chinese pharmaceutical firms against which they had taken regulatory action because of their failure to comply with relevant standards for good manufacturing practices. From the list, FDA identified 61 firms that had shipped products to the United States and targeted these firms as priorities for inspection.

FDA's countrywide Import Alert (IA) 16-131 on five species of aquaculture fish has been in place since 2007 and FDA continues to find positive samples of illegal drugs and additives from Chinese aquaculture shipped to the United States. In November 2012 and May 2013, FDA and General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) held a series of workshops on key issues associated with this public health concern.

During a 2012 FDA inspection of a dietary supplement manufacturer in China, FDA found significant problems, which could lead to serious public health effects. FDA reported these issues to CFDA, which responded by conducting its own inspection of the facility. CFDA then revoked the firm's license, which stopped firm's operations.

FDA Transparency

51. Mr. Aderholt: Please provide the Committee with an update on the current status of the FDA Transparency initiative that was begun in fiscal year 2010?

Response: FDA launched its Transparency Initiative to make available more useful, user-friendly information about Agency activities and decision-making. *FDA Basics*, an online resource providing user-friendly FDA information for a general audience, was launched in 2010 and has received over 4 million views and 6,100 public comments.

In 2012 FDA released a report announcing an exploratory program to investigate ways to increase access to Agency compliance and enforcement data. Thereafter, FDA formed working groups that have been evaluating eight specific initiatives FDA has publicly announced to increase such access. The findings and recommendations of this Agency-wide endeavor are expected to be issued later this year.

Other actions taken:

- The Agency launched *FDA Basics for Industry* to provide information about FDA's regulatory process to members of regulated industry. To date, it has been viewed over 1.1 million times.

- Each Center has posted on FDA Basics for Industry a process for industry to submit general regulatory questions, and for directing inquiries to individuals with additional expertise.
- FDA has compiled all Center guidance and standard operating procedures on FDA employees' meetings with sponsors about product applications and posted this information on FDA Basics for Industry.
- FDA has described on FDA Basics for Industry: the types of notifications it provides to industry associated with the product application review process; its practice of providing the sponsor with contact information of the individual who should be contacted with questions about product applications; and the processes used to strive for consistency of product application review.
- FDA has described ways in which interested individuals can provide input to the Agency about guidance development on FDA Basics for Industry.
- FDA has published on FDA Basics for Industry contact information for each import program manager and updates this list annually.

Sodium Intake

52. Mr. Aderholt: In last year's questions for the record, FDA was asked to comment on recent studies that show that reduced levels of sodium can cause serious health problems. FDA's response was that the Centers for Disease Control and the Institute of Medicine (IOM) were going to look at that issue and those studies. The IOM is currently conducting such a review and is expected to issue its report in the near future. However, even though there is significant scientific controversy in this area, and even though the IOM has yet to issue its report, the FDA has chosen to spend valuable food safety resources urging people to beware of foods, specifically processed foods, because of sodium content. I am referring specifically to the FDA Food Safety web home page and button number 3 on that page. Wouldn't the prudent approach for the FDA be to wait for the IOM findings before engaging in a PR effort?

    Response: The current scientific consensus is that sodium intake is higher than desirable for public health. This consensus is widely shared by domestic and international organizations, such as the American Heart Association, the American Medical Association, and the World Health Organization, and is reflected in the 2010 Dietary Guidelines for Americans published jointly by FDA and USDA. Recent studies have raised the question of how much current intake levels should be reduced to find the optimal intake level for the general population and certain subgroups. This is currently being considered by the IOM committee. However, we do not expect that the IOM Committee's report will call into question the consensus that current sodium intake in the United States is too high. The IOM committee was charged with examining the design, methodologies, and conclusions of these recent studies. The IOM committee was specifically asked to review and assess the benefits and adverse outcomes (if any) of reducing sodium intake in the population, especially in the range of 1,500-2,300 mg per day. Current levels of sodium intake in the United States are well above 2,300 mg per day. Therefore, we believe that continuing to provide dietary advice on reducing sodium intake is a worthwhile contribution to improving public health.

GAO/OIG Reports

53. Mr. Aderholt: Please provide a listing of all GAO reports conducted on FDA programs and activities in fiscal year 2011 and fiscal year 2012.

Response: I would be happy to provide that for the record.

The information follows:

Listing of All GAO Studies Conducted on FDA Programs and Activities in Fiscal Year 2011 and Fiscal Year 2012				
Job Code Number	Name of Study	Notification Letter Issued	Final Report	Final Report Title and number
290772	Heparin Issue	5/1/2009	10/29/2010	Food and Drug Administration: Responses to Heparin Contamination Helped Protect Public Health; Controls That Were Needed for Working With External Entities Were Recently Added
290823	FDAA Inspections of Foreign Drug Establishments	9/28/2009	10/28/2010	Drug Safety: FDA Has Conducted More Foreign Inspections and Began to Improve Its Information on Foreign Establishments, but More Progress Is Needed
290824	Medical Device Recalls	12/2/2009	6/22/2011	MEDICAL DEVICES: FDA Should Enhance Its Oversight of Recalls" (GAO-11-468)
290824	FDAA Beyond Our Borders	11/20/2009	11/28/2010	Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-term Planning Is Needed. (GAO-10-960, September 30)
290831	Pediatric Drug Research	12/4/2009	5/11/2011	PEDIATRIC RESEARCH: Products Studied under Two Related Laws, but Improved Tracking Needed by FDA.
290839	HHS' Efforts to Monitor Antibiotic Resistance	1/11/2010	7/5/2011	ANTIBIOTIC RESISTANCE: Data Gaps Will Remain Despite HHS Taking Steps to Improve Monitoring
361166	Qualified Health Claims on Food	2/1/2010	1/14/2011	Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims (GAO-11-102)
290847	Influenza Vaccine Technologies	2/17/2010	6/27/2011	INFLUENZA VACCINE: Federal Investments in Alternative Technologies and Challenges to Development and Licensure (GAO-11-435)
361137	Pharmaceuticals in Water	2/25/2010	6/8/2011	Action Needed to Sustain Agencies' Coordination on Pharmaceuticals in Drinking Water (GAO-11-346)
361179	Seafood Safety	3/24/2010	3/16/2011	Seafood Safety: FDA Needs to Improve

Listing of All GAO Studies Conducted on FDA Programs and Activities in Fiscal Year 2011 and Fiscal Year 2012

Job Code Number	Name of Study	Notification Letter Issued	Final Report	Final Report Title and number
				Oversight of Imported Seafood and Better Leverage Limited Resources (GAO-11-286)
450827	Lessons Learned from H1N1 Pandemic	4/27/2010	6/27/2011	Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated Into Future Planning (GAO-11-632)
361177	USDA Protocols to Ensure School Meal Safety	3/3/2010	3/3/2011	School Meal Programs: More Systematic Development of Specifications Could Improve the Safety of Foods Purchased through USDA's Commodity Program
361200	Food Safety/Gulf Coast Oysters	5/25/2010	10/11/2011	FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters (GAO-11-607)
361204	Food Emergency Response and Recovery	5/27/2010	9/13/2011	Homeland Security: Actions Needed to Improve Response to Potential Terrorist Attacks and Natural Disasters Affecting Food and Agriculture (GAO-11-652)
320779	Cross-Border and Illicit Trade in Tobacco Products	6/8/2010	3/7/2011	Illicit Tobacco: Various Schemes Are Used to Evade Taxes and Fees (GAO-11-313)
361218	Fragmentation and Overlap of Food Safety System	7/15/2010	3/18/2011	Federal Food Safety Oversight: Food Safety Working Group Is a Positive First Step but Government-wide Planning Is Needed to Address Fragmentation (GAO-11-289)
310948	Public Health Situational Awareness Network	4/28/2010	12/17/2010	Additional Strategic Planning Needed to Guide HHS's Efforts to Establish Electronic Situational Awareness Capabilities
290890	Prescription Drug Abuse	10/6/2010	12/22/2011	Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness
361253	Antibiotic Use in Food Animals	8/10/2010	9/14/2011	Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals (GAO-11-801)
361235	Economically Motivated Adulteration of Food and Medical Products	10/1/2010	11/20/2011	Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect the Public Health
290899	Development of New Antibiotic Drugs	10/14/2010	1/31/2012	FDA Needs to Do More to Ensure That Drug Labels Contain Up-to-Date Information
340874	NHTSA's Process & Oversight of Auto Safety Recalls	1/14/2011	6/15/2011	Auto Safety: NHTSA Has Options to Improve the Safety Defect Recall Process (GAO-11-603)
290905	DHS and HHS' CBRN Medical Countermeasures	1/21/2011	10/26/2011	NATIONAL PREPAREDNESS: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources

Listing of All GAO Studies Conducted on FDA Programs and Activities in Fiscal Year 2011 and Fiscal Year 2012				
Job Code Number	Name of Study	Notification Letter Issued	Final Report	Final Report Title and number
290000	Report on Cord Blood Unit Donation and Collection	2/4/2011	10/7/2011	NATIONAL CORD BLOOD INVENTORY: Practices for Increasing Availability for Transplants and Related Challenges
631260	USDA's Efforts to Reduce E. Coli	1/21/2011	3/9/2012	Preslaughter Interventions Could Reduce E. coli in Cattle
361261	Funding for Nanotechnology EHS Research	3/2/2011	6/20/2012	Improved Performance Information Needed for Environmental, Health, and Safety Research
290015	Pediatric Medical Device Development	3/3/2011	12/20/2011	Provisions Support Development, but Better Data Needed for Required Reporting
120818	Tobacco Trade Tax Differentials	4/1/2011	4/18/2012	Tobacco Taxes Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes
310863	FDA IT Modernization	4/8/2011	4/16/2012	FDA Needs to Fully Implement Key Management Practices to Lessen Modernization Risks (GAO-12-346)
290956	Drug Shortages	5/24/2011	12/15/2011	FDA's Ability to Respond Should Be Strengthened
290949	Cybersecurity Electronic Implantable Med Devices	5/25/2011	8/31/2012	FDA Should Expand Its Consideration of Information Security for Certain Types of Devices
361299	FDA's Mandatory Food Recall Authority	6/2/2011	7/26/2011	Food Safety: FDA's Food Advisory and Recall Process Needs Strengthening
361297	Seafood Safety - Third Party Certification Program	6/20/2011	10/31/2012	Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources
361263	FDA Staffing/Resources for Food Safety	7/8/2011	1/4/2012	none - only briefing slides provided to requesters
290959	Use of Psychotropic Drugs for Children	7/12/2011	1/9/2013	Children's Mental Health: Concerns Remain about Appropriate Services for Children in Medicaid and Foster Care
290917	FDA Review Times for Medical Devices	8/12/2011	3/29/2012	Medical Devices: FDA Has Met Most Performance Goals but Device Reviews Are Taking Longer
361302	USDA and FDA Pesticide Residue Monitoring	8/12/2011	7/26/12	Food Safety: FDA's Food Advisory and Recall Process Needs Strengthening (GAO-12-489)
540390	Health Effects of Cell Phones	8/15/2011	7/24/2012	Telecommunications Exposure and Testing Requirements for Mobile Phones Should Be Reassessed
310973	Agencies' Implementation of FOIA	9/27/2011	9/4/2012	Freedom of Information Act Additional Actions Can Strengthen Agency

Listing of All GAO Studies Conducted on FDA Programs and Activities in Fiscal Year 2011 and Fiscal Year 2012

Job Code Number	Name of Study	Notification Letter Issued	Final Report	Final Report Title and number
				Efforts to Improve Management
290999	HHS' Medical Countermeasures for Thermal Burns	10/3/2011	2/22/2012	National Preparedness: Countermeasures for Thermal Burns
290979	U.S. Spending on Preventive Health Activities	10/13/2011	1/7/2013	Preventive Health Activities: Available Information on Federal Spending, Cost Savings, and International Comparisons Has Limitations
320875	PEPFAR Policies on Treatment and Cost	10/13/2011	5/31/2012	President's Emergency Plan for AIDS Relief: Agencies Can Enhance Evaluation Quality, Planning, and Dissemination
192343	(Special Investigations) Psychotropic Drugs	8/8/2011	12/14/2011	FOSTER CHILDREN: HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions
361364	Seafood Safety II	6/2011	6/8/2012	Seafood Safety: Responsibility for Inspecting Catfish Should Not Be Assigned to USDA
290990	Infection Control Practices for Blood Borne Pathogen	1/6/2012	7/13/2012	HHS Has Taken Steps to Address Unsafe Injection Practices, but More Action Is Needed
361365	Adverse Event Reporting for Dietary Supplements	1/18/2012	3/18/2013	Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products
291008	FDA Review Times for Drugs	8/12/2011	4/30/2012	FDA Has Met Most Performance Goals for Reviewing Applications
330894	Global Drug Procurement and Supply Chain Safeguards	2/13/2012		
291030	FDA Staff Performance Metrics	2/16/2012	5/18/2012	Food and Drug Administration: Employee Performance Standards for the Timely Review of Medical Product Applications
441017	Domestic Methamphetamine Production	5/18/2012		
291033	Pediatric Chemical, Biological Radiological and Nuclear (CBRN) Medical Countermeasures	6/8/2012		
450982	Regulations and Global Competitiveness	6/26/2012		
441094	Wait Times for Cargo Inspections	8/7/2012		
291078	Electronic Drug Labeling	8/31/2012		

Listing of All GAO Studies Conducted on FDA Programs and Activities in Fiscal Year 2011 and Fiscal Year 2012				
Job Code Number	Name of Study	Notification Letter Issued	Final Report	Final Report Title and number
291002	FDA's Review of Tobacco Products	8/16/2012		
291073	Health Care Fraud and Abuse Control (HCFAC)	8/12/2012		
291083	Internet Pharmacies	8/24/2012		
291032	Combat Casualty Care Research	7/19/2012	2/13/2013	Actions Needed to Help Ensure Combat Casualty Care Research Achieves Goals
291064	Drug Shortages of Controlled Substances	7/26/2012		

54. Mr. Aderholt: Provide a listing of all OIG audits and investigations on FDA programs and activities in fiscal year 2011 and fiscal year 2012.

Response: I would be happy to provide that for the record.

The information follows:

Listing of All OIG Studies Conducted on FDA Programs and Activities in Fiscal Year 2011 and Fiscal Year 2012				
Job Code Number	Name of Study	Notification Letter Issued	Final Report	Final Report Title and number
OEI-01-08-00100	Medicaid Payments for Unapproved Drugs	2/13/2009	11/24/2010	FDA's Approval Status of Drugs Paid for by Medicaid
A-07-10-01-01143	Review of Medicare Part D Expenditures for Gender Specific Drugs	1/11/2010	3/2/2011	Review of Erectile Dysfunction Drugs in the Medicare Part D Program
OEI-01-10-00470	CDRH's Policies and Procedures for Resolving Scientific Disputes	8/2/2010	6/4/2012	Scientific Disagreements Regarding Medical Device Regulatory Decisions
OEI-02-09-00430	FDA Oversight of State Food Facility Inspections	3/28/2009	12/13/2011	Vulnerabilities in FDA's Oversight of State Food Facility Inspections
A-07-11-06023	Review of FDA's Oversight of Less-than-Effective Drugs	5/18/2011		

Listing of All OIG Studies Conducted on FDA Programs and Activities in Fiscal Year 2011 and Fiscal Year 2012				
Job Code Number	Name of Study	Notification Letter issued	Final Report	Final Report Title and number
A-07-11-06012	Review of FDA's Drug Approval Process	5/16/2011		
OEI-04-11-00510	REMS	12/19/2011	2/12/2013	FDA Lacks Comprehensive Data To Determine Whether REMS Improve Drug Safety
OEI-01-11-00210	FDA's Oversight of Claims Made on Dietary Supplements	3/16/2011	10/2/2012	Dietary Supplements: Structure/Function Claims Fail To Meet Federal Requirements
A-18-11-30530	FY 2011 Audit of FDA's Network Management Controls	7/12/2011	6/1/2012	Continuing Information Security Weaknesses Pose Risk to Operations and the Mission of the Food and Drug Administration
A-01-12-00518	Xubir	3/29/2012		
A-14-11-00530	Awardee Eligibility for Small Business Innovation Research Awards (SBIR) Across HHS	9/19/2011		
OEI-01-11-00211	FDA's Oversight of Claims Made on Dietary Supplements	3/16/2011	10/2/2012	Dietary Supplements: Companies May Be Difficult To Locate in an Emergency
OIG Investigations of FDA Matters				
CDRH Whistleblower Investigation				
Investigation of Office of Criminal Investigations				

Medical Countermeasures initiative (MCMi)

55. Mr. Aderholt: Provide a current update on the $23,538,000 that the Congress provided to FDA in fiscal year 2013. Include a copy of the spend plan that accompanied this increase, and any modifications to that plan since it was submitted.

Response: To be sent in 2nd batch

New User Fees

56. Mr. Aderholt: For each of the new user fees that FDA proposes for fiscal year 2014, provide the following:

Proposed legislative language; the way in which proposed fee amounts were derived; the customer(s) who would pay?; estimated number of fee paying applicants; estimated fiscal year 2013 spending on current FDA-related activity; programs/activities that the fee will support, including FTE, by center/field; number of meetings held with affected industry prior to the fee being proposed; and, estimated collections.

Response: These user fee proposals would authorize the Food and Drug Administration to collect funds to support its activities. FDA will continue its work with its stakeholders to authorize these fees.

Food Facility Registration and Inspection User Fee

Proposed legislative language: The agency is currently working on draft legislative language that would give us authority to collect the Food Facility and Registration User Fee in the President's Budget.

Proposed fee amounts were derived: This annual fee has been proposed on several occasions. It was originally included in earlier versions of the FDA Food Safety Modernization Act (FSMA) and at that point a $500 fee was proposed to be paid per food or feed facility required to register under the FD&C Act. In discussions with industry over the last few years, one of the most troubling aspects to industry of registration fees was the "flat fee" approach. The current draft legislative language therefore sets forth a tiered approach based on revenue with the higher revenue producing firms paying higher rates than lower revenue producing firms as follows:

Fee Amount*	Annual Revenue Range
$1,000	≥$50 M
$ 500	$1M - <50M
$ 125	< $1M

*Cap established so large firms with multiple facilities would be limited to $175,000 in fees in a single year.

Customer(s) who would pay: The owner, operator, or agent in charge who is identified in the registration of a registered facility would be responsible for paying the fee on an annual basis, unless they reached the cap and at that point they would not have to pay for any additional facilities. Because farms are, by definition, not facilities that are required to register under the FD&C Act, most farms would not be required to pay this fee.

Estimated number of fee paying applicants: The estimate that was used assumed 244,000 facilities (114,000 domestic and 130,000 foreign).

Estimated fiscal year 2013 spending on current FDA-related activity: Given the crosscutting nature of these activities, it is difficult to estimate the FY 2013 spending.

Programs or activities that the fee will support, including FTE, by center and field: The planned allocation of the proposed registration user fee revenues in FY 2014 would be $23 million for the Center for Food Safety and Applied Nutrition (CFSAN) and $27 million for related field activities and $1.5 million for the Center for Veterinary Medicine (CVM), and $1 million for related field activities. The fee would also provide $4 million for program support activities and $2 million for rent activities.

These resources would be devoted to food safety activities, such as the design, development, and implementation of new food and feed FSMA regulations and guidances. It would also support the development and implementation of preventive controls training for FDA inspectors and other personnel, as well as our regulatory partners at the state, local, and tribal levels. In addition, the funds would be used to improve inspection and compliance planning efforts; increase state funding through grants; and increase coordination of laboratory and response capabilities associated with food borne illness outbreaks. FDA would also expand national standards for laboratories; establish verification program efforts; enhance efforts supporting laboratory accreditation programs; implement inspector certification programs; and improved risk based modeling.

Number of meetings held with affected industry prior to the fee being proposed: Since a registration fee was included in the President's FY 2013 Budget Request, FDA began doing its due diligence with the food and feed industries to determine the level of support for this fee to help with funding implementation of FSMA, a statute fully supported by the food industry. During some of the preliminary discussions with the industry, it became clear that one of the real concerns with the proposal was the flat fee approach with no delineation between small business and big business. The result of that input led to the revised tiered approach mentioned above. Also during these early discussions, the industry suggested that we consider an import fee (see discussion on import fee below). From July 2012 to April 2013, FDA has participated in 25 meetings with a broad cross section of the food and feed industry regarding their thoughts and ideas for implementing the FSMA food safety program in a way that meets their commercial needs while remaining primarily focused on the core principle of food safety for FDA and the American consumer. Finally, we discussed alternative ways to resource these new programs and services. The more frequent discussions focused on the import fee but there were also discussions regarding the proposed registration fee.

Estimated collections: $59 million in FY 2014 if legislation is passed.

Food Import User Fee

Proposed legislative language: The agency is currently working on draft legislative language that would give us authority to collect the Food Import User Fee in the President's Budget.

Proposed fee amounts were derived: The fee would be derived from a modest fee with a large volume of fee-paying lines that would generate the needed revenue of $166 million to accomplish both the improvements identified by the industry as well as the FDA needs for incremental resources to fully implement the many and varied requirements for improving the food import program under FSMA. Based on discussions with the industry FDA is also proposing a cap on the total fees to be paid by the largest volume the importers of record, as well as exemptions from fees for the very small by volume importers as well as those importing for research and personal use.

Customer(s) who would pay: The fee would be the responsibility of the "Importer of Record" for the import line being imported.

Estimated number of fee paying applicants: FDA estimates that approximately 5,000 importers of record would meet the requirements mentioned above, for paying fees.

Estimated fiscal year 2013 spending on current FDA-related activity: Given the crosscutting nature of these activities, it is difficult to estimate the FY 2013 spending.

Programs or activities that the fee will support, including FTE, by center and field
The planned allocation of the proposed import user fee revenues in FY 2014 would be $14 million for the Center for Food Safety and Applied Nutrition (CFSAN) and $120 million for related field activities and $1.4 million for the Center for Veterinary Medicine (CVM), and $13 million for related field activities. The fee would also provide $9 million for program support activities and $7 million for rent activities.

These resources would be devoted to improving the import program at FDA, including activities such as establishment of a help desk to assist importers; expanded outreach and education efforts for importers; design, development, and implementation of the Foreign Supplier Verification Program; improvement of the overall quality management of the FDA import program; expansion of staffing at critical ports of entry and hours of operations in order to facilitate the entry of safe foods into the U.S.; and increased use of handheld and screening methodologies.

Number of meetings held with affected industry prior to the fee being proposed:
The import fee proposal is a result of earlier industry discussions on a registration fee. Since a registration fee was included in the President's FY 2013 Budget Request, FDA began doing its due diligence with the food and feed industries to determine the level of support for a facility registration fee to help with funding implementation of FSMA, a statute fully supported by the food industry. During these early discussions, the industry suggested that we consider an import fee. From July 2012 to April 2013, FDA has participated in 25 meetings with a broad cross section of the food and feed industry regarding their thoughts and ideas for implementing the FSMA food safety program in a

way that meets their commercial needs while remaining primarily focused on the core principle of food safety for FDA and the American consumer. Finally, we discussed alternative ways to resource these new programs and services. The more frequent discussions focused on the import fee but there were also discussions regarding the proposed registration fee.

Estimated collections: $166 million in FY 2014 if legislation is passed.

Cosmetic User Fee

Proposed legislative language: FDA does not have proposed authorizing language for this user fee at this time. FDA is seeking to establish a system of user fees under new legislative authorities to support the FDA Cosmetics Safety Program.

Way in which proposed fee amounts were derived: The user fee request represents the level of resources required to administer these additional authorities for cosmetic safety. A fee structure would be developed through negotiations with industry.

Customer(s) who would pay: The customers who would pay are the cosmetic product industry.

Estimated number of fee paying applicants: The estimated number of fee paying applicants is unknown. As of early 2013, more than 1,700 cosmetic establishments had registered voluntarily with FDA, covering over 44,000 products. However, these numbers represent only a fraction of the number of cosmetic establishments and products on the market. FDA has seen a dramatic increase in the number and type of cosmetic products sold annually. Having a more complete picture about what is on the market will better enable FDA to evaluate cosmetic ingredients and finished products for safety.

Estimated fiscal year 2013 spending on current FDA-related activity: The estimated fiscal year 2013 spending on current FDA-related activity is approximately $12.2 million and 47 FTE.

Programs/activities that the fee will support, including FTE, by center/field: FDA will conduct CFSAN and ORA activities with the new user fee resources. The fees provide $12.3 million and 42 FTE for CFSAN to establish and maintain a Cosmetic Registration Program; acquire, analyze, and apply scientific data and information to set U.S. cosmetic standards; maintain a strong U.S. presence in international standard-setting efforts; and provide education, outreach, and training to industry and consumers. The fees provide $4.4 million and 18 FTE for ORA to refine inspection and sampling of imported products and apply risk-based approaches to post-market monitoring of domestic and imported products, inspection, and other enforcement activities. The fee also includes $1 million and 3 FTE for program support activities and $1.4 million for rent activities.

Number of meetings held with affected industry prior to the fee being proposed: FDA has been engaged in discussions with regulated industry since summer of 2011.

Estimated collections: $19,074,000 in FY 2014 if legislation is passed.

Food Contact Substance Notification (FCN) Fee

Proposed legislative language: FDA does not have proposed authorizing language for this user fee at this time. FDA is seeking to establish a system of user fees to support the food contact substance safety review program.

Way in which proposed fee amounts were derived: The user fee request was based on average yearly FCN filings and the level of resources required to administer the FCN process in addition to base budget authority resources. A fee structure would be developed through negotiations with industry, to potentially include fees for reviews of each FCN and an annual fee for listing each authorization in FDA's Inventory of Effective Food Contact Substance Notifications, which appears on FDA's website. The monies generated from these user fees are expected to grow each year as more food contact substances are added to the agency's inventory, thereby gradually generating additional fees for the program when authorized substances are listed.

Customer(s) who would pay: The customers are the food contact product industry, including food manufacturers, distributors, and marketers.

Estimated number of fee paying applicants: In estimating the number of fee paying applicants, annually, there is an average of 94 new FCN filings, with 79 becoming effective. As of March 2013, there were 966 effective FCNs.

Estimated fiscal year 2013 spending on current FDA-related activity: The estimated fiscal year 2013 spending on current FDA-related activity is approximately $6.7 million and 16 FTE.

Programs/activities that the fee will support, including FTE, by center/field: The programs/activities that the fee will support are $4.5 million and 7 FTE for CFSAN to support the efficient and timely review of food contact notifications; update standards and provide guidance for industry; conduct education, outreach, and training; and participate in international harmonization and standard setting for food contact substances. The fee also includes $272,000 and 1 FTE for program support and $179,000 for rent activities.

Number of meetings held with affected industry prior to the fee being proposed: N/A

Estimated collections: $4,790,000 in FY 2014 if legislation is passed.

International Courier User Fee

Proposed legislative language: FDA has not been authorized to collect this user fee at this time.

Way in which proposed fee amounts were derived: FDA is basing this fee on historical data.

Customer(s) who would pay: The customers who would pay are the international food courier industry.

Estimated number of fee paying applicants: The customers are several large international express courier facilities offering international service with next-day delivery, who import FDA-regulated products into the U.S. and have requested that FDA increase staffing to help meet industry needs. The fees will be assessed and resources will be allocated based on historical entry volumes by courier. FDA is still collecting information and does not have an estimated number of fee paying applicants to provide at this time.

Estimated fiscal year 2013 spending on current FDA-related activity: The estimated fiscal year 2013 spending on current FDA-related activity is undetermined at the present time. The estimated fiscal year 2012 spending on current FDA-related activity is $5.5 million for staffing after hours and on weekends.

Programs/activities that the fee will support, including FTE, by center/field: The programs and activities that the fee will support are $4.8 million and 20 field Full Time Equivalent (FTE) to conduct entry reviews and physical examinations which include sample collections, and physical exams to determine product admissibility into the U.S., initiate compliance actions to prevent release of unsafe products into U.S. commerce, and establish import controls to prevent future unsafe products from entering U.S. commerce. The fee will also support $289,000 and 1 FTE for FDA Headquarters indirect and support costs and $483,000 for GSA Rent and Rent Related costs.

Number of meetings held with affected industry prior to the fee being proposed: The number of meetings held with affected industry prior to the fee being proposed is undetermined at the present time.

Estimated collections: $5.6 Million in FY 2014 if legislation is passed.

Medical Products Reinspection User Fee: FDA has not been authorized to collect medical product reinspection user fees at this time. Furthermore, FDA would like to rescind from this fee being authorized and included in our budget.

Way in which proposed fee amounts were derived: This user fee was derived from historical data.

Customer(s) who would pay: The customers affected by these fees are medical product manufacturers.

Estimated number of fee paying applicants: The domestic inventory of medical product establishments is approximately 16,350.

Estimated number of fee paying applicants The estimated fiscal year 2013 spending on current FDA-related activity is undetermined at the present time. The estimated fiscal year 2012 spending on current FDA-related activity is $20 million.

Programs/activities that the fee will support, including FTE, by center/field: FDA will conduct CFSAN and ORA activities with the new user fee resources. The fees provide CFSAN the opportunity to acquire, analyze, and apply scientific data and information to set U.S. cosmetic standards; maintain a strong U.S. presence in international standard-setting efforts; and provide education, outreach, and training to industry and consumers. The fee also includes $17 million for 75 field investigators and staff; $1 million for Headquarters indirect and support costs – such as legal, science review, and IT – and 4 FTE; and $1.7 million for GSA Rent and Rent Related costs. Additionally, FDA's Office of Regulatory Affairs – ORA – conducts inspections of human drugs, biologics, animal drugs and medical device manufacturers to assess their compliance with current Good Manufacturing Practice requirements. Revenue from the user fee will reimburse ORA for resources required to re-inspect firms that fail to comply with FDA regulations that are designed to protect the public from unsafe products.

Number of meetings held with affected industry prior to the fee being proposed: The number of meetings held with affected industry prior to the fee is undetermined at the present time.

Estimated collections: $14.8 million in FY 2014 if legislation is passed.

QUESTIONS SUBMITTED BY CONGRESSMAN TOM LATHAM

Food Industry Fees

Mr. Latham: Dr. Hamburg, why doesn't FDA request a realistic method for funding the Food Safety Modernization Act, instead of relying upon fees that have no chance of becoming law?

Response: FDA believes that user fees are a viable way to fund FDA's serious needs in protecting the food and feed supply and is supporting these fees now because of their high priority. FDA will work with the authorizing committees, appropriations committees, and industry to ensure the fees are practicable.

Mr. Latham: This Subcommittee has received a letter from over 50 food groups opposing the new fees you are proposing, yet we have heard that FDA is in discussions with those in the food industry who might agree with these fees. How do you reconcile the real concern we have been told there is, with claims that you are engaging the industry on the issue? The opposition appears to be growing.

Response: We do not believe that opposition to these fees is growing. Over the last year FDA has worked with stakeholders to discuss the registration and inspection fee that was included in our FY 2013 budget request. This was done through a series of meetings with a broad cross section of the food and feed industry. It was through these discussions that significant changes were made to the proposed registration and inspection fee; and the ideas regarding the potential for a modest import fee emerged. FDA will continue to engage the industry on the development of necessary, high priority user fees.

Misrepresentation of NARMS Data

Mr. Latham: Dr. Hamburg, I appreciate FDA's recent efforts to set the record straight on how government data was used inappropriately to make false and alarmist claims about "superbugs" in meat. Looking ahead how is FDA prepared to ensure future government reports are not used to misrepresent the facts?

Response: FDA agrees it is important to provide some context to the information being released to help prevent misinterpretation and, in some cases, unnecessary public concern or distress, and we intend to provide such context when necessary. FDA is committed to providing the public with accurate and up-to-date information. However, as with all data, those contained in reports released by FDA are subject to interpretation from various groups representing various positions. FDA believes such sharing of information can lead to positive dialogue and advance scientific debate about issues important to public health.

Artificial Pancreas for Diabetes Patients

Dr. Hamburg, Diabetes impacts almost 200,000 people in my state of Iowa. I am greatly concerned about the quality life for these people and the cost of this disease as a result of complications. It is important to see that our federal agencies are doing everything possible, particularly the FDA, in moving key technologies and therapies through the pipeline to address this disease. I am pleased that the FDA issued the final guidance in November 2012 for the development of artificial pancreas systems, which I understand are in development across the country, but not yet approved by the FDA. Because of their ability to dramatically improve the health and quality of life, I want to make sure they get into the hands of patients as soon as possible. The FDA's official guidance issued last November is a critical step in accelerating the development of the technology, as it provides the FDA's general expectations for stakeholders conducting human outpatient clinical trials and for marketing approval of the devices.

Mr. Latham: Dr. Hamburg, could you tell me how the FDA plans to support this momentum so that these innovative systems can be tested without delay and made available in the near future?

Response: We believe that the development of an Artificial Pancreas - AP - is within technological reach and have assigned significant resources to facilitate such development. At the beginning of 2012, we streamlined the applicable review structure. This move has resulted in quicker turnaround times in the review of investigational protocols and in review of premarket submissions. To date, the group has reviewed 42 investigational protocols within its 30 day goal,

without a single disapproval. Among those, we have approved several outpatient studies in adults and a diabetes camp study in children.

We co-sponsored a public workshop with the National Institutes of Health - NIH - and Juvenile Diabetes Research Foundation - JDRF - in March of 2013. The workshop initiated a multidisciplinary discussion which will help to accelerate the development and delivery of an AP. We continue to pursue outreach efforts with investors, researchers, clinicians, policymakers, manufacturers, and patient advocates to help clarify expectations, and help solve challenges as they arise. We look forward to working together with the diabetes community to advance quickly towards an approved AP.

Biosimilars Pathway

Mr. Latham: Dr. Hamburg, how is the Agency progressing on implementing the biosimilars pathway since enactment of the Biologics Price Competition and Innovation Act (BPCIA) in 2010.

Response: FDA continues to develop rigorous scientific standards to ensure that all biosimilar and interchangeable products meet these statutory requirements, and thus will be safe and effective. Some of this effort is reflected in three draft guidances FDA issued in 2012 that provide FDA's scientific recommendations on demonstrating biosimilarity, and we have begun developing guidance on additional key scientific issues as well. FDA is actively engaging with sponsors interested in developing biosimilar products to ensure that the development programs will provide the necessary scientific evidence to meet the statutory requirements for biosimilarity. Health care professionals and consumers can be assured that FDA will require licensed biosimilar biological products to meet the Agency's exacting standards of safety and efficacy.

Mr. Latham: Have applications been filed or other significant actions taken by potential applicants?

Response: To date, FDA has not received an application for a proposed biosimilar product. The Center for Drug Evaluation and Research (CDER) continues to meet with sponsors interested in developing biosimilar products. As of May 7, 2013, CDER has received 56 requests for initial meetings to discuss development programs involving 12 different reference products and has held 38 initial meetings with sponsors. Many biosimilar development programs that have had an initial advisory meeting with CDER have moved into the development phase and are requesting biosimilar product development (BPD) meetings. CDER is actively engaging with these sponsors, including holding BPD meetings and providing written advice, for ongoing development programs for proposed biosimilar products. To date, CDER has received 17 Investigational New Drugs (INDs) for biosimilar development programs, but several additional development programs are proceeding undera pre-IND.

Mr. Latham: As to the naming of biosimilar drugs, it's my understanding that the Agency in 2006 issued a statement in support of the international naming regime. Is that still the policy position of the Agency? If not, please explain what has changed.

Response: FDA is currently considering the appropriate naming convention for biosimilar and interchangeable products licensed under the pathway established by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) enacted as part of the Affordable Care Act. FDA is carefully reviewing and considering the comments submitted to FDA's biosimilar guidance and public hearing dockets. We will take into consideration all received comments as we move forward in finalizing the guidance documents and developing future policies regarding biosimilar products and interchangeable products.

Menu Labeling Options

Dr. Hamburg, you were recently quoted as saying that the implementing rules for restaurant menu labeling "has gotten extremely thorny." However, you appear to have some options available to you, including the "Option 2" alternative that FDA proposed that has a less expansive, less onerous scope while still fulfilling the intent of the law.

Mr. Latham: Couldn't the FDA solve these issues by going forward and finishing the regulations by adopting this Option 2?

Response: FDA is currently developing a final regulation for implementing the restaurant menu labeling requirements of the Affordable Care Act. We received about 900 comments on the proposed rule and we are considering this feedback as we draft the final regulation. There are a number of complex issues involved in the regulation besides the scope of covered establishments such as how calorie information should be displayed on menus and menu boards and how other nutrition information should be provided in written form.

Bisphenol-a Assessment Update

Mr. Latham: Dr. Hamburg, it has been more than four years since the release of the FDA's draft risk assessment for BPA, and it has yet to publicly issue an updated assessment in light of extensive additional study of the issue that has occurred. When will the FDA release an updated BPA risk assessment?

Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for effects of BPA and in interpreting the myriad of exploratory research studies on BPA that have become available in the past few years. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. Once the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. Pending no unforeseen delays to the completion of the studies,

an updated safety assessment may be available as early as mid-2014. If a safety issue were identified during our ongoing review, FDA would act to mitigate the issue in support of public safety. However, the preliminary results from the FDA studies so far support FDA's assessment that the use levels of BPA in food packaging and containers are safe.

QUESTIONS SUBMITTED BY CONGRESSMAN ALAN NUNNELEE

Sequestration – FDA Human Drug Review

Dr. Hamburg, you highlight the Food and Drug Administration Safety and Innovation Act (FDASIA) and the new authorities you were granted to increase the speed and predictability of medical product reviews, protection of the drug supply chain, reduce drug shortages, and speed the review of more affordable versions of drugs that are essential in holding down health care costs. You also highlight that, "in 2012, FDA approved 39 novel medicines, and the great majority were approved in the U.S. before any other country in the world." Enter sequestration. The 5% sequester will be applied to all non-defense discretionary spending, including prescription drug user fees. And since OMB has deemed user fees sequesterable, a roughly $30-35 million sequester of PDUFA user fees is expected to occur under the current continuing resolution (CR). Since FDA is currently operating below the FTE ceiling authorized by congressional appropriations and PDUFA, furloughs are not expected to be issued for the human drug review program. However, FDA indicated that the Agency would not be in a position to initiate new hiring in support of the PDUFA-V regulatory science programs until after the release of sequestered user fees has been achieved.

Mr. Nunnelee: Do the fees become permanently unavailable for obligation, or can sequestered PDUFA user fees be re-appropriated in a following fiscal year?

Response: PDUFA funds that have been sequestered are only available for obligation if Congress provides specifiauthorization to do so.

Mr. Nunnelee: What ability will the FDA have to prioritize activities within the human drug review program to protect critical public health functions from the sequester cuts, such as drug safety activities and the review and approval of innovative medicines?

Response: FDA will align resources efficiently to ensure the health, safety and well-being of the American people; however, sequestration may impact FDA's ability to meet performance goals and commitments within the specified timeframes of the PDUFA V commitment letter.

Mr. Nunnelee: What will be the impact of the sequester on the FDA's ability to advance important regulatory science initiatives as outlined in the PDUFA-V commitment letter and the Food and Drug Administration Safety and Innovation Act?

Response: FDA is committed to completing the work that is specified in the PDUFA V commitment letter. However, this additional work was accompanied by an increase in user fees paid by the regulated industry to fund FDA's efforts. This was part of the negotiated PDUFA V agreement. In Fiscal Year 2013, sponsors are paying fees for this increase but FDA does not

have access to the full amount of the funds due to the sequestration. While FDA has begun work on the PDUFA V enhancements, the agency will not be able to accomplish this work within the specified timeframes as long as the resources to support this work are sequestered.

Mr. Nunnelee: How can FDA work with its core constituencies to help minimize or mitigate the impact of the sequester on the human drug review program and other key functions related to access to critical groundbreaking therapies?

Response: The sequestration impacts FDA's ability to meet the commitments FDA made related to program enhancements in PDUFA V. This is work that must be done by FDA, not other FDA constituencies. Many of these enhancements will have long term benefits for human drug development. The delay of these enhancements resulting from the sequestration will postpone these benefits. Key performance goals may be at risk, resulting in delays in the availability of novel and critical new drugs for patients. If sequestration is mitigated in the future, FDA will have enhanced capacity to meet commitments in PDUFA V and the Food and Drug Administration Safety and Innovation Act.

Bisphenol-a (BPA)

Mr. Nunnelee: In 2008, FDA issued a draft assessment concluding that an adequate margin of safety exists for bisphenol-a (BPA) at current levels of exposure from food contact uses. In 2010, FDA issued an interim update and today, according to the FDA website, "FDA's current assessment is that BPA is safe at the very low levels that occur in some foods. This assessment is based on review by FDA scientists of hundreds of studies including the latest findings from new studies initiated by the agency." According to FDA records, there has not been a food-borne illness from the failure of a metal can in over 37 years. Despite this commentary, and similar commentary when the subject arose on a popular television show in January, there has not been an official release of FDAs risk assessment of BPA. This has led to uncertainty and instability in the metal food packaging industry. This uncertainty means a delay in industry investment in metal packaging plants to either upgrade existing plants or add new capacity. Specifically this uncertainty means a hold on additional job creation.

Mr. Nunnelee: I guess I do not understand, if you have a statement on your website, and you are responding in a similar manner through a television program, why has nothing officially been released by FDA?

Response: The review process for FDA's assessment is in progress Studies recently completed at FDA's National Center for Toxicological Research (NCTR) continue to support FDA's conclusion that BPA is safe at the very low levels that occur in some foods. The next formal FDA assessment will incorporate these data as well as data from additional studies in progress at the NCTR that should enhance our understanding of the potential for effects of BPA and in interpreting the myriad of exploratory research studies on BPA that have become available in the past few years. FDA's assessment will then be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media.

Mr. Nunnelee: Can you confirm that what is reflected on the website is FDA's current position on BPA?

Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for effects of BPA and in interpreting the myriad of exploratory research studies on BPA that have become available in the past few years. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. After the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media. Pending no unforeseen delays to the completion of the studies, an updated safety assessment may be available as early as mid-2014. If a safety issue were identified during our ongoing review, FDA would act to mitigate the issue in support of public safety. However, the preliminary results from the FDA studies so far support FDA's assessment that the use levels of BPA in food packaging and containers is safe. Therefore, the statement from our website still reflects FDA's current position on BPA.

Mr. Nunnelee: When will FDA be providing a clear and substantive position on BPA to the public?

Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for effects of BPA and in interpreting the myriad of exploratory research studies on BPA that have become available in the past few years. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. After the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media. Pending no unforeseen delays to the completion of the studies, an updated safety assessment may be available as early as mid-2014. If a safety issue were identified during our ongoing review, FDA would act to mitigate the issue in support of public safety. However, the preliminary results from the FDA studies so far support FDA's assessment that the use levels of BPA in food packaging and containers is safe. Therefore, the statement from our website still reflects FDA's current position on BPA.

Mr. Nunnelee: Please provide the basis of FDA's current assessment as to the safety of BPA, along with the review of studies by FDA scientists, both referred to on the website, be made available to the public?

Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for effects of BPA and in interpreting the myriad of exploratory research studies on BPA that have become available in the past few years. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. After the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media. Pending no unforeseen delays to the completion of the studies, an updated safety assessment may be available as early as mid-2014. If a safety issue were identified during our ongoing review, FDA would act to mitigate the issue

in support of public safety. However, the preliminary results from the FDA studies so far support FDA's assessment that the use levels of BPA in food packaging and containers is safe. Therefore, the statement from our website still reflects FDA's current position on BPA.

Mr. Nunnelee: Other than briefly describing these studies on the FDA website, how does FDA intend to inform the public of the results of these new studies?

Response: Studies are in progress or recently completed at FDA's National Center for Toxicological Research (NCTR) that should enhance our understanding of the potential for effects of BPA and in interpreting the myriad of exploratory research studies on BPA that have become available in the past few years. FDA intends to update its safety assessment, once these studies are published and the results are made available to the public. After the studies are completed and incorporated into the FDA safety assessment, FDA's assessment will be peer-reviewed prior to public release. At that time we intend to provide related updates on our website, consumer information page, and to the media. Pending no unforeseen delays to the completion of the studies, an updated safety assessment may be available as early as mid-2014. If a safety issue were identified during our ongoing review, FDA would act to mitigate the issue in support of public safety. However, the preliminary results from the FDA studies so far support FDA's assessment that the use levels of BPA in food packaging and containers is safe. Therefore, the statement from our website still reflects FDA's current position on BPA.

Emergency Contraception for Minors Without Parental Consent

Mr. Nunnelee: On December 7, 2011, Secretary Sebelius, Health and Human Services, along with the support of the President, overruled a decision by the U.S. Food and Drug Administration (FDA) to make emergency contraception available over-the-counter to women of all ages. On April 5, 2013 the United States District Court for the Eastern District of New York reversed Secretary Sebelius' decision, making access to emergency birth control medication unrestricted. On April 30, FDA approved Plan B One-Step emergency contraceptive without a prescription for women 15 years and older. Was FDA aware that 51 members of Congress wrote President Obama urging him to appeal the District court's reversal of Secretary Sebelius's decision? What communication was there between FDA, HHS, and the White House that this was the best decision moving forward?

Response: The Agency's decision to act on Teva Branded Pharmaceutical Products R & D's (Teva) application to market Plan B One Step (PBOS) without a prescription to women 15 and over was independent of any action taken with regard to the court ruling. As is typical in any situation where the Department and/or one of its Agencies has been ordered by a court to take an action, FDA staff worked with their colleagues at HHS and the Department of Justice to evaluate the legal options in response to that order.

Mr. Nunnelee: Commissioner Hamburg stated via the FDA press release, "Research has shown that access to emergency contraceptive products has the potential to further decrease the rate of unintended pregnancies in the United States. The data reviewed by the agency demonstrated that women 15 years of age and older were able to understand how Plan B One-Step works, how to use it properly, and that it does not prevent the transmission of a sexually transmitted disease." Please provide the subcommittee with a copy of the cited research.

Response: A table on page 93 of "Disparities in rates of Unintended Pregnancy In the United States, 1994 and 2001" shows that between 67% to 82% of pregnancies in young women aged 15 to 19 years are unintended.[1] Studies have shown that PBOS is effective in preventing up to 84% of expected pregnancies.[2] Copies of those studies have been provided.

In addition, the drug sponsor's application included two studies – the label comprehension study and the actual use study. Copies of the published results of these studies have been provided.

Mr. Nunnelee: FDA is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use. What consideration was given to the potentially harmful effects this type of contraception could have on the health of the minor? How does FDA plan to ensure that this product is not used by minors as a regular contraceptive method?

Response: PBOS was already approved for women ages 16 and under as a prescription product. The safety and efficacy of this product in women under 16 was considered as a part of the review of the prescription product. In addition, Teva provided data from actual use and label comprehension studies that demonstrated that females who may need emergency contraception understood it was not for routine use. Copies of the published results of these studies have been provided.

On April 10, 2013, Judge Edward R. Korman of the Eastern District of New York entered a judgment requiring that FDA make levonorgesterel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within 30 days. On June 10, 2013, the U.S. Department of Justice advised Judge Korman that FDA and HHS had complied with the court's judgment by sending a letter to Teva inviting it to promptly submit a supplemental new drug application to FDA that would permit PBOS to be sold without a prescription and without age or point-of-sale restrictions and indicating that FDA would approve such an application without delay.

After receipt of FDA's letter, Teva submitted a supplemental new drug application, and FDA has now approved that application. With this approval, there is no age or point-of-sale restrictions on the sale of PBOS.

Mr. Nunnelee: I understand that an education plan for consumers, pharmacy staff, and health care professionals about the product's new status is going to be implemented. Please provide the subcommittee with a copy of this agreement. Do pharmacy staff and health care professionals have to verify that they meet the education plan before they begin administering the contraceptive to minors ages 15-17? Do minors ages 15-17 have to verify via signature that they have been educated on the contraceptive before they receive it?

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[1] Finer LB, Henshaw SK. Disparities in rates of unintended pregnancy in the United States, 1994 and 2001. Perspect on Sex and Reprod Health. 2006 Jun;38(9)90-6..

[2] Cochrane review, 2012 (page 11).

Response: As noted above, under the Court's order, FDA approved the supplemental new drug application submitted by Teva and PBOS will soon be available without any point-of-sale or age restrictions.

Mr. Nunnelee: Additionally, an audit of the age verification practices will be completed to ensure that the age limitation is being followed. What specific valid forms of identification will minors ages 15-17 have to provide to receive the contraceptive? What is the start and completion timeline for the audit of age verification practices?

Response: As noted above, under the Court's order, FDA approved the supplemental new drug application submitted by Teva, and PBOS will soon be available without any point-of-sale or age restrictions.

QUESTIONS SUBMITTED BY CONGRESSMAN JEFF FORTENBERRY

Contamination of Imported Produce and Seafood

Mr. Fortenberry: Dr. Hamburg, in your testimony you note that, of the imported produce and seafood refused entry at the border, 70-85% is for potentially dangerous violations, including the presence of disease-causing organisms and chemical contamination. Please identify the major contaminants detected by FDA as well as their country/sources of origin.

Response: In FY 2012, a total of 3,504 lines of seafood and fresh produce were refused entry into the U.S. Seafood refusals accounted for 3,050 lines while fresh produce accounted for 454. A line can include varying amounts of product-- some lines include a large amount of a food product, and other lines include only a small amount of a food product.

Of the 3,050 seafood lines refused, 1,011 lines were refused for containing food-poisoning bacteria, including:

- *Salmonella* - Indonesia had the highest number of lines refused due to *Salmonella.*
- *Listeria* - Canada had the highest number of lines refused due to *Listeria.*
- *E. coli 0157* - New Zealand had the highest number of lines refused due to *E.coli.*

There were also 232 lines refused for containing chemical agents, including:

- Chloramphenicol - Indonesia had the highest number of lines refused for the presence of Chloramphenicol.
- Nitrofurans - Malaysia had the highest number of lines refused for the presence of Nitrofurans.
- Lead - Chile and Australia had an equal number of lines refused for the presence of Lead.

Of the 454 fresh produce lines refused, 149 lines were refused for containing *Salmonella*:

- *Salmonella* - Mexico had the highest number of lines refused due to *Salmonella*.

There were also 266 lines of fresh produce refused for containing illegal pesticides. Mexico had the highest number of refusals due to illegal pesticides.

QUESTIONS SUBMITTED BY CONGRESSMAN DAVID G. VALADAO

Cigars

1. Mr. Valadao: The premium cigar industry is responsible for approximately 85,000 jobs and many small businesses. How will FDA and CTP ensure that this industry and its jobs are not harmed by overreaching regulation?

Response: The Agency's tobacco product authorities included in Chapter IX of the FD&C Act do not automatically apply to cigars. Instead, FDA must issue a regulation deeming cigars to be subject to the law. In the 2011-2013 editions of the Unified Agenda, including the most recent January 2013 edition, FDA included an entry for a proposed rule that would deem products meeting the statutory definition of "tobacco product" to be subject to Chapter IX of the FD&C Act.

During the past year, FDA has had meetings with representatives of the premium cigar industry and has learned a great deal about these products. While we cannot comment on the details of pending rulemaking, it is important to note that the process for issuing any proposed rule would provide the opportunity for public comment as part of the rule-making process. FDA routinely allows a minimum of 60 days for public comment and carefully considers these comments when it develops the final rule.

2. Mr. Valadao: Does FDA see "premium cigars" as a distinct type of tobacco product and if so, how does FDA intend to define "premium cigar"?

Response: As noted in the previous response, FDA cannot comment on the details of pending rulemaking, such as proposed definitions. We do understand that different tobacco products may raise different questions of public health and thus may need to be treated differently. This is something we are looking at as we consider potential regulatory action. And, as always, industry and other stakeholders will have an opportunity to submit comments on the proposed rule as part of the rulemaking process.

Tissue Banking

In July 2007, the FDA Office of Combination Products (OCP) issued a document entitled, Guidance for Industry and FDA Staff: Minimal Manipulation of Structural Tissue Jurisdictional Update (Jurisdictional Update). In issuing the Jurisdictional Update, the FDA did not provide a formal comment period.

While FDA felt justified in doing so, stating that it was not a Level 1 guidance, some disagree. In examining the application of that guidance, it is clear that FDA not only altered

key definitions (i.e., minimal manipulation) but also introduced new terms (e.g., "original" and "relevant"). Further, especially in the past several years, it is clear that FDA may be applying the guidance document differently than initially interpreted by industry.

Given that FDA has now had nearly six years of experience with such guidance, I urge the FDA to rescind this guidance document. And, if the agency wishes to republish the document, do so with a formal, public comment period.

Mr. Valadao: Will you agree to look at this issue and report back to the Committee how you plan to move forward with this guidance document?

Response: We have heard that some stakeholders have questions about this policy document, and we understand that there is a need for improved communication regarding regulatory policy in this area. We are currently considering how best to address this concern. We agree to look at this issue and report back on how we are addressing stakeholder communications regarding the policies described in this document.

QUESTIONS SUBMITTED BY RANKING MEMBER SAM FARR

Sunscreen Approvals

It seems to be taking forever to get new sunscreen products approved. Currently, there are eight new sunscreen ingredients that have Time and Extent Applications (TEAs) pending at FDA for over 10 years, which could help address melanoma and skin cancer outbreaks. Ironically FDA has listed final action on the sunscreen products as a priority in its Unified Agenda each year since 2008. Originally, the FDA estimated that under the Time & Extent process it would be able to complete TEA evaluations between 90-180 days and approve 30 applications per year.

Mr. Farr: Why has it taken FDA over a decade to take final action on the sunscreen TEA applications for products that have a history of safe and effective use in other countries? When will FDA complete consideration of the eight pending sunscreen TEA applications? How do you intend to reform the TEA process to ensure American businesses are able to bring important products like the best sunscreens to market?

Response: FDA's review of the 8 sunscreen TEA applications is best understood in the context of the general Over the Counter (OTC) Drug Review (OTC monograph system) and our ongoing monograph proceedings, of which it is a part. OTC drug monographs are regulations that describe "conditions"(including active ingredients) for a given category of OTC drugs to be considered as generally recognized as safe and effective (GRAS/E) and not misbranded, and thus enable conforming drugs to be marketed without a product-specific approved new drug application. For example, the OTC sunscreen monograph includes 16 active ingredients, and a great number and variety of sunscreen products are currently available to U.S. consumers in accordance with its terms. Inclusion in a monograph was originally available only for active ingredients or other conditions marketed in the U.S. before this system began in the early 1970s, but was expanded through establishment of the TEA process, which provides a potential pathway to add new active ingredients and conditions to the OTC monograph. The process requires a threshold "eligibility" determination based on marketing data; and a determination that the drug is generally recognized as safe and effective (GRAS/E) for its intended OTC use based on

appropriate scientific evidence. These determinations require extensive submissions, FDA data review, and multi-step rulemaking proceedings.

Sunscreens are a high priority, as their public health importance is increasingly apparent, but they present unique scientific and regulatory challenges. Scientific understanding and questions regarding sunscreens have been evolving since sunscreen TEAs were submitted. Simultaneously, use of sunscreens as a preventive drug product has expanded greatly. What was occasionally used in only the fairest skinned is now commonly and extensively used by a large segment of U.S. population.

Completing TEA reviews for new sunscreen active ingredients while ensuring they meet strong and current standards of safety and effectiveness is challenging. FDA has devoted efforts to updating the sunscreen regulations to ensure that both currently marketed and future products are appropriately formulated, scientifically tested, and labeled to provide safe and effective protection against harmful solar radiation. We also are evaluating important scientific questions on OTC sunscreen ingredient safety that directly informs our review of the 8 TEA ingredients.

FDA has issued eligibility determinations for the 8 sunscreen TEAs submitted to date, finding each eligible to continue to the next stage of the TEA process, the GRAS/E determination, which is now ongoing. We are now turning attention to communicating with TEA sponsors about whether there are sufficient safety and effectiveness data to support proposed monograph status for these active ingredients. TEA ingredients and other conditions must satisfy the same GRAS/E standard and evidentiary requirements that apply to other active ingredients and conditions under the general OTC monograph process. And, consistent with the general monograph process, ingredients found eligible for review under TEA applications are subject to multi-step notice and comment rulemaking procedures before they may be included in a final OTC drug monograph.

Because of the public health importance of OTC sunscreens, FDA is actively working to complete our review of these TEA ingredients, and expects to take action on them in the near future. We are committed to finding ways to facilitate the marketing of additional OTC sunscreen products, but must assure their safety, effectiveness, and overall risk-benefit profile.

The TEA process was established through the regulations to provide a mechanism for introducing new active ingredients and other conditions into the OTC monograph system. We are currently considering ways to improve the TEA process within the confines of these regulations.

In the meantime, we have tried to make firms that choose to submit applications through the TEA process aware that there are no mandated timelines associated with this process. The most rapid way to bring a drug containing a new active ingredient to the market would be through the NDA review process.

Draft Guidance for New Dietary Ingredients

Last year this subcommittee suggested the FDA withdraw the Draft Guidance for New Dietary Ingredients and start over, taking care to work more closely with the dietary supplement industry. However, I'm not aware that FDA has changed anything with regard to this *Draft Guidance*.

Mr. Farr: Why not? How can the FDA redesign or rework this *Guidance* document so it doesn't infringe on the ability of the industry to manufacture its product?

Response: In the *Federal Register* of July 5, 2011 (76 FR 39111), FDA made available to the public a draft guidance entitled "Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" and gave interested parties an opportunity to submit comments by October 3, 2011. In the *Federal Register* of September 9, 2011 (76 FR 55927), we extended the comment period to December 2, 2011. A number of comments suggested that the draft guidance would benefit from revisions on certain topics and recommended that the revised draft guidance be reissued for another round of public comment. We are revising the draft guidance accordingly and plan to ask for comments by announcing its availability in a *Federal Register* notice. As part of this process we have met with industry representatives several times to better understand their concerns about the draft guidance and identify gaps and misconceptions that could be resolved through clarifications or revisions to the text. FDA is actively working on the revised draft guidance and intends to issue it as soon as possible.

Biologics Price Competition and Innovation Act (BPCIA) Implementation

The BPCIA was enacted as part of the Affordable Care Act. Its intent was to expand access and lower the cost of biosimilars.

Mr. Farr: How is the Agency progressing on implementing the biosimilars approval process? Have applications been filed by potential applicants?
As to the naming of biosimilars, it's my understanding that the Agency in 2006 issued a statement in support of the international naming regime. Is that still the policy position of the Agency?

Response: FDA continues to develop rigorous scientific standards to ensure that all biosimilar and interchangeable products meet these statutory requirements, and thus will be safe and effective. Some of this effort is reflected in three draft guidances FDA issued in 2012 that provide FDA's scientific recommendations on demonstrating biosimilarity, and we have begun developing guidance on additional key scientific issues as well. FDA is actively engaging with sponsors interested in developing biosimilar products to ensure that the development programs will provide the necessary scientific evidence to meet the statutory requirements for biosimilarity. Health care professionals and consumers can be assured that FDA will require licensed biosimilar biological products to meet the Agency's exacting standards of safety and efficacy.

To date, FDA has not received an application for a proposed biosimilar product. The Center for Drug Evaluation and Research (CDER) continues to meet with sponsors interested in developing biosimilar products. As of May 7, 2013, CDER has received 56 requests for initial meetings to discuss development programs involving 12 different reference products and has held 38 initial meetings with sponsors. Many biosimilar development programs that have had an initial advisory meeting with CDER have moved into the development phase and are requesting biosimilar product development (BPD) meetings. CDER is actively engaging with these sponsors, including holding BPD meetings and providing written advice, for ongoing development programs for proposed biosimilar products. To date, CDER has received 17 Investigational New Drugs (INDs) for biosimilar development programs, but several additional development programs are proceeding under a pre-IND.

FDA is currently considering the appropriate naming convention for biosimilar and interchangeable products licensed under the pathway established by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) enacted as part of the Affordable Care Act. FDA is carefully reviewing and considering the comments submitted to FDA's biosimilar guidance and public hearing dockets. We will take into consideration all received comments as we move forward in finalizing the guidance documents and developing future policies regarding biosimilar products and interchangeable products.

Compounding Pharmacies

It is my understanding that FDA recently undertook inspections of a significant number of compounding pharmacies producing high volumes of high-risk sterile drug products.

I note that these facilities are more like manufacturing plants than traditional compounding pharmacies where an on-site individual pharmacist compounds medicine for a particular individual based on a specific prescription.

Mr. Farr: I would like your assurance that FDA recognizes and acknowledges the difference between these two very different compounding situations and that any actions the FDA may take to correct high-volume compounding facilities do not negatively impact the ability of the individual pharmacist from producing medicines for individuals.

Response: FDA recognizes that there is a difference between pharmacies that compound medicine pursuant to a valid prescription for an individually identified patient and a firm that compounds high volumes of medicine in advance of, or without receiving, such valid prescriptions.

The recent inspections of compounding pharmacies used a risk-based model to identify pharmacies known to have produced high-risk sterile drug products in the past and to determine whether they posed a significant threat to public health from poor sterile drug production practices. In addition, the Agency continued for-cause inspections of pharmacies when states requested our assistance or after receiving reports or complaints about serious adverse events.

As a result of these recent inspections, the Agency uncovered serious concerns with sterile practices, resulting in recalls of drug products and corrective actions by firms. Often these concerns were associated with firms that lack prescriptions for individually identified patients for some or even all of the drugs compounded and shipped by the pharmacy across state lines. Subsequent actions taken by the Agency and the firms themselves have been based on inspectional findings that either did or had the potential to adversely affect product sterility.

The Agency's actions are not intended to curtail the traditional practice of pharmacy in which a pharmacist prepares a compounded drug product pursuant to a valid prescription for an individually identified patient. In fact, for such pharmacies, the Agency generally intends to refer inspectional findings regarding sterile processing issues to the appropriate state board of pharmacy.

FDA remains committed to working with Congress and other stakeholders to enact legislation to create a system of rational, risk-based regulation that takes into account both federal and state roles in the oversight of pharmacy compounding. In the absence of legislation, the Agency will continue working closely with state and other federal officials to address quality concerns associated with sterile compounded drug products.

Food Safety Modernization Act Sect: 204
High Risk Reporting

FSMA Section 204 requires the agency to make a "high risk" designation on a number of specified factors, including "the *known* safety risks of a particular food, including the history and severity of foodborne illness outbreaks *attributed* to such food." (emphasis added).

The Proposed Produce Rule already separates out certain commodities for which more stringent standards are *not* required to "minimize the risk of serious adverse health consequences or death" because of final preparation by cooking.

Mr. Farr: Commissioner Hamburg, can you provide the Committee with assurance that the agency will adhere to the clear authorization under section 204 of FSMA that additional recordkeeping requirements would be imposed only on foods FDA designates as "high risk"?

Response: FDA fully intends to abide by the provisions of Sec. 204 of FSMA, such that any additional recordkeeping requirements FDA establishes under Sec. 204 will apply only to foods FDA designates as high risk. Given the intent of FSMA to move towards a food safety system built on prevention and that enhanced product tracing provides greater public health protection in a food contamination event by preventing additional illnesses, FDA encourages strong industry leadership and innovation in advances for a more uniform and rapid product tracing system. FDA will consider development of voluntary guidance for foods not designated as high risk to support the industry efforts to enhance public health protection and aid in efficiency of operations especially for firms that may produce both types of food products.

Definitions of Farm and Facility

Mr. Farr: FDA has opined that it is restricted in its definitions of farm and facility by the Bioterrorism Act of 2002, resulting in the convoluted definitions and proposed regulations for "farm mixed-type facilities" in the Preventive Controls rule. How much of a restriction is this really?

Response: : FSMA requires FDA to connect the scope of the Preventive Controls rule to the scope of the food facility registration requirement established by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("BT Act").

When FDA developed the farm definition used for the food facility registration requirement, the practical impact of an activity's classification as inside or outside that definition was limited to the potential to trigger the registration requirement and certain recordkeeping required under the BT Act. With FSMA, the farm definition has taken on more importance because activities within the farm definition would not be subject to the proposed Preventive Controls rule, but activities outside the farm definition would be subject to the proposed rule. Therefore, FDA proposes to clarify the scope of the farm definition, including the classification of manufacturing, processing, packing and holding activities relevant to that definition, and adjust it if appropriate. In section VIII of the proposed Preventive Controls rule, FDA articulates a comprehensive set of organizing principles for classifying activities to more accurately reflect the scope of activities traditionally conducted by farms and to allow for more certainty among industry with regard to how their activities will be regulated. We are seeking comment on this proposal.

"Farm mixed-type facilities" are establishments that grow and harvest crops or raise animals and may conduct other activities within the farm definition, but that also conduct activities that trigger the registration requirement. In other words, such facilities conduct some "farm" activities and some "facility" activities. FDA interprets FSMA to mean that Congress did not intend the "farm" portion of such a facility to be covered by the Preventive Controls rule, but that Congress did intend the "non-farm" portions of such a facility to be potentially subject to that rule. The proposed Preventive Controls rule reflects this interpretation

Numerical Standards

Mr. Farr: Why did FDA propose numerical standards in the Produce Safety rule that science, so far, cannot justify but cannot be changed once the rule is finalized? Examples include the preharvest intervals for compost/manure and the testing frequencies and organism to test for in irrigation water.

Response: In the Produce Safety Standards proposed rule, FDA is setting forth science-based minimum standards for growing, harvesting, packing, and holding of covered produce on farms based on the best science available to the Agency, recognizing that knowledge gaps exist. FDA is proposing to rely on a numerical standards approach where the effectiveness of individual measures is not complete or fully known and/or because much of what affects the on-farm route

of contamination is outside the control of the farm. In some of these cases like composting of biological soil amendments of animal origin, we have provided measures that are well established to meet the numerical standard under a wide range of conditions, while also recognizing that other measures, if properly validated, may also be suitable. For such measures, we proposed to permit the use of alternative measures under specified conditions to ensure the same level of public health protection as the applicable requirement. We recognize the value in making this regulation flexible, where appropriate, to accommodate future changes in science and technology. FDA has specifically requested comment on this approach and anticipates input from stakeholders on this issue.

Mr. Farr: Why did FDA allowed for "alternatives" to some of the numerical standards in the proposed Produce Safety rule, but not to all. Why the limitation?

Response: FDA recognizes the value in making this regulation flexible, where appropriate, to accommodate future changes in science and technology. Therefore, in the Produce Safety Standards proposed rule, we list the specific proposed requirements for which we believe alternatives may be appropriate, provided that alternatives must be supported by adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the requirement and would not increase the likelihood that covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 342]. In identifying proposed requirements for which alternative measures may be appropriate, we considered factors such as covered produce, practices, and conditions, including agro-ecological factors, such as sunlight intensity, which are known to contribute to pathogen die-off that could be accounted for in achieving the same level of public health protection as the proposed requirement. We specifically asked for public comment on our proposed provisions related to alternatives, and we will consider changes based on comments received.

In addition to the list of specific proposed requirements for which we believe alternatives may be appropriate, FDA has proposed a mechanism by which a State or a foreign country from which food is imported into the United States may request a variance from one or more proposed requirements, where the State or foreign country determines that: (a) The variance is necessary in light of local growing conditions; and (b) the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under Section 402 of the FD&C Act and to provide the same level of public health protection as the requirements in the proposed rule.

Exclusions for Produce

Mr. Farr: Why did FDA allow exclusions for produce "rarely consumed raw" but provide no provision for other exclusions that science may justify in the future?

Response: The Produce Safety Standards proposed rule excludes several categories of produce. Specifically, the Produce Safety Standards proposed rule would not apply to produce that is (1) rarely consumed raw, (2) produced for personal or on-farm consumption, or (with certain

documentation) (3) destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern.

The Produce Safety Standards proposed rule proposes an approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop. A qualitative assessment of risk (QAR) of hazards related to produce production and harvesting indicated that produce commodities are potentially subject to similar microbiological hazard pathways. Therefore, we are proposing to adopt a regulatory approach for minimizing potential risks associated with those hazards. This focus on microbiological hazard pathways also led us to propose not covering certain produce that we have determined present the lowest risk.

Valuing flexibility and appropriate alternatives for certain requirements, FDA also proposed to allow the use of alternatives when supported by adequate scientific data or information. FDA has also proposed a mechanism by which a State or a foreign country from which food is imported into the United States may request a variance from one or more proposed requirements.

FDA is aware that there is a great deal of ongoing research in the area of produce safety. We have specifically solicited comment on other approaches that would minimize the risk of microbiological hazards associated with produce and intend to work with the regulated industry and other stakeholders as options become available in the future that provide the same level of public health protection as the requirements in the proposed rule.

Public Health Protection

Mr. Farr: FDA has allowed alternatives and variations that "achieve the same level of public health protection". How is public health protection measured and how does a government or operation know whether they have achieved it?

Response: FDA is proposing to allow the use of alternatives to certain requirements in the proposed rule that use numerical standards. We proposed reliance on a numerical standards approach where the effectiveness of individual measures is not complete or fully known and/or because much of what affects the on-farm route of contamination is outside the control of the farm. In some of these cases, such as composting of biological soil amendments of animal origin, we have provided measures that are well established to meet the numerical standard under a wide range of conditions, while also recognizing that other measures, if properly validated, may also be suitable. For such measures, we proposed to permit the use of alternative measures under specified conditions to ensure the same level of public health protection as the applicable requirement. In identifying proposed requirements for which alternative measures may be appropriate, we considered factors such as covered produce, practices, and conditions, including agro-ecological factors like sunlight intensity, which are known to contribute to pathogen die-off that could be accounted for in achieving the same level of public health protection as the proposed requirement. We specifically asked for public comment on our proposed provisions related to alternatives, and we will consider changes based on comments received.

For variance petitions, FDA proposes to evaluate the information provided on a case-by-case basis and in light of the local growing conditions that necessitated the request for a variance. Under the proposed provisions, a State or foreign country would be required to submit relevant and scientifically-valid information or materials specific to the covered produce or covered activity to support the request for a variance. This would include information about the crop, climate, soil, and geographical or environmental conditions of a particular region, as well as the processes, and procedures, or practices followed in that region. FDA has specifically solicited comment on the proposed variance process and the information required for a request.

Fresh Produce Testing Times

Mr. Farr: Last year, I asked you about testing of fresh produce and the time it takes for FDA to turn around those tests. Have things improved over the past year?

Response: The average time reported for imported produce samples has steadily declined over the last three years. In FY 2010, the average time to analyze an imported produce sample was 12.2 hours, which decreased to 10.9 hours in FY 2011, and to 9.7 hours in FY 2012. In FY 2013 to date, FDA has averaged a reported 8.6 hours per imported produce sample.

Mr. Farr: Please provide summaries of the time it takes from the time the shipment is sampled until the results are reported to the shipper.
Response: The time to collect a sample to final disposition has continued to improve from year to year. In FY 2009, the average number of calendar days was 11. In FY 2010, FY 2011 and FY 2012 the average number of days was reduced to 6.0, 6.6, and 6.9 days, respectively.

In FY 2012, FDA collected 2,945 samples from 2,189,157 lines of imported fresh produce resulting in an average time of 6.9 days from the date of the sample collection to final disposition. This average includes all sample collection and analyses timeframes regardless of analyses performed and whether a violation was or was not identified.

QUESTIONS SUBMITTED BY CONGRESSWOMAN DeLAURO

Chicken Jerky Treats

Ms. DeLauro: Commissioner, can you give us an update on the FDA's investigation into chicken jerky treats for pets from China – the latest estimates for just pet dogs indicate more than 3200 confirmed illnesses and 500 deaths here in the U.S. And those figures are from January. Do you have more current estimates? What is the timeline of the FDA's investigation and what are you currently doing on this front?

Response: As of May 6, 2013, FDA received over 2,910 reports of illness in dogs since 2007, involving over 3,520 dogs, of which more than 570 are reported as having died. Following the market withdrawal of several nationally marketed jerky pet treat brands in January 2013, the

number of complaints received by FDA has steadily declined. FDA continues to investigate reports of illnesses associated with the treats through patient diagnostic sampling, product testing, and epidemiological analysis of the reported complaints of illness. FDA does not have a time line for the investigation as it is evolving rapidly, but continues to track cases and look for possible causes in conjunction with state and university partners through its Veterinary Laboratory Investigation and Response Network (Vet-LIRN).

Supply Chain Management

Ms. DeLauro: It appears that the FDA is requesting new funding for setting standards for food and feed safety. FDA's request highlights the importance of all the parties in the "global food chain" implementing preventive measures. Yet, the proposed preventive controls rule the agency released in January does not include a supplier approval and verification program – a key supply chain management tool that could have leveraged industry practices to see that everyone in the food chain complied with the new law. Would you describe how much funding you are seeking, how the funding will be spent, and why the agency decided against including a supply chain management provision in the preventive controls rule?

Response: FDA agrees that supply chain management is critical to ensuring the safety of food and feed. In the President's FY 2014 budget, FDA is requesting an additional $27 million for standards setting and an additional $155 million for import safety. There are activities related to supply chain management in both initiatives. FDA is requesting funding to support the development of risk-based standards and guidances for safe production of food and feed, working with industry to ensure that these documents are practical and effective and adequately detailed to support industry efforts to adopt preventive controls and produce safety standards. FDA will also use these resources to train FDA personnel and deliver training to our regulatory partners in preventive control inspection and enforcement to ensure that they are prepared to conduct sound, effective inspections that will also assist industry in implementing preventive controls.

Further, FDA is requesting resources to develop and implement a variety of approaches to ensure the safety of imported foods and feeds, including assessments of foreign food safety systems and capacity building for foreign industry and regulatory partners. This investment will also allow support for the Foreign Supplier Verification Program (FSVP) and provide program oversight. The FSVP will require importers to conduct risk-based foreign supplier verification activities to verify that imported food is not, among other things, adulterated and that it was produced in compliance with FDA's preventive controls requirements and produce safety standards, where applicable. In the Preventive Controls for Human Food proposed rule, FDA noted that supplier approval and verification activities are widely accepted in the domestic and international food safety community. FDA requested comment on inclusion of supplier approval and verification in a final rule and asked about the appropriate level of specificity of such a program. FDA anticipates receiving a number of comments on supplier approval and verification programs, which will inform the Agency's decision for the final rule.

Comparable Food Safety Systems

Last year the FDA completed its first comparability assessment of a foreign country's food safety system. New Zealand is now considered "comparable" to the U.S. in terms of its food safety system and the agency is working with Canada on another comparability assessment. Would you please tell us:

Ms. DeLauro: What does comparability mean in terms of how it affects FDA's inspection resources?

Response: FDA would use systems recognition determinations as one factor in prioritizing resources dedicated to foreign facility inspections, import field exams, and import sampling.

Systems recognition has the potential to offer FDA an objective basis for relying on information provided by comparable foreign authorities and avoiding the duplication of work conducted in countries with comparable food safety systems. FDA anticipates that systems recognition will offer FDA an opportunity to foster stronger ties with food safety authorities in other countries, and to enhance data sharing and information exchange to support food safety efforts. Systems recognition arrangements could complement new or existing Confidentiality Commitments whereby comparable food safety authorities will be able to exchange non-public information with FDA related to food safety to address food safety issues in a timely and proactive manner, improving the safety of foods for consumers in each country.

Ms. DeLauro: Translate these assessments into budgetary terms. How much does it cost to conduct a comparability assessment and what does it save us?

Response: Systems recognition provides an objective and transparent process for implementing FDA strategies to help ensure the safety of food, in a time of increasing globalization. The program, once implemented, will allow FDA to foster close partnerships and leverage the work done by competent authorities in countries that have comparable food safety systems, and to allocate FDA resources based on risk.

Having completed only one pilot assessment to date, we have at this time a limited data set from which to extrapolate direct agency costs. A general approximation is as follows:

Initial systems recognition assessments, maintenance and program management	$85,000
Direct cost for in-country assessment (per country)	6 full time FTEs*

*The program requiring 6 FTEs per year will cost about $1 million total per year. This total annual investment will allow FDA to allocate our very scarce inspection and investigation resources at the border away from the countries that have the best and safest food safety systems and toward the countries with greater risk. It is likely that only a handful of countries will meet the high bar of systems recognition. However, FDA will benefit greatly from our ability to

strengthen our regulatory partnerships with these countries and to allocate our finite resources, based on risk, where most needed.

Ms. DeLauro: Do the assessments free up resources and, if so, how would those resources be repurposed within the FDA?

Response: A main goal of the systems recognition approach is to allow the agency to focus resources where most needed to help ensure the safety of imported foods, shifting resources to higher risk country-commodity products. FDA intends to rely on the work conducted by food safety authorities in countries where systems recognitions arrangements have been established, including relying on the domestic inspection programs in those countries.

Likewise, systems recognition will help allow FDA to implement import provisions of the FDA Food Safety Modernization Act (FSMA) in a risk-based manner, taking into account our confidence in these select countries to provide assurances that foods produced under the oversight of their food safety authorities is safe.

Ms. DeLauro: How many countries that export food to the United States do you anticipate reviewing in the future and what is the imported food footprint of those countries on our market?

Response: FSMA provides FDA with a variety of new authorities to help ensure the safety of imported foods, and is consistent with taking into account the capability of the regulatory system of the exporting country to ensure compliance with U.S. food safety standards for a given food. FSMA also directs FDA to consider bilateral and multilateral arrangements and agreements, including provisions, under specific situations, to provide for the responsibility of countries for the safety of food they export. To the extent possible, FDA will leverage the work done by competent foreign authorities to help ensure the safety of imported foods.

Likely only a select number of countries will pursue this system-wide approach. Countries with well-established commodity-specific export programs may pursue accreditation through FDA's future Third Party Accreditation Program.

We have completed an initial pilot with New Zealand, and are currently working with Canada on a second pilot. A third pilot is now being planned with Australia. We will assess these pilots, adjust where needed, and continue work planning.

Ms. DeLauro: Does a comparability agreement work both ways, i.e.do our exports benefit from this process?

Response: Recognizing that food safety authorities in other countries may have different statutory requirements, the issue of reciprocity likely will be addressed on a case-by-case basis. However, FDA intends to conduct systems recognition activities on a reciprocal basis, ensuring that FDA may leverage work done by food safety authorities in other countries and those food safety authorities may also leverage work done in the U.S. to help ensure the safety of products exported from the U.S. As a program, systems recognition's main benefits include the leveraging of work conducted by food safety authorities and avoiding duplication of work conducted in each country. Countries that are good candidates for systems recognition are those

countries with long histories of sending safe foods to the U.S. Therefore, the rate of sampling at the border, which is based in part on compliance history, of foods from these select countries is already quite low. Therefore the actual trade benefits to countries that participate are minor, in comparison to the benefits of increase regulatory partnership activities.

Ms. DeLauro: How confident are you that the assessments can be relied on and how frequently must they be reviewed in-person?

Response: FDA has developed a robust and transparent process for the assessment of other countries' food safety systems for systems recognition, and we are confident that the results of these assessments are reliable. Our assessment includes an internal data review of the country's compliance history, a thorough review of documentation submitted describing the country's food safety legislation, regulations and programs, and on-site audits of the implementation of the country's food safety system.,

Systems recognition arrangements, once established, will not be static documents. The signing of a systems recognition arrangement marks the establishment of closer regulatory partnerships, which will involve ongoing dialogue and notification of changes to food safety systems in the U.S. and partner countries. In addition to increased communication with respect to food safety issues, FDA plans to conduct periodic reviews at roughly 5 year intervals. Having completed only one of our three systems recognition pilots and having not yet established a systems recognition program, we have not yet determined set guidelines and timing for these re-review activities.

FDA Fees

Looking at the food fees already authorized, the FDA does not appear to have collected any of these authorized fees in spite two years of authorization under FSMA to do so. Please tell us:

Ms. DeLauro: How many re-inspections did the FDA conduct last year?

Response: FDA conducted 19 re-inspections in FY 2012 that would have met the criteria to assess Re-Inspection Fees under FSMA.

Ms. DeLauro: How much has the FDA invoiced for re-inspections?

Response: As of April 26,, 2013, FDA has not invoiced for any re-inspections.

Ms. DeLauro: How much has the FDA collected for those re-inspections?

Response: As of April 26, 2013, FDA has not collected any fees for re-inspections.

Ms. DeLauro: When do you anticipate collecting food program fees that are already authorized? Do you expect to collect any in Fiscal Year 2013 and/or 2014?

Response: As FDA has communicated publicly, FDA does not intend to issue any invoices for the food reinspection or recall fees until the guidance documents relating to the burden of these

fees on small businesses are published. FDA does intend to assess and collect Re-Inspection and Recall Fees incurred for Fiscal Year 2013 and Fiscal Year 2014 once the guidance documents mentioned above publish.

Imported Foods

Ms. Delauro: The largest new expenditure under food safety is on "Import Safety," an area that clearly needs more attention and resources. Each year, the FDA inspects less than two percent of the huge volume of imported food and it conducts a chemical analysis of less than one percent. The budget request related to import safety appears to be more focused on speeding up imports than inspecting them. Could you take a little time to dissect the various parts of this program for me in terms of money, fees, personnel, and how they will improve the FDA's record on border inspections? For example, the FDA is going to establish a national call center to help importers assess the status of their imports. How much of this is supported by new fees and how much is budget authority?

118. and 119. Ms. DeLauro: Could you take a little time to dissect the various parts of this program for me in terms of money, fees, personnel, and how they will improve the FDA's record on border inspections? For example, the FDA is going to establish a national call center to help importers assess the status of their imports.

Arsenic in Rice and Rice Products

Ms. DeLauro: As you know, last year, Consumer Reports released results of its tests regarding arsenic in rice and rice products. Arsenic is a big concern in these products because not only is it a human carcinogen, but arsenic exposure also can set up children for other health problems in later life. Last year, the FDA said that it would release the results of its analysis of 1,000 samples of rice and rice products, in addition to the results of the roughly 200 samples tests that had already been released. When can we expect these results to be released – please provide a specific timeline. In addition, will FDA be releasing the country of origin of the rice/rice product samples tested? If not, why not?

Response: The analysis of the additional samples has been completed and the results are under review and clearance, in preparation for posting on our website. We anticipate releasing a summary of the study results and the analytical information about each individual sample in the study. A release date has not been established; however, we anticipate final clearance and posting the data by the end of May 2013.

Yes, FDA will be releasing the country of origin for all samples in the study for which this information was available.

Medical Device Single Audit

Your testimony outlines a Medical Device Single Audit pilot program with Brazil, Canada and Australia. Please provide the Committee with detailed information on the pilot program, including at least the following:

Ms. DeLauro: How the countries participating in the pilot program were selected;

Data on the impact of the pilot program on the number of inspections performed by FDA staff;

A detailed timeline on implementation of the pilot program;

Any risk assessments or comparability assessments of the medical device inspection program of the partner countries; and,

If such assessments were not completed prior to the pilot program an explanation for why such assessments were not completed.

Response: FDA selected countries that are trusted regulatory partners that have been working on harmonization and convergence within the Global Harmonization Task Force, which has now been replaced by the International Medical Device Regulators Forum - IMDRF. FDA started with Health Canada - HC - because FDA and HC collaboratively ran the pilot multi-purpose audit program from 2006 to 2010. This program allowed third party auditing organizations that were both a qualified FDA-accredited person and a recognized registrar by HC under the Canadian Medical Devices Conformity Assessment System - CMDCAS - to perform a single audit that both FDA and HC could accept and utilize. FDA selected Australia as an additional regulatory partner because the Australian Therapeutics Good Administration - TGA - Inspectorate was also already recognized under the HC CMDCAS program. FDA selected Brazil, a member of IMDRF, because Brazil agreed to work within the Medical Device Single Audit Program - MDSAP - to utilize the single audit for their regulatory purposes. Brazil currently has a backlog of approximately 5 years in allowing medical device imports into Brazil due to the limiting requirement of a regulatory audit performed by their regulatory body ANVISA. Therefore, including Brazil in the pilot program benefits US industry and allows for additional leveraging of resources amongst the regulators.

The four regulatory agencies have worked closely in the development of MDSAP, which will be piloted starting January 2014. The EU was also approached about the pilot but declined due to the ongoing revisions of their medical device legislation. Japan, the remaining IMDRF partner, could not be included in the pilot at this time due to language barriers and the requirement that the audit report be written in English. In February 2012, the IMDRF established a Working Group on MDSAP that plans to produce four fundamental documents by November 2013 for utilization by all IMDRF Management Committee members regardless of their participation in the pilot.

I will be happy to provide several tables that provide the applicable data.

MDSAP Regulatory Authority Personnel Projections
Calculations include the necessary audits of auditing organizations - AOs - seeking and maintaining MDSAP recognition. The recognition of seventeen AOs is included in the calculations and reflects two regulatory authority - RA - assessors per audit.

MDSAP Regulatory Authority Assessment Audits, FY 2014 – FY 2018

Fiscal Year -FY-	Total Number of AO Assessment Audits required per FY "n"	Assessment Audits per Regulatory Authority per FY "n ÷ 4"	Internal Audits of MDSAP per RA per FY	Physical Meetings of Participating Regulators per FY
2014	60.00	15.00	0	1
2015	84.00	21.00	0	2
2016	116.00	29.00	0	2
2017	88.00	22.00	0	2
2018	108.00	27.00	1	2

Canadian Licensed Manufacturers of Class II, III, IV Devices subject to annual CMDCAS audits, which would be converted to MDSAP audits:

U.S.	Canada	Rest of the World – ROW -
1,551	408	1,353

MDSAP Cost Savings Projections
Projected increase in the number of MDSAP audits FDA could utilize and FDA cost savings, per annum, up to 70 percent of the Canadian inventory until conclusion of pilot when Canadian system converted fully to MDSAP:

Percent of HC Licensed Manufacturers of Class II, III, and IV devices electing to participate	Increase in US Establishment Inspections (EIs)	Increase in Canadian EIs	Increase in ROW EIs	Increase in Total EI's	Total FDA cost savings Calculated at $29,600 per Domestic and $31,900 per Foreign EI-	Total FDA cost savings Calculated at $14,800 per Domestic and $15,950 per Foreign EI - less 50 percent overhead
10	155	41	135	331	$10,202,400	$5,101,200
20	310	82	271	663	$20,436,700	$10,218,350
30	465	122	406	993	$30,607,200	$15,303,600
40	620	163	541	1324	$40,809,600	$20,404,800
50	776	204	677	1657	$51,073,500	$25,536,750
60	931	245	812	1988	$61,275,900	$30,637,950
70	1086	286	947	2319	$71,478,300	$35,739,150

The detailed timeline for the **MDSAP Pilot – January 2014 through December 2016** – is as follows:

Tasks and target dates:

1. IMDRF Contributions – November 2013
    a. Recognition for organizations undertaking audits of medical device manufacturers
    b. Auditor competency and training requirements for organizations undertaking audits of medical device manufacturers
    c. Assessment program and auditing strategy of recognized auditing organization undertaking audits of medical device manufacturers
    d. Assessor competency and training requirements for regulatory authorities undertaking assessments of AOs
2. Develop Certification, Surveillance, and Recertification Audit Processes – June 2013
3. Develop Training Material for AOs on the MDSAP Audit Processes – June 2013
4. Develop MDSAP Business Process Procedures - December 2013
5. Identify AOs Willing to Participate in the Pilot, Initiate Training, Application Review and Audits
    a. Receive applications from AOs identified to participate in the pilot - December 2013 for the first group
    b. Schedule and conduct Stage 1, document reviews, and Stage 1 and 2 on-site audits of AOs - May 2014 for the first group
    c. Schedule and conduct witness audits of AO auditors - November 2014 for the first group
    d. Receive applications from AOs - May 2014 for the second group
    e. Schedule and conduct Stage 1, document reviews, and Stage 1 and 2 on-site audits of AOs - November 2014 for the second group
    f. Schedule and conduct witness audits of AO auditors - May 2015 for the second group
    g. Repeat cycle until all CMDCAS AOs wishing to participate and that meet the MDSAP requirements are assessed - May 2016
6. Schedule and Conduct Witness Audits of Manufacturers to Support the Recognition of the AO - November 2014 for the First Group
7. Report on Results of Pilot Study - June 2016
8. Adjust and Revise MDSAP Based on Pilot Study Results - Fall 2016
9. Make the MDSAP Program Fully Operational – December 2016

FDA and HC on November 1, 2010, published *"Final Joint Report of the Pilot Multipurpose Audit Program -PMAP-.*[3]*"* The report concluded:

> Based on this review of ten multipurpose audit reports, a qualified/competent auditing organization can perform a single audit/inspection of a medical device manufacturer's quality management system - QMS - in order to satisfy the regulatory requirements of Health Canada and FDA.

[3] http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/md-im/activit/int/md_pmap_rep_im_ppafm_rap-eng.pdf

In addition, when a manufacturer undergoes a multipurpose type audit, Health Canada and FDA have confidence in the ability of a qualified and competent auditing organization to plan, carry out, and report on the audit/inspection according to basic Health Canada and FDA requirements.

The report notes benefits to HC, FDA and manufacturers:
This pilot program provided both regulatory bodies the chance to compare processes and prepare for future best practices in the area of medical device manufacturing regulatory oversight. There is potential for convergence in the areas of audit/inspection best practices. Potential benefits for manufacturers for a future single audit program include:

- saving of audit/inspection time in person days -and associated costs- and less disruption of the manufacturer's day-to-day operations; and,
- greater control over the scheduling of regulatory audits/inspections.

The regulators benefit from a single audit process through the leveraging of resources and sharing of information from a single audit process. This was a limited sample size; however, it shows the ability to perform a single audit including not only FDA and Health Canada but potentially other regulatory partners.

Because the Australian TGA was also a CMDCAS recognized AO, similar conclusions were drawn since equivalent practices and procedures are utilized. For Brazil, the regulatory partners undertook an educational mission in March 2012 and a series of observed audits with the Brazilian ANVISA inspectorate in 2012 and 2013 to compare and analyze the requirements, processes, and areas of commonality.

Assessments were completed per the previous response. It is important to note that the goal of the Medical Device Single Audit Program Pilot Study is to provide objective evidence confirming the "proof-of-concept" that an audit of a medical device manufacturer's quality management system conducted by a MDSAP-recognized auditing organization, whether that auditing organization is a third party or a regulatory inspectorate, can fulfill the needs of multiple regulatory jurisdictions. The prescribed inspection process for MDSAP will cover the various requirements for Australia, Brazil, Canada, and the United States of America. This was made possible by approximately 20 years of work in harmonizing and convergence in quality management system regulatory requirements and other regulatory convergence efforts.

QUESTIONS SUBMITTED BY CONGRESSWOMAN PINGREE

GMO Labeling

Just this week in Maine, a bill to label GMO foods had a hearing in the legislature. Similar hearings are happening all over the country in the 25 other states that have introduced consumer right to know, GMO labeling bills.

In 2001, the FDA concluded that GMO labeling was permitted, and food manufacturers were allowed to voluntarily indicate if their product contained GMOs.

12 years later, exactly zero major food manufacturers have taken the FDA up on the offer to voluntarily label their products.

In last week's Senate budget hearing, I was disappointed to see you reaffirm your outdated support for voluntary labeling.

64 other countries around the world including China, Japan, Russia, Australia, the EU and South Korea all have mandatory labeling rules.

That means that any company selling products into any of those countries are already complying with GMO labeling standards – Pepsi, Kraft, Kellogs, Mars – are all granting consumers their right to know in in other countries.

To be clear, FDA has existing authority to require the labeling of GE foods. The law was written by Congress to prevent consumers from being misled by clarifying that a food label is misbranded if it omits significant, "material" information.

Ms. Pingree: Has FDA taken any steps towards a mandatory labeling system?

Response: FDA is currently reviewing 2 citizen petitions requesting FDA to require mandatory labeling for bioengineered foods. One petition further requests that FDA reevaluate its policy on materiality with respect to bioengineered foods contending that the use of bioengineering in the development of a food is a material fact. Thus, in developing responses to these petitions, FDA is considering all relevant information currently available, the agency's legal authority, and whether the absence of labeling disclosing the fact that a food was developed using bioengineering misbrands the food.

Ms. Pingree: I have heard you say that a consumer has the right to know. If that is the case, what are the next steps for the FDA?

Response: FDA regulates the labeling of food under the Federal Food, Drug, and Cosmetic Act. The Act generally provides that food labeling is misleading if it fails to reveal "material facts." The agency's policy has been that "material facts" refers to attributes of the food itself. In the context of bioengineered foods, FDA has explained that if a food has been significantly or "materially" changed from its traditional counterpart, for example, in its nutritional profile or functionality, the labeling for the food must disclose such fact to consumers. To that end, FDA currently requires information describing such a change when it occurs in a bioengineered food. FDA is currently reviewing 2 citizen petitions requesting FDA to require mandatory labeling for bioengineered foods. The agency is considering all relevant information and issues, and will take necessary steps should the outcome of our evaluation of the petitions result in a finding that the method of production for bioengineered foods is material information.

Ms. Pingree: If the overwhelming majority of American's want labeling, what is the FDA waiting for?

Response: We recognize that many consumers are interested in knowing whether the food they serve their families is produced using bioengineering and that they would like this information on the food label. Currently, food manufacturers may indicate through voluntary labeling

whether foods have or have not been developed through bioengineering, provided that such labeling is truthful and not misleading. FDA is supportive of such voluntary labeling. FDA regulates the labeling of food under the Federal Food, Drug, and Cosmetic Act. The Act prohibits food labeling that is false or misleading, and generally provides that food labeling is misleading if it fails to reveal "material facts." FDA's policy has been that materiality refers to attributes of the food itself, such as the food's nutritional profile or functionality. Under this rationale, FDA's policy has been that use of bioengineering in the development of a food is normally not a material fact within the meaning of the FD&C Act. Federal courts have accepted this policy. These courts have held that absent a "material" fact or difference in a food developed through bioengineering, the Act does not require labeling indicating such fact. Further, courts have held that consumer desire alone is not sufficient to require such labeling. FDA to address mis-branded foods that omit serious material information.

Antibiotics in Livestock – Labeling

I appreciate the steps the agency has taken to address this serious public health threat, in particular as it relates to the overuse and misuse of medically-important antibiotics in food animal production.

Draft Guidance #213 was proposed just over a year ago to encourage drug makers to remove growth promotion label claims for antibiotics going to livestock and poultry. That is an important first step. I am concerned, however, that the guidance draft does not clearly show how the agency will work with industry to reduce routine, customary uses of these antibiotics for so-called "disease prevention."

Ms. Pingree: Also, the agency has not taken steps to create a baseline of useful data on antibiotic use or sales that would enable the public health community to know whether overuse is actually declining under your plan. Can you tell us not only when the agency expects to finalize Guidance 213, but also how it will address these two significant weaknesses?

Response: We want to assure you that finalizing draft Guidance for Industry (GFI) #213 is among FDA's priorities for 2013.

In addition to outlining a process animal drug sponsors can use to revise their product labels to eliminate the use of medically important antimicrobial drugs for growth promotion purposes, draft GFI #213 once finalized would also facilitate veterinary oversight of the remaining therapeutic uses of these drugs. This represents a significant change to how antibiotics have been used in animal agriculture for decades. FDA believes such veterinary oversight is critically important for ensuring that these drugs are used judiciously, and will help ensure that use for disease prevention is judicious and appropriate.

FDA believes having additional information regarding the use of medically important antimicrobial drugs in food-producing animals will support the implementation of the agency's antimicrobial resistance strategy announced on April 11, 2012. FDA published an Advance Notice of Proposed Rulemaking in July 2012 to solicit comments from the public on possible enhancements to the existing requirements related to the collection of antimicrobial drug

sales/distribution data as well as input on alternative methods for monitoring antimicrobial use in food-producing animals. Based on the comments received, FDA is actively developing possible mechanisms for collecting additional information that would be more reflective of use practices on the farm, including possible collaborations with other Federal agencies and academia.

Antibiotics in Livestock – NARMS budget

Last year, a study conclusively linked the routine use of antibiotics in food-animal production to methicillin-resistant *Staphylococcus aureas* (MRSA). The study demonstrated that MRSA originated from a weaker bacterial strain that could be cured with antibiotics. Once in animals, the bacteria became resistant to antibiotics – likely as a result of routine antibiotic use in food-animal production.

As you know, the National Antimicrobial Resistance Monitory System (NARMS) is a critical program that monitors the prevalence of certain antibiotic-resistant bacteria in the food supply, like MRSA.

Ms. Pingree: Can you provide additional information on the FY14 budget proposal for NARMS? How does this compare to previous years?

I am concerned that NARMS already is underfunded, at a time when it should be expanding to include additional testing for pathogens such as MRSA that a serious threat to public health.

Response: We agree that NARMS is a critical program for monitoring the prevalence of certain antibiotic-resistant bacteria in the food supply, however it does not track MRSA. CVM has conducted a pilot study on MRSA where various meat commodities were collected over a period of one year. The overall prevalence of MRSA in retail meat is low. These data support the current position of the FDA, CDC and USDA that retail meat does not appear to be a major source of community acquired MRSA infections. The FY 2014 budget proposal for NARMS is estimated at $7.8 million. The NARMS budget has remained at $7.8 million since FY 2011, the last year FDA received an increase for that program. NARMS is critical to FDA's strategy to preserve the effectiveness of antibiotics. Data generated by NARMS are used for evaluating new food animal antibiotics, conducting risk assessments, guiding policy and regulations on the use of antibiotics, and tracking changes in resistance among bacterial isolates to identify potential human and animal health problems.

Flavored Milk

In March 2009, the FDA was petitioned to make significant changes to front of the label rules for milk containing sweeteners like aspartame.

As you know, current labeling rules require the front of the label to read "low calorie" if milk

contains non-nutritive sweeteners. The petition contends that in order to better market to children in schools, the label should not contain the words "diet" or "low calorie".

I understand that the FDA is currently taking comments until next month on the petition, and I assure you that I will weigh in, but I want to be clear today: mis-labeling to market to children should not be allowed.

Parents and the general public are rightfully mad about this. I sincerely hope you will seriously consider the thousands of comments submitted in opposition to the petition before making a decision.

Ms. Pingree: I would welcome any comments you have on the subject.

Response: We thank you for your interest in this issue and look forward to receiving any input you provide on the citizen petition. Please be assured that we will review and consider all comments received in response to the request for comments that we published in the Federal Register before any decisions are made on the merits of the petition.

GE Salmon

This week, I joined several of my colleagues in sending you a letter, expressing our concerns over the potential approval of genetically engineered salmon.

We believe the process has not been adequate enough to ensure this genetically engineered salmon is safe for our environment and our consumers, and therefore it should not be approved at this time.

The FDA must develop and implement a robust review process for GE salmon that includes adequate consultation with our wildlife and expert agencies, and set an appropriate path forward for future food animal applications.

I also believe that FDA should develop clear and transparent labeling requirements should this GE Atlantic salmon or other food animal product be approved.

Ms. Pingree: What is your agency doing to ensure these concerns are taken into account?

Response: FDA is reviewing the application associated with AquAdvantage Salmon under the new animal drug provisions of the Federal Food Drug and Cosmetic Act. The introduction of AquAdvantage Salmon, or food from this animal, into the U.S. without FDA approval is prohibited. The criteria for approval include a demonstration of safety to the target animal, reasonable certainty of no harm to humans from the consumption of food derived from the genetically engineered animal, and a demonstration of effectiveness of the claim. The human food safety standard is the same one applied to food additives. In addition, under the National Environmental Policy Act, FDA must also consider the potential impacts of an approval on the quality of the human environment of the U.S. under the specific conditions of use proposed by the sponsor in the application.

FDA regulates the labeling of food under the Federal Food, Drug, and Cosmetic Act. Under the FD&C Act, FDA may require special labeling for a genetically engineered food when the food differs materially from other foods, for example where the foods differs in nutritional profile or functionality. But, absent a material difference in the food, the fact that a food is produced using genetic engineering does not, by itself, trigger required labeling. FDA is currently reviewing 2 citizen petitions requesting FDA to require mandatory labeling for genetically engineered foods and is considering the issues.
We recognize that many consumers are interested in knowing whether the food they serve their families is produced using genetic engineering. Currently, food manufacturers may indicate through voluntary labeling whether foods have or have not been developed through genetic engineering, provided that such labeling is truthful and not misleading. FDA is supportive of such voluntary labeling.

Ms. Pingree: Will the FDA be conducting a full environmental impact statement (EIS)?

Response: FDA issued a draft environmental assessment (EA) and Finding of No Significant Impact (FONSI) for public comment on December 26, 2012. In response to a request for an extension to allow interested persons additional time to submit comments, on February 13, 2013, FDA extended the comment period to April 26, 2013. If, after review of the comments, the agency finds cause to change its preliminary FONSI, we may prepare an EIS.

Ms. Pingree: Will the FDA assess the impacts of raising these GE salmon in the US as is the company's intention?

Response: Should AquaBounty wish to raise AquAdvantage Salmon in the U.S., the company would be required to file with FDA a supplemental application, describing the exact conditions under which it would intend to raise the salmon, including the location and confinement conditions. The supplemental application would require a new environmental assessment.

The conditions of use in the application associated with AquAdvantage Salmon that is currently under FDA review include egg production in Prince Edward Island and grow-out at a land-based facility in the highlands Panama. If approved, the conditions in the approval would stipulate the specific locations in Canada and Panama where GE eggs and fish are produced. Any change in the conditions of use would require a supplemental application.

Ms. Pingree: Lastly, can you talk about collaboration with Fish and Wildlife Service and the National Marine Fisheries Service?

Response: FDA consulted with the Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) in its environmental review. Their statements on the adequacy of FDA's environmental review are found in Appendix D of the draft environmental assessment. An expert in salmon aquaculture from NMFS accompanied FDA aquaculture experts on visits to the grow-out facility and found no deficiencies.

Prescription Drug Access

I am very interested in prescription drug access and affordability. I come from the State of Maine, where people need look no further than across the border into Canada where safe and effective prescription drugs are sold at a fraction of the cost folks in the U.S. are paying for those same medications.

I hear all the time about how frustrated people in Maine are that these drugs that are manufactured in the U.S. before being transported to Canada are not available at the same reasonable prices in their own communities, and they ask me why we can't simply reimport these vital medications to help bring down the costs of prescription drugs and save the U.S. billions of dollars on health care spending, and I've got to tell you, I still haven't got a great answer as to why the FDA couldn't ensure the safety and effectiveness of re-imported drugs from Canada if given the proper resources to do so.

But now on top of these affordability issues, I am extremely concerned that we are running into challenges with basic access to lifesaving medication in the U.S. I know that the FDA is doing a lot of work in the area of drug shortages, and that you testified earlier that drug shortages have been cut in half compared to 2011, but I am still hearing from patients and providers across Maine who report sudden shortages in common drugs used in cancer treatment and anesthesiology, just to name a few examples.

Ms. Pingree: Can you tell me more about the FDA's work in this area, including future plans to address this critical problem?

Response: Regarding future plans to address drug shortages, FDA has and will continue to work with manufacturers to help prevent, mitigate, and resolve drug shortages in order to have treatment options available for healthcare providers and their patients. Early notification has proven to be, and remains, a key factor in FDA's ability to mitigate shortages. Once FDA becomes aware of a potential drug shortage, FDA works with pharmaceutical manufacturers to manage the shortage.

FDA may be able to help firms qualify additional manufacturing sites or raw material supplies, if those firms are interested in having additional manufacturing capacity; identify alternate manufacturers who can initiate/increase production; help manufacturers find and qualify new or additional sources of raw materials; consult with sponsors on resolution of manufacturing issues; or use enforcement discretion for temporary importation of non-U.S. product, after ensuring the drug does not pose undue risks for U.S. patients, and ensuring it is manufactured in a facility that meets FDA quality standards

FDA cannot provide adequate assurance that drugs sold to consumers in the United States by unregulated entities, regardless of the country which they claim the drugs are from, are the same products that FDA has approved through its rigorous safety and efficacy review process. In a 2005 study, many drugs that U.S. consumers purchased from Canada and believed were made in Canada actually were shipped from, or originated in, dozens of countries around the world. In examining imported drugs sent through the mail, FDA has identified products to be counterfeit and/or falsely or improperly labeled.

Under federal and state laws, distribution and sales of prescription drugs must be done only by businesses that are properly licensed as a wholesale drug distributor and/or pharmacy by state authorities. These safety measures place high standards upon regulated entities (manufactures, distributors, and pharmacies) to ensure that prescription drugs are manufactured, transported, stored, and dispensed under proper conditions.

Regulation of Cosmetics

Many people assume the FDA regulates cosmetics the same way it does food and drugs to ensure they are safe, but cosmetics are actually one of the least regulated consumer products on the market today. Yet we know that cosmetics frequently include dangerous chemicals, including carcinogens and reproductive and developmental toxins, and that most consumers apply multiple products directly to their bodies every day, exposing themselves to unknown risks posed by thousands of different chemicals.

I am a strong supporter of The Safe Cosmetics Act, a bill that would give the FDA better authority to effectively regulate the cosmetic industry by implementing a safety standard, post-market testing, and recall authority. I know the FDA has also been involved in discussions with the cosmetic industry about strengthened standards, and the President's budget proposal includes a cosmetic user fee of $19 million to build on the FDA's current work around cosmetics regulation.

Ms. Pingree: Can you give us an update on the FDA's current work around this issue, including some specific information about how the user fees might be used to support and improve this work?

Response: FDA has been involved in discussions with multiple stakeholders, including industry, about strengthened standards for cosmetics. The additional authorities, including user fees, are essential for strengthening FDA's ability to protect American consumers from potentially unsafe cosmetic products or ingredients. Further, these authorities will better enable the Agency to develop necessary guidance and safety standards, enhance post-market surveillance, and strengthen science-based safety evaluation.

Uer fees would provide necessary resources , which could include allowing FDA to establish and maintain a Mandatory Cosmetic Registration Program (MCRP), including facility registration and submission of product ingredient statements; developing new regulations and guidance in areas critical to public health; overseeing a mandatory adverse event monitoring system; requiring companies to recall unsafe products from the market; and enabling FDA to maintain a robust cosmetics safety evaluation and research program encompassing cosmetic products and ingredients, as well as contaminants. to increase its emphasis on risk-based approaches for cosmetic facility inspection, to refine inspection and testing of imported and domestic products, and to provide education to consumers and industry. Finally, FDA's participation in international standard-setting activities would be strengthened.

Cigar Regulation

In my first term in Congress I was proud to vote in favor of the Family Smoking Prevention and Tobacco Control Act in 2009, giving the FDA authority over the manufacture, sale and marketing of all tobacco products, including cigars. In doing so, Congress gave the FDA the flexibility to determine the type of regulation that is appropriate for different tobacco products. Like many of my colleagues, I am very interested in FDA's forthcoming proposed rule on tobacco regulation, and particularly the provisions that apply to cigars. There is a lot of evidence to support the fact that cigars, like cigarettes, are both addictive and carcinogenic, and that they are often marketed to youth, resulting in escalating rates of cigar use by young people.

Ms. Pingree: Can you give us an update on the status of this proposed rule?
Response: In the 2011-2013 editions of the Unified Agenda, including the most recent January 2013 edition, FDA included an entry for a proposed rule that would deem products meeting the statutory definition of "tobacco product" to be subject to Chapter IX of the FD&C Act. This most recent edition of the Unified Agenda listed a proposed rule publication date of April 2013. This rule presents complex regulatory issues that require careful analyses, and it has taken the Administration longer than originally anticipated to complete the proposed rule. The deeming rule continues to be a top priority for FDA, and the Agency continues to work diligently to issue the proposed rule in the very near future. It is important to note that the process for issuing any proposed rule will provide the opportunity for public comment as part of the rule-making process. FDA routinely allows a minimum of 60 days for public comment and carefully considers these comments when it develops the final rule.

Food Safety Modernization Act -- retail food establishment

During debate on the Food Safety Modernization Act, congress had a healthy discussion about one sized fits all regulations and how to best access where risk actually comes from.

I was encouraged when my colleague Senator Tester was successful in including a provision in the final version of the bill that will make regulations workable for small and mid-size farms involved in low-risk supply chains. I understand that the FDA is still working on the regulations, and remain concerned about the impact of the final rules on small producers and processors.

Ms. Pingree: Recognizing that different supply chains pose different levels of risk to our food supply, Congress required FDA to clarify the definition of "retail food establishment" to clarify that the sale of food directly to consumers through roadside stands, farmers markets, and community supported agriculture programs are included in the definition. Despite the Congressional mandate, FDA has not clarified this definition in the proposed rules. Can you please discuss how and when the agency will make this clarification?

Response: FSMA Section 102- Registration of Food Facilities – contains the requirement to amend the definition of "retail food establishment" in section 1.227(b)(11) of Title 21, Code of Federal Regulations – the definitions that apply to Registration of Food Facilities. FDA intends to amend this definition as part of its upcoming regulation on the Registration provisions of FSMA.

Food Safety Modernization Act – compliance costs

While I am encouraged to see that the agency has included longer compliance periods and modified requirements for certain small farms and businesses, I am concerned about the cost of compliance that FDA estimates for small businesses.

For example, FDA estimates that the costs to comply with its proposed produce rule for farms with less than $250,000 in annual revenue will face over $22,000 in compliance costs. These additional costs could make or break any small business.

Ms. Pingree: Can you talk more about what the agency plans to do to assist small businesses, including limited resource producers, in complying with the proposed rules and in easing this cost burden?

Response: In addition to the staggered compliance dates and modified requirements, FDA is committed to assisting small businesses in complying with the produce safety and preventive controls for human food rulemakings. FDA has created three Alliances to help industry, particularly small- and medium-sized companies, to comply with these rulemakings – those Alliances are the Preventive Controls Alliance, the Produce Safety Alliance, and the Sprout Safety Alliance. The Agency will also be developing Small Entity Compliance Guides to accompany each of these rulemakings, which will assist small businesses in understanding how the provisions apply to them and how they can comply.
FDA has also entered into a memorandum of understanding with USDA to establish a competitive grant program to provide food safety training, education, extension, outreach, and technical assistance to: 1) owners and operators of farms; 2) small food processors; and 3) small fruit and vegetable merchant wholesalers as directed by FSMA. FDA is currently working with USDA to execute the competitive grant program that will prioritize projects that will target small and medium sized farms.

Food Safety Modernization Act – integrated rules

I was encouraged to see that the proposed FDA rule takes an "integrated" approach instead of a "commodity-specific" approach. Congress mandated that the agency minimize the number of separate standards that apply to separate foods, and the agency has implemented that approach.

I urge you to retain this approach in the final rule; taking a commodity-specific approach would be very burdensome for many Maine farmers, who grow many different varieties of fruits and vegetables to meet growing consumer demand for local and regional food.

I am concerned, however, about the impacts of the proposed rules on farms that are involved in on-farm processing and aggregation activities. Part of running a successful agricultural operation is not only growing food but also selling food and preparing it to be sold. Many on-farm processes and aggregation activities would result in farms having to comply with both the produce rule and the preventive controls rule.

Ms. Pingree: Can you please discuss what the agency plans to do to clarify the definition of

"farm" and "facility" so that farmers know which rule they are subject o and when?

Response: Section VIII of the proposed Preventive Controls rule includes a proposal addressing this issue.

FSMA requires FDA to connect the scope of the Preventive Controls rule to the scope of the food facility registration requirement established by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("BT Act").

When FDA developed the farm definition used for the food facility registration requirement, the practical impact of an activity's classification as inside or outside that definition was limited to the potential to trigger the registration requirement and certain recordkeeping required under the BT Act. With FSMA, the farm definition has taken on more importance because activities within the farm definition would not be subject to the proposed Preventive Controls rule, but activities outside the farm definition would be subject to the proposed rule. Therefore FDA proposes to clarify the scope of the farm definition, including the classification of manufacturing, processing, packing and holding activities relevant to that definition, and adjust it if appropriate. In section VIII of the proposed Preventive Controls rule, FDA articulates a comprehensive set of organizing principles for classifying activities to more accurately reflect the scope of activities traditionally conducted by farms and to allow for more certainty among industry with regard to how their activities will be regulated. We are seeking comment on this proposal.

"Farm mixed-type facilities" are establishments that grow and harvest crops or raise animals and may conduct other activities within the farm definition, but that also conduct activities that trigger the registration requirement. In other words, such facilities conduct some "farm" activities and some "facility" activities. FDA interprets FSMA to mean that Congress did not intend those "farm" activities to be covered by the proposed Preventive Controls rule, but that Congress did intend the "non-farm" activities to be potentially subject to that rule.

Interstate Sale of Raw Milk

I come from a state with a very good raw milk program. Consumers have access to the products they want, and the state is able to provide testing and oversight to help ensure the products is safe.

One issue I hear about a lot relates to how USDA enforces rules, and resources. I continue to hear complaints from farm groups that the prohibition of interstate of raw milk is being over enforced.

Ms. Pingree: While I fully understand the prohibition on the interstate sale of raw milk, and I think we should save the merits of that prohibition for another day, I would like to know how much of the limited FDA budget goes to enforcing these rules.

Response: While the FDA issued a regulation prohibiting the interstate sale of raw milk in 1987, the FDA does not allocate budget resources directly to the enforcement of raw milk. Resources

for investigation and any subsequent enforcement actions taken by the FDA in this area are assigned as needed in response to specific issues or outbreaks of illness that take place directly related to raw milk.

Since 2003, FDA has acted against raw milk producers who were violating federal law in about one dozen instances. Most (nine) of those actions were administrative and involved the issuance of warning letters. FDA has also enjoined two raw milk producers from violating 21 CFR 1240.61 and it has prosecuted one raw milk producer, which it had also enjoined.

As an example, in 2012 a permanent injunction was granted to FDA preventing an individual from distributing raw milk and raw milk products in final package form for human consumption across state lines. A federal court granted this injunction after Rainbow Acres Farms attempted to circumvent the ban on interstate sales of raw milk by having customers participate in a "private buying club" and providing "cow share" agreements in which members purchased "shares" of individual cows and then claimed that their purported ownership entitled them to raw milk from those cows.

Ms. Pingree: How does that compare to other enforcement efforts?

Response: In 1987, FDA prohibited distribution of non-pasteurized dairy products in interstate commerce. However, sale of non-pasteurized dairy products within the state where they are produced is regulated by each state, and some states permit sale of these products. Illnesses and outbreaks associated with consumption of these products continue to occur despite the federal ban on the sale of non-pasteurized dairy products in interstate commerce, the broad use of pasteurization by the dairy industry, and the infrequency with which non-pasteurized dairy products are consumed.

As a result of the Centers for Disease Control and Prevention (CDC) efforts to enhance outbreak surveillance starting in 1998, the total number of outbreak reports increased substantially and it was found that the incidence of outbreaks caused by non-pasteurized dairy products was higher in states that permitted the sale of non-pasteurized dairy products than in states that prohibited such sale. FDA commits the necessary resources to respond to these outbreaks; absent a budget set aside for this response, the Agency cannot compare these responses to other enforcement efforts.

Ms. Pingree: Have you heard similar feedback?

Response: While the perceived nutritional and health benefits of raw milk consumption have not been scientifically substantiated, the health risks are clear. Since 1987, there have been 143 reported outbreaks of illness – some involving miscarriages, still births, kidney failure and deaths – associated with consumption of raw milk and raw milk products that were contaminated with pathogenic bacteria such as *Listeria, Campylobacter, Salmonella, and E. coli.* Because *E. coli* can spread from one person to another, the risk is not just to the one that drank the milk.

As a science-based, public health regulatory Agency, FDA strongly supports the application of effective measures, such as pasteurization, to protect the safety of the food supply and maintain public confidence in such important, healthy staples of the diet as milk.

With respect to the *interstate* sale and distribution of raw milk, FDA has never taken, nor does it intend to take, enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her own personal consumption.

We urge consumers who purchase raw milk to understand the health risks involved. While raw milk puts all consumers at risk, the elderly, immune-compromised people, children and pregnant women are especially vulnerable to the hazards of raw milk consumption. FDA's consumer education will continue to focus on helping consumers understand the risk to these populations.

FDA's position on raw milk is in concert with the CDC and the American Academy of Pediatricians.

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