

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2013

HEARINGS BEFORE A SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS HOUSE OF REPRESENTATIVES ONE HUNDRED TWELFTH CONGRESS SECOND SESSION

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

JACK KINGSTON, Georgia, *Chairman*

TOM LATHAM, Iowa
JO ANN EMERSON, Missouri
ROBERT B. ADERHOLT, Alabama
CYNTHIA M. LUMMIS, Wyoming
ALAN NUNNELEE, Mississippi
TOM GRAVES, Georgia

SAM FARR, California
ROSA L. DELAURO, Connecticut
SANFORD D. BISHOP, Jr., Georgia
MARCY KAPTUR, Ohio

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

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

PART 5

Food and Drug Administration	Page 1
USDA Food Safety and Inspection Service	255



Printed for the use of the Committee on Appropriations

U.S. GOVERNMENT PRINTING OFFICE

COMMITTEE ON APPROPRIATIONS

HAROLD ROGERS, Kentucky, *Chairman*

C. W. BILL YOUNG, Florida ¹
JERRY LEWIS, California ¹
FRANK R. WOLF, Virginia
JACK KINGSTON, Georgia
RODNEY P. FRELINGHUYSEN, New Jersey
TOM LATHAM, Iowa
ROBERT B. ADERHOLT, Alabama
JO ANN EMERSON, Missouri
KAY GRANGER, Texas
MICHAEL K. SIMPSON, Idaho
JOHN ABNEY CULBERSON, Texas
ANDER CRENSHAW, Florida
DENNY REHBERG, Montana
JOHN R. CARTER, Texas
RODNEY ALEXANDER, Louisiana
KEN CALVERT, California
JO BONNER, Alabama
STEVEN C. LATOURETTE, Ohio
TOM COLE, Oklahoma
JEFF FLAKE, Arizona
MARIO DIAZ-BALART, Florida
CHARLES W. DENT, Pennsylvania
STEVE AUSTRIA, Ohio
CYNTHIA M. LUMMIS, Wyoming
TOM GRAVES, Georgia
KEVIN YODER, Kansas
STEVE WOMACK, Arkansas
ALAN NUNNELEE, Mississippi

NORMAN D. DICKS, Washington
MARCY KAPTUR, Ohio
PETER J. VISCLOSKEY, Indiana
NITA M. LOWEY, New York
JOSE E. SERRANO, New York
ROSA L. DELAURO, Connecticut
JAMES P. MORAN, Virginia
JOHN W. OLVER, Massachusetts
ED PASTOR, Arizona
DAVID E. PRICE, North Carolina
MAURICE D. HINCHEY, New York
LUCILLE ROYBAL-ALLARD, California
SAM FARR, California
JESSE L. JACKSON, JR., Illinois
CHAKA FATTAH, Pennsylvania
STEVEN R. ROTHMAN, New Jersey
SANFORD D. BISHOP, JR., Georgia
BARBARA LEE, California
ADAM B. SCHIFF, California
MICHAEL M. HONDA, California
BETTY MCCOLLUM, Minnesota

¹ Chairman Emeritus

WILLIAM B. INGLEE, *Clerk and Staff Director*

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

WEDNESDAY, FEBRUARY 29, 2012.

FOOD AND DRUG ADMINISTRATION

WITNESSES

**MARGARET HAMBURG, M.D., COMMISSIONER, FOOD AND DRUGS, U.S.
FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**PATRICK MCGAREY, ASSISTANT COMMISSIONER FOR BUDGET, FOOD
AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**NORRIS COCHRAN, DEPUTY ASSISTANT SECRETARY FOR BUDGET,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Mr. KINGSTON. The committee will come to order. And I welcome Dr. Margaret "Peggy" Hamburg, the Commissioner of the Food and Drug Administration, and Mr. Patrick McGarey, who is the Assistant Commissioner for Budget, and Mr. Norris Cochran, the Deputy Assistant Secretary for Budget at Health and Human Services—HHS.

The FDA has responsibility for the safety, efficacy and security of human and veterinary drugs, medical products and a large portion of our nation's food supply that together comprise 20 percent of the U.S. consumer spending. This subcommittee has responsibility that the FDA has the necessary resources to carry out that mission. And we are always very interested in the FDA. There are so many things that you guys get involved in, and certainly a very important part of the American economy.

BUDGET REQUEST

The request for FY 2013, including user fees, is \$3.87 billion, of which \$2.517 billion is direct appropriation from this committee. The direct appropriation is an increase of \$11.5 million which in this economy is very moderate, and I think shows a great sensitivity to the difficult budget battle that we are facing.

There are a lot of people who do not want you to have any increase, and there are many people who will want you to have more increase. But, realizing the mission that you have taken on and the increased responsibilities that we give you, we know this is a very delicate balancing act, and so we certainly appreciate it.

The largest single increase is \$17.7 million for state-of-the-art laboratories at White Oak and then \$10 million for increased inspections in China, which as you know, many members of our committee feel very passionate about. It also includes money for data consolidation and information technology, and the request proposed \$583 million in new user fees. And the authorizing committee, I know, has been working with you on PDUFA 5, and we may have some questions on that.

So with that, let me yield to Mr. Farr.

Mr. FARR. Well, thank you very much, Mr. Chairman, and I want to also thank the panel for being here. Dr. Hamburg, very good to see you here.

I want, again, thank you for coming out to the district and really understanding how specialty crop agriculture is produced, harvested and guarded for food safety. It is good to see the Assistant Commissioner Patrick McGarey here, and I am looking forward to chatting with Norris Cochran, your Deputy Assistant Secretary of the Budget.

On any single day FDA is working to assure that the drugs that reach our drugstores, our physicians, and ultimately our body are safe and effective. FDA is working to assure that the medical devices that can save lives reach those that need them, and FDA is playing a critical role in safeguarding our nation's food supply. This agency carries a heavy responsibility to ensure that it protects and safeguards the things that go into our body, and approving the medications and devices the same. And you do it, I learned this morning, with only one-fourth the budget that NASA has.

It is an interesting priority of this government, where we put protection of food and drugs compared to what we put space travel. And I appreciate all the decisions going into that. All these budgets are tough. It is a cut, squeeze and trim mode we are in, and I look forward to asking you some questions about how we balance that and still assure safety for this nation.

So thank you for coming today, and thank you, Mr. Chairman.

Mr. KINGSTON. Thank you, Mr. Farr. Any other members? If not, Dr. Hamburg.

Dr. HAMBURG. Well, thank you, Chairman Kingston and ranking member Farr, and other subcommittee members.

I am delighted to be here and I am joined by Patrick McGarey, FDA's Assistant Commissioner for Budget, and Norris Cochran, the Deputy Assistant Secretary for Budget at HHS, as you noted. I want to begin by thanking you for your efforts in recent years to shrink the gap between the agency's budget and its vast and evolving responsibilities.

Your leadership has put us on a path toward more appropriate funding levels for FDA's unique and essential mission. We are sending these funds, responsibly, to reinforce our core functions and to obtain the most public health value for the dollar during these challenging fiscal times. We are deploying smarter and more flexible regulatory approaches and better targeting our inspection resources.

INFRASTRUCTURE

We have consolidated our IT infrastructure into modern data centers and expanded our efforts to leverage both financial and human capital through collaborations with public and private partners. And, with your support, we have produced concrete results. For example, we lead the world in the number and speed of drug approval, while maintaining high standards for safety and efficacy.

INNOVATIVE DRUGS

Last year, we approved 35 innovative new drugs, many of them groundbreaking. That represented the second highest number of approvals in the past decade. Last year, a total of 195 drug shortages were prevented through proactive collaboration with patients, healthcare providers and manufacturers, and by exercising regulatory flexibility. And, just a year after the enactment of the Food Safety Modernization Act, we have already issued guidances and interim final rules and are well on the way to meeting the five-year inspection frequency mandate for high risk, domestic food facilities.

The volume and complexity of the products we regulate, and the complexity of the supply chains by which they reach American consumers, has increased dramatically. We received thousands of medical products submissions each year and serve as the watchdog for the safety of tens of thousands of products already on the market. We oversee the safety of roughly 80 percent of the nation's food supply.

FOOD IMPORTS

As we reported in our fiscal year 2013 budget, imports of food products alone come from more than 200 countries and from more than 250,000 foreign facilities each year. Our core responsibilities are expanding, as well, to include additional product areas, such as tobacco, and evolving to accommodate scientific and technological advances along with the challenges of globalization. Our budget request reflects these complexities and new demands.

The fiscal year 2013 budget recommends \$4.5 billion for FDA, a 17 percent increase from fiscal year 2012. User fees account for 98 percent of the increase. We are proposing cuts or savings in two areas: IT and related systems, and buildings and facilities. FDA is also absorbing more than 80 percent of inflationary rent costs. Our fiscal year 2013 BA increases will support import safety, medical countermeasures, White Oak facilities, the Commission core pay raise, and about 20 percent of our rent increase.

CHINA

To strengthen the safety of food and drugs in China, FDA is requesting \$10 million. Exports from China are experiencing unprecedented growth. In the past five years, shipments of FDA regulated products from China increased by 62 percent, which is really a fundamental shift of our economic and security landscape. These additional resources requested will strengthen our capacity to inspect Chinese facilities and our ability to perform risk analysis and risk-based approaches to Chinese product.

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

NEW LABS

The President's budget also proposes an increase of \$17.7 million to outfit the new life sciences, bio defense laboratory, and ensure that all bio safety systems are operational before we could occupy the laboratory. User fees clearly represent a substantial part of our fiscal year 2013 budget. The current user fee programs for drugs and medical devices expire on September 30th of this year.

The reauthorization process for those is now well under way. New user fee agreements for generic drugs and bio similars have also been put forward. Also, to implement FSMA and reduce the burden of food-borne illness on consumers and American food producers, FDA is proposing a new food facility registration fee that would generate \$220 million. Additional proposals include new user fees to support cosmetic and food contact substance programs, compensate FDA for medical product reinspections, and support import operations at courier hubs.

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

**STATEMENT OF MARGARET A. HAMBURG, M.D.
COMMISSIONER OF FOOD AND DRUGS
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE SUBCOMMITTEE ON AGRICULTURE,
RURAL DEVELOPMENT,
FOOD AND DRUG ADMINISTRATION,
AND RELATED AGENCIES
U.S. HOUSE OF REPRESENTATIVES**

February 29, 2012

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Chairman Kingston, Ranking Member Farr and members of the Subcommittee, I am Dr. Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration. I am pleased to present the President's fiscal year 2013 budget request for the Food and Drug Administration (FDA).

I want to begin by thanking you for your efforts over the past few years to shrink the gap between the agency's budget and its vast and evolving responsibilities. As a science-based regulatory agency of global scope, FDA's mission is both exciting and daunting. Our core responsibilities are evolving and expanding to include additional product areas such as tobacco, to accommodate scientific and technological advances, and to step up to the global leadership role that FDA must play if we are to promote innovation and protect the American consumer.

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

1. Concrete Investments = Concrete Results

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

FDA now has the highest first action approval rate for new drugs we have ever had, and we continue to look for ways to improve the predictability, consistency and transparency of our drug review process. In FY 2011, we approved 35 innovative drugs, many of them ground breaking. This performance was among the highest number of approvals in the past decade, surpassed only by 2009. We lead the world in the number and speed of drug approvals: of the 57 novel drugs approved by both FDA and the EU between 2006 and 2010, 75% were approved first in the United States. All 23 cancer drugs approved by FDA and the EU were approved first in the United States. Last year also saw breakthroughs in personalized medicine, including two novel drugs that were developed and approved with diagnostic devices that will allow doctors to target the drug to those patients most likely to respond.

To achieve these results, and speed access for the American people, we made use of accelerated approvals and flexible clinical trial requirements and made sure manufacturers know that marketing applications can be based solely on foreign clinical data that meets certain clear and specific standards.

On the device side, in 2011, FDA released the Plan of Action for Implementation of 510(k) and Science Recommendations, 25 specific actions that we would take in 2011 to improve the predictability, consistency, and transparency of our premarket programs. 75% of those actions, plus eight additional actions, are already completed or well underway. We issued guidance on the Agency's regulatory expectations for personalized medicine diagnostic devices that are developed along with a therapeutic product, to target that therapeutic product to the appropriate population. We launched the Innovation Initiative, which proposed actions that the Agency could take to help accelerate and reduce the cost of development and regulatory evaluation of innovative medical devices in a way that maintains or improves patient safety and is based on sound science.

We also have successfully prevented at least 114 drug shortages. FDA has sent letters to pharmaceutical manufacturers, reminding them of their legal obligations to report certain discontinuances to the Agency, and urging them to voluntarily notify FDA of all potential disruptions of the prescription drug supply, even when not required by law. This has resulted in a significant increase in the number of potential shortages reported to FDA, and thus enhanced our ability to take action. Just last week, we announced a series of steps to increase the supply of critically needed cancer drugs that were in short supply, including exercising enforcement discretion to allow temporary importation of a replacement drug and approving a new manufacturer on an expedited basis.

We are also playing our part to address the rising costs of health care, by implementing a new approval pathway for biosimilar biological products and a user fee program to support review and evaluation of biosimilar products. We are also proposing a new generic drug user fee program that will support faster, more predictable reviews for generic drugs, that will effectively eliminate the current generic application backlog, and that will help assure quality by providing resources for regular surveillance inspections of manufacturers of generic drugs.

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. We have already issued interim final rules describing criteria for administrative detention of adulterated products and have used this authority several times. We met the FSMA mandate for foreign food safety inspections, and are well on the way to meeting the 5-year inspection frequency mandate for high-risk domestic food facilities. We also have issued a new guidance to the seafood industry on food safety hazards. We anticipate issuing several proposed rules called for in FSMA shortly. We post regular progress reports on implementation milestones on our web site.

Since enactment of the Tobacco Control Act of 2009, we have been working to achieve four goals: to prevent youth from using tobacco; to help adults who use tobacco to quit; to provide accurate information on the contents of tobacco and consequences of tobacco use to the public; and to use regulatory tools, including tobacco product standards, to reduce the public health burden of tobacco in the United States. To that end, we have created the new Center for Tobacco Products, which is already enforcing a ban on cigarettes with characterizing flavors (other than menthol), enforcing requirements for new warnings on smokeless tobacco products, and restricting youth access to cigarettes.

We have established a world-class testing laboratory with expertise and capacity to increase our understanding of the health risks of these products, and have supported innovative research on the impact of altering nicotine levels in tobacco products.

In June, FDA issued our “Pathway to Global Product Safety and Quality” report, describing the challenges of regulating in the globalized world in which FDA now operates, calling for a paradigm shift in how we approach our duties in light of such challenges, and describing the concrete actions we will take in four areas: 1) assembling global coalitions of regulators dedicated to building and strengthening the product safety net around the world; 2) developing a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets; 3) expanding FDA’s capabilities in intelligence gathering and use, with an increased focus on risk analytics and thoroughly modernized IT capabilities; and 4) effectively allocating agency resources based on risk, leveraging the combined efforts of government and industry. The essence of this strategy marries creative international coalitions with cutting-edge investigative tools to continue to provide the consistently high level of safety and quality assurance the public expects—and deserves.

In all that we do, we are guided by science, by our obligation to the American people to be innovative and efficient and, most important, by our mission to protect and promote the public health.

2. Maximizing the Impact of Agency Funds

At this time of fiscal restraint, it is more important than ever to focus on our core functions and to actively look for opportunities to streamline activities and leverage human and financial resources.

Focusing on our core functions means recognizing how those functions are evolving, and substantially changing the agency’s operating model to address the scientific, technologic, and globalization challenges of the 21st century. To this end, I have instituted a series of reorganizations designed to ensure that the agency better reflects its evolving responsibilities, but that also recognizes our responsibility to make the most efficient use of our limited resources. Early in my tenure, I appointed a new Deputy Commissioner for Foods, to ensure coordination of our growing and rapidly evolving responsibilities for oversight of the domestic and global food supply chain. Building on that success, last year I created the new position of Deputy Commissioner for Global Regulatory Operations and Policy, to fully recognize the need to integrate domestic and foreign inspections, streamline procedures, and seek greater harmonization and opportunities for collaboration with our counterparts in other countries. I also appointed a new Deputy Commissioner for Medical Products and Tobacco, reflecting our recognition that the review of medical products increasingly cuts across Center boundaries and that a new framework was necessary to address challenges like personalized medicine and combination products. Together, these changes build efficiencies into our organizational structure from the ground up and will make it easier to identify new opportunities for streamlining in the years to come.

We have made significant progress in consolidating our IT infrastructure into modern data centers. Simultaneously, we have modernized and standardized our hardware and software infrastructure, resulting in savings in power consumption and the ability to use FDA equipment and IT support resources more efficiently. You will see savings from this consolidation reflected in our proposed budget for FY 2013, as well as additional proposed savings.

We have expanded our efforts to leverage both financial and human capital through collaborations with public and private partners. For example, we recently entered a new collaboration with the European Medicines Agency (EMA) for shared efficiencies in our inspection programs for human and veterinary pharmaceutical products. Our Center for Drug Evaluation and Research is working in partnership with the Critical Path Institute, an independent, publicly funded institute, to establish public-private consortia to address key questions in regulatory science. And FDA's Center for Tobacco Products is partnering with the Environmental Protection Agency's eRulemaking program to develop a web-based tool to improve access to and participation in the federal regulatory process.

Another key area for improved efficiencies is improved targeting of inspection resources. We have been working hard to ensuring that our import inspection programs are risk-based, for the most efficient targeting at port-of-entry. We are redeploying current food inspection resources and pursuing efficiencies to support initial implementation of FSMA.

3. Preparing FDA for the Challenges Ahead

FDA's mission is challenging, even in the best of times, with scientific advances occurring at breakneck speed, and the pace of globalization accelerating. Our responsibilities are vast and growing, a trend that will only continue. We receive thousands of medical product submissions each year, and serve as the watchdog for the tens of thousands of products on the market to be sure they continue to meet the highest standards.

We have evolved from a country that once consumed simple, primarily domestically-produced goods to one that consumes complex products manufactured in every corner of the globe. We enjoy a greater variety of products from a greater range of places than ever before. The complexity of the products we regulate and the complexity of the supply chains by which they reach the eventual consumer has only increased. All of this means that FDA's job has gotten more complex and the stakes have continued to increase.

As our FY 2013 budget points out, imports of FDA-regulated food products come from more than 300,000 foreign facilities in 200 countries. Nearly 40% of the drugs Americans take are made overseas, and about 80% of active pharmaceutical ingredients are imported. Approximately half of medical devices used in the United States come from abroad. Food imports have increased nine-fold since 1993. About seventy percent of seafood and about 35 percent of fresh produce consumed in the United States comes

from foreign countries. At the Port of Savannah alone, the entering lines of FDA regulated product jumped from 20,000 in 2002 to 158,000 last year.

FDA oversees the safety of four-fifths of the nation's food supply. The public needs to know that industry and the government are using the best modern tools to prevent problems. According to the CDC, this country sees 48 million foodborne illnesses occur every year resulting in 128,000 hospitalizations and 3,000 deaths, with an aggregated annual cost of illness of \$77.7 billion

We are grateful that Congress has begun to help give FDA the tools needed to effectively regulate in a modern, complex, globalized environment. We are on the right path, but the road is long and challenging. The proposed FY 2013 budget, described in more detail below, will continue the forward motion that you have supported.

4. Next Steps: Investing in FY 2013

At the end of this Fiscal Year, FDA's drug and device user fee programs will expire. These programs make it possible for FDA to ensure the safety, effectiveness and quality of the nation's medical products. But they do far more. The user fee proposals you see in our FY 2013 budget, both those reauthorizing existing programs and those authorizing new programs, reflect time spent this past year listening to all our stakeholders and coming to agreement with them, not only on the scope but also on the direction these programs should take to best promote and protect the public health.

In this budget, you will see our commitment to smart regulation and efficacy in medical product review. We propose investment in improved standardization of electronic submissions for drugs, and modernization of FDA's food-related data bases and data sharing systems. Proposals for smarter engagement with Chinese regulators will allow FDA to make better evidence-based decisions and allocate FDA resources based on risk. We propose a new focus on potential uses of meta-analysis for drugs, and streamlined review goals for medical devices.

Enhanced communication and additional guidance development across all our user fee programs will further enhance both efficiency and transparency. Public workshops to discuss frameworks for evaluating benefits and risks will provide further transparency, as well as smarter regulatory action. For the proposed new user fee program for generic drugs, transparency means requiring the identification of facilities involved in the manufacture of generic drugs and associated active pharmaceutical ingredients, and improving FDA's communications and feedback with industry.

Our commitment to fostering innovation is woven into the fabric of this budget. For example, we propose to augment our clinical pharmacology and statistical capacity to address drug applications that rely on biomarkers. We propose deployment of hand-held mobile devices for food inspections, and a new laboratory facility that will support cutting-edge regulatory science.

FDA is often the last line of defense between the consumer and unsafe medical and food products. That is why, in this budget, you will see our commitment to significant safety initiatives. These include the first cosmetic user fee program to strengthen FDA's efforts to ensure the safety of cosmetics and remove unsafe cosmetics from the market. Our PDUFA V proposal includes the Sentinel Initiative, FDA's effort to develop an active post-market drug safety surveillance capacity through evaluation of post-market safety signals in population-based databases. Enhanced engagement with our regulatory counterparts in China will broaden the range of our inspections, allow follow up inspections, and foster improved interactions intended to improve the safety and quality of food and medical products.

Just as the food supply of 2002 is not the food supply of today, so too the FDA of 2002 must not be the FDA of today. That is why, in this budget, you will see our commitment to building a strong and reliable food safety system, focused on prevention and leveraging the valuable work of our partners in state and local governments. FSMA requirements represent rare consumer-industry consensus on food safety goals and the means of achieving them – in this budget we must commit to a new user fee program that can make these shared goals a reality. Food safety gives peace of mind to every family.

These are just a few examples of the many ways that our proposed FY 2013 budget reflects our commitment to innovative, efficient, and transparent approaches to our public health mission. Our full Fiscal Year 2013 Budget Request follows.

FOOD AND DRUG ADMINISTRATION FISCAL YEAR 2013 BUDGET REQUEST

I. FY 2013 Budget Summary

The FY 2013 budget recommends \$4.5 billion for FDA, a 17 percent increase from FY 2012. The FY 2013 increase for user fees, including increases for current law user fees and amounts for seven new user fee programs, accounts for 98 percent of the FDA budget increase.

FDA user fee programs support safety and effectiveness reviews of human and animal drugs, biological products, medical devices, and other FDA-regulated products. Fees also allow FDA programs to achieve timely and enhanced premarket review performance. Finally, fees support the programs and operations of the FDA Center for Tobacco Products

For FY 2013, FDA is proposing cuts in two areas – information technology (IT) and the FDA Buildings and Facilities (B&F) account. In addition to these budget authority reductions, FDA is also absorbing more than 80 percent of the inflationary cost of rent activities.

After accounting for these savings, the net increase in budget authority is \$11.5 million for FY 2013. Our increases support import safety, medical countermeasures, White Oak laboratory facilities, a portion of the increased cost of our rent activities, and the military pay raise that FDA Commissioned Corps officers will receive.

The federal investment in FDA is small compared to the breadth of our mission and the \$2 trillion in products that we regulate. The investment in FDA is also an investment in the economic health of two of the largest sectors of America's economy: the U.S. food industry and the medical products industry.

II. FDA Budget Authority

A. FY 2013 Reductions

FDA made significant progress in recent years to consolidate our IT infrastructure into modern data center facilities. During the consolidation, FDA modernized and standardized its hardware and software infrastructure. This effort provides an FDA computing environment that reduces our costs and provides agility not previously possible. The result is savings in power consumption and more efficient use of FDA equipment and resources for IT support.

Under this FY 2013 initiative, FDA will realize savings that flow from the consolidation effort. FDA will generate additional IT savings by streamlining other data management activities, reducing redundant IT devices, and reducing other IT costs, for a total savings of \$19.7 million. Finally, FDA will also save \$3.5 million by deferring repair and maintenance projects supported by our Building and Facilities account.

B. Food and Drug Imports from China

FDA is requesting a budget authority increase of \$10 million to strengthen the safety of foods, drug products and ingredients exported from China to the United States. During the past decade, the global economy has been shaped by a number of powerful forces, including a rapidly increasing flow of goods into the United States. These foreign goods often follow complex paths through multi-step supply chains to reach the United States.

This dynamic is very evident in our trade with China. From FY 2007 to 2011, the number of shipments of FDA-regulated products from China increased by 62 percent. This represents a fundamental change in our economic and security landscape, a change that requires FDA to alter its approach to protecting the health of the American public. To address this change, FDA must strengthen its capacity to inspect Chinese facilities that ship products to the United States and strengthen its ability to perform risk analysis on FDA-regulated products from China.

The addition of \$10 million will strengthen FDA's ability to protect American consumers and patients in important and fundamental ways.

- FDA will improve its food and drug inspection and analytical capabilities by increasing its presence in China with 16 inspectors, and by adding three U.S.-based analysts.
- FDA will broaden the range of its inspections. In addition to inspecting Chinese facilities that manufacture food and medical products for export to the United States, FDA will inspect sites of clinical trials. FDA will also conduct follow-up inspections to ensure that firms continue to manufacture food and medical products under safe conditions.
- FDA will strengthen the understanding of Chinese regulators and the exporting industry about U.S. safety standards through targeted workshops and seminars. This process will foster a constructive dialogue on the critical role of inspections and other approaches for improving the safety and quality of food and medical products.

FDA views this initiative as a unique opportunity to engage the Chinese industry and our regulatory counterparts in China. Through this initiative, Chinese regulators will enhance their understanding of FDA requirements and strengthen their regulatory capacity to assure the safety of the food and drugs that their industries export to the United States. With these resources, FDA will develop more robust knowledge about the complexities of regulatory pathways and supply chains within an increasingly globalized environment. This understanding will allow FDA to make better evidence-based decisions and allocate FDA resources based upon risk.

C. FDA Medical Countermeasures Initiative

The FDA Medical Countermeasures Initiative (MCMi) is designed to help meet America's national security and public health requirements for medical countermeasure (MCM) readiness. MCMs include drugs, vaccines, diagnostics, and other medical products needed to respond to chemical, biological, radiological, nuclear (CBRN) threats and emerging infectious diseases.

Thanks to the efforts of this subcommittee, FDA received an appropriation of \$20 million in FY 2012 to provide a base of funding for FDA's MCMi. For FY 2013, the FDA budget includes an additional \$3.5 million for FDA medical countermeasures activities.

With the FY 2012 base funding and the additional FY 2013 resources, FDA will support partnerships with industry, academia, and government partners to improve the development timelines and success rates for MCMs. FDA will also expand technical assistance to developers of the highest priority MCMs.

The top priorities for these MCM funds include FDA action teams to support the development of MCMs to address the following priorities:

- warfighter care for American soldiers exposed to trauma or CBRN threats
- diagnosing and treating the multiple manifestations of acute radiation syndrome

- meeting the special needs of pediatric patients and pregnant women
- developing next generation in vitro diagnostic tests for CBRN threats
- working closely with HHS to establish flexible manufacturing capacity in the U.S.

Since the announcement of the FDA MCMi in August 2010, FDA and its drug, device and biologics programs have worked aggressively to ensure that the United States has access to high-priority MCMs during a public health emergency. Our accomplishments to date include:

- issuing a five-year strategic plan for the MCMi
- launching a rigorous MCM regulatory science program
- sponsoring an Institute of Medicine workshop on the challenging scientific issues related to MCM development
- establishing a partnership with the Defense Advanced Research Projects Agency (DARPA) to collaborate on regulatory science research
- hosting a meeting of state and local public health leaders to address emergency preparedness and response
- conducting public workshops and advisory committee meetings to advance development of high priority MCMs
- initiating threat briefings to ensure that FDA reviewers are fully aware of the threats – and therefore the risks – as they conduct benefit- risk analyses on MCM products.

D. FDA Regulatory Science Facilities

On August 18, 2010, the General Services Administration (GSA) awarded the construction contract for the new laboratory complex at White Oak, and construction is well underway.

An FY 2013 increase of \$17.7 million will allow FDA to outfit the new CBER-CDER Life Sciences-Biodefense Laboratory complex that will support FDA's core regulatory science needs. FDA must make this investment now to ensure that all laboratory biosafety hazard systems are operational and the laboratory is ready for occupancy during FY 2014.

As GSA completes construction of the Life Sciences-Biodefense Laboratory complex, FDA's FY 2013 budget request contains resources to make the facilities operational and to fully certify the new laboratory. The new laboratory is essential to support more efficient development of new and innovative medical products and to better assess product safety and effectiveness. With these resources, FDA will operate in modern laboratory facilities that allow FDA to fulfill FDA's public health responsibilities.

E. Pay and Rent

The FY 2013 budget also contains \$1.5 million to support the military pay increase for Commissioned Corps personnel that serve at FDA and \$2.0 million to pay a portion of

the inflationary rent costs for FDA food safety and nutrition programs. Funding these elements of the FY 2013 budget will help ensure that FDA can retain the professional staff to perform our mission of protecting patients and consumers and improving public health.

III. FDA User Fees

A. Prescription Drug User Fees

PDUFA History and Background: The timely review of the safety and effectiveness of New Drug Applications and Biologics License Applications is central to the FDA mission to protect and promote the public health. Before PDUFA was enacted by Congress in 1992, FDA's review process was understaffed, unpredictable, and slow. FDA lacked sufficient staff to perform timely reviews or develop procedures and standards to make the process more rigorous, consistent, and predictable. Access to new medicines for U.S. patients lagged behind other countries.

In response to concerns expressed by industry and patients, Congress enacted PDUFA, which provided additional funds through user fees to allow FDA to hire reviewers and support staff and to upgrade FDA information technology systems. At the same time, FDA committed to complete application reviews in a predictable time frame. These changes revolutionized the drug approval process in the United States and allowed FDA to speed the application review process for new drugs, without compromising the FDA's high standards for demonstrating safety, efficacy, and quality of new drugs prior to approval.

PDUFA Achievements: Through PDUFA, FDA has received a stable, consistent source of funding that allows FDA to focus on promoting innovative therapies and on bringing critical products to market. Since Congress enacted PDUFA in 1992, this user fee program has provided patients with faster access to more than 1,500 new drugs and biologics. These new drugs and biologics include treatments for cancer, infectious diseases, neurological and psychiatric disorders, and cardiovascular diseases.

FY 2011 PDUFA Performance: During FY 2011, FDA approved 35 new, groundbreaking medicines, including two treatments for hepatitis C, a drug for late-stage prostate cancer, the first drug for Hodgkin's lymphoma in 30 years, and the first drug for lupus in 50 years. Of the 35 innovative drugs approved in FY 2011, 34 met their PDUFA target dates for review.

Reversal of the Drug Lag: As these statistics demonstrate, PDUFA has led to the reversal of the drug lag that prompted Congress to adopt this law. Since the enactment of PDUFA, FDA has steadily increased the speed of Americans' access to important new drugs compared to the European Union (EU) and the world as a whole. Of the 35 innovative drugs approved in FY 2011, 24 (nearly 70 percent) were approved by FDA before any other regulatory agency in the world, including the European Medicines Agency. Of 57 novel drugs approved by both FDA and the EU between 2006 and 2010, 43 (75 percent) were approved first in the United States.

Prompt Approval and Launch of New Drugs: In recent years, the average FDA drug review time also has been significantly faster than those in the EU. For priority drugs approved between 2006 and 2010, FDA's median time to approval was six months (183 days). This is more than twice as fast as the EU time to approval for those drugs, which took a median time of 13.2 months (403 days). For standard drug reviews, FDA's median time to approval was 13 months (396 days), which is 53 days faster than the EU time to approval of 14.7 months (449 days) for those drugs.

Providing Guidance to the Drug Industry: Increased resources from user fees have enabled FDA to provide a large body of technical guidance to industry that clarifies the drug development pathway for many diseases. The resources also allow FDA to meet with companies during drug development to provide critical advice on specific development programs. During the past five years alone, FDA has held more than 7,000 meetings soon after we received a request from the product sponsors. Innovations in drug development are being advanced by many new companies as well as more established ones, and new sponsors may need, and often seek, more regulatory guidance during development. In FY 2009, more than half of the meetings FDA held with companies at the early investigational stage and midway through the clinical trial process were with companies that had no approved product on the U.S. market.

Weighing Drug Benefit and Risk: FDA assesses benefit-risk for new drugs on a case-by-case basis, considering the degree of unmet medical need and the severity and morbidity of the condition the drug is intended to treat. This approach has been critical to increasing patient access to new drugs for cancer and rare and other serious diseases, where existing therapies have been few and may have limited effectiveness. Some of these products have serious side effects but they were approved because the benefit outweighed the risk.

For example, in March of last year, FDA approved Yervoy (ipilimumab) for the treatment of unresectable or metastatic melanoma. Yervoy also poses a risk of serious side effects in 12.9 percent of patients treated, including severe to fatal autoimmune reactions. However, FDA decided that the benefits of Yervoy outweighed its risks, especially considering that no other melanoma treatment has been shown to prolong a patient's life.

FY 2013 User Fee Increase for PDUFA V: The legislation that the Administration submitted to Congress to reauthorize PDUFA recommends \$713 million in PDUFA fees for FY 2013. The current law expires on September 30, 2012, and FDA is ready to work with Congress to ensure timely reauthorization of this vital program. To sustain and build on our record of accomplishments, reauthorization must occur seamlessly, without any gap between the expiration of the old law and the enactment of PDUFA V.

Specifics of PDUFA V: We are very pleased to report that the enhancements for PDUFA V address many of the top priorities identified by public stakeholders, the top concerns identified by industry, and the most important challenges identified within FDA. I will briefly summarize these enhancements for the subcommittee.

Enhancing Application Review – To foster greater efficiency in the review process for new, innovative products – new molecular entities (NMEs) and original biologics license applications (BLAs) – PDUFA V promotes enhanced communication and additional meetings with firms that sponsor these applications. To accommodate this increased interaction during review, the FDA review clock for this subset of applications would not start until the 60-day administrative filing review period ends.

Enhancing Regulatory Science & Expediting Drug Development – PDUFA V includes five enhancements to advance regulatory science and expedite drug development.

- **Innovation through Enhanced Communication** – Under PDUFA V, FDA will promote innovation through enhanced communication between FDA and sponsors during drug development.
- **Methods for Meta-Analysis** – FDA will evaluate best practices for and the limitations of meta-analysis, a valuable form of statistical analysis that combines data or findings from multiple studies to explore drug benefits and risks.
- **Biomarkers and Pharmacogenomics** – FDA will augment its clinical, clinical pharmacology and statistical capacity to adequately address applications that rely on biomarkers.
- **Use of Patient-reported Outcomes** – FDA will improve its clinical and statistical capacity to address applications that include study outcomes known as patient-reported-outcomes and other clinical endpoint assessment tools.
- **Drugs for Rare Diseases** – FDA will foster the development of drugs for rare diseases by issuing guidance, increasing FDA outreach to the rare disease patient community, and providing specialized training in rare disease drug development for sponsors and FDA staff.

Enhancing Benefit-Risk Assessment – FDA will hold public workshops to discuss frameworks for evaluating benefits and risks that are most appropriate for drug and biological review. FDA will also conduct a series of public meetings between its review divisions and patient advocacy communities to receive their input on the severity of condition and degree of unmet medical need for specific indications or disease states.

Enhancing and Modernizing the FDA Drug Safety System – PDUFA V includes two important post-market, safety-focused initiatives. Under the first, standardizing Risk Evaluation and Mitigation Strategies (REMS), FDA will initiate a public process to explore strategies and initiate projects to standardize

REMS with the goal of reducing burden on practitioners, patients, and others in the health care setting. FDA will also conduct public workshops and develop guidance on methods for assessing the effectiveness of REMS and the impact on patient access and burden on the health care system. Under the second, evaluating drug safety issues through the Sentinel Initiative, FDA will initiate a series of projects to establish the use of active post-market drug safety surveillance to evaluate post-market safety signals in population-based databases.

Electronic Submissions and Standardization of Electronic Application Data –

The predictability of the FDA review process relies heavily on the quality of sponsor submissions. FDA currently receives submissions of original applications and supplements in formats ranging from paper-only to electronic-only, as well as hybrids of the two. The variability and unpredictability of submitted formats and clinical data layout present major obstacles to conducting a timely, efficient, and rigorous review within current PDUFA goal time frames. PDUFA V enhancements include a phased-in requirement for standardized, fully electronic submissions for all marketing and investigational applications. Through partnership with open standards development organizations, FDA will also conduct a public process to develop standardized terminology for clinical and non-clinical data submitted in marketing and investigational applications.

B. Medical Device User Fees

Introduction: Action by Congress in 2002 to enact the Medical Device User Fee and Modernization Act (MDUFMA I) was prompted by growing concerns about the capacity and performance of the medical device review program. MDUFMA I and MDUFA II (enacted in 2007) authorized user fees for the review of medical device premarket applications, reports, supplements, and premarket notification submissions. The additional resources generated by MDUFA fees allowed FDA to make its reviews more timely, predictable, and transparent to applicants. MDUFA fees and other appropriations for the medical device program helped FDA expand available expertise, modernize its information management systems, provide new review options, and provide more guidance to prospective applicants.

MDUFA II Performance: FDA has been meeting or exceeding goals agreed to by FDA and industry under MDUFA II for most of the submissions that FDA reviews each year. For example, FDA completes at least 90 percent of 510(k) reviews within 90 days or less.

FDA's performance during MDUFA II has not been limited to achieving quantitative goals for the timely review of premarket submissions such as applications for Premarket Approval (PMAs) and requests for 510(k) clearance. FDA also accomplished a number of qualitative goals set by MDUFA II in 2007, including issuing more than 50 new and updated guidances for industry. Guidance documents are important resources for industry because they describe FDA's interpretation of or policy on regulatory issues. Guidances are critical to support industry efforts to comply with the law and to develop new products that may benefit American patients. The availability of guidance documents also fosters regulatory predictability and consistency.

It is important to note that MDUFA metrics reflect FDA time only. The metrics do not reflect the time taken by device sponsors to respond to requests for additional information. Overall time to decision – the time that FDA has the application plus the time the manufacturer spends answering any questions FDA may have – has increased steadily since 2001.

FDA bears some responsibility for the increase in total time to decision, and we have been instituting management, policy, and process changes to address this issue. As a result, in 2011, FDA for the first time began reducing what previously was an increasing backlog of unresolved 510(k) submissions.

Smart Regulation and Fostering Medical Device Innovation: FDA recognizes that, if the United States is to maintain its leadership role in this area we must continue to streamline and modernize processes and procedures to make device approval not just scientifically rigorous, but clear, consistent, and predictable without compromising safety. FDA is committed to continuing to improve the device approval process to address legitimate concerns raised by industry and other stakeholders.

Nearly two years ago, FDA recognized that, given the growing complexities of medical product development, FDA needed to re-evaluate and modernize regulatory review processes to ensure that patients had timely access to safe and effective medical devices. At that time, CDRH began a new, systematic approach to device regulation, moving away from the traditional misperception that safety and effectiveness considerations are incompatible with fostering innovation. Rather than focus on more regulation or less regulation, we began to focus on smart regulation.

The new approach is to ensure that safety and effectiveness and innovation are complementary, mutually supporting aspects of FDA's mission to promote public health. To improve CDRH's internal systems, we first reached out to stakeholders to hear their concerns and listen to their recommendations about premarket programs. This is what we heard:

- Industry felt that inadequate predictability, consistency, and transparency were stifling innovation and driving jobs overseas.
- Consumer groups, third-party payers, and some health care professionals believed that one of the premarket pathways – the 510(k) program – did not provide adequate protection for American patients and did not generate sufficient information for practitioners and patients to make well-informed treatment and diagnostic decisions.

In turn, CDRH employees expressed concerns that the 510(k) program had not adapted to the increasing complexity of devices, and that poor-quality 510(k) submissions, poor-quality clinical studies conducted in support of PMA applications, and an ever-growing workload were straining already overburdened premarket programs.

FDA also began two assessments of device premarket programs to identify issues, their root causes, and the appropriate solutions. One assessment focused on the 510(k) program. The other examined how FDA uses science in regulatory decision-making, touching on aspects of several of the device premarket review pathways, such as our clinical trials program. In addition, FDA contracted with the Institute of Medicine (IOM) to conduct an independent evaluation of the medical device 510(k) program.

In August 2010, following extensive public input, FDA released two reports that identified issues regarding the medical device premarket programs and proposed potential actions to address the underlying root causes. The number one problem was insufficient predictability in device premarket programs, which can create inefficiencies, increase costs for industry and FDA, and delay bringing safe and effective products to market. We identified several root causes of these issues. They include:

- very high reviewer and manager turnover at CDRH (almost double that of FDA's drug and biologics centers)
- insufficient training for staff and industry
- extremely high ratios of employees to front-line supervisors
- insufficient oversight by managers
- CDRH's rapidly growing workload, caused by the increasing complexity of devices and the number of overall submissions we review
- unnecessary or inconsistent data requirements imposed on device sponsors
- insufficient guidance for industry and FDA staff
- and poor-quality submissions from industry.

While it is true that providing more user fee resources alone will not solve the problems of the device premarket programs, funding needs is the root of, or a contributing factor to, several of these problems. Adequate and stable funding is one key component to FDA and industry success in bringing safe and effective devices to market quickly and efficiently.

After considering extensive and varied public input on our recommendations, in January 2011, FDA announced a Plan of Action that included 25 specific actions that we would take in 2011 to improve the predictability, consistency, and transparency of device premarket programs. As of February 2012, 75 percent of these actions, plus eight additional actions, are already completed or well underway.

In addition, during February 2011, FDA announced the Innovation Initiative, which included several proposals to help maintain the position of the U.S. as the world's leader in medical device innovation, including the creation of a new approach for important, new technologies called the Innovation Pathway.

Since then, FDA has announced additional efforts to improve medical device premarket programs, including actions to improve the program for clinical trials and the Investigational Device Exemption (IDE) program. The actions we are taking can be grouped into three main areas of emphasis. Overall, FDA actions seek to:

- create a culture change toward greater transparency, interaction, collaboration, and the appropriate balancing of benefits and risks
- ensure more predictable and consistent recommendations, decision-making, and application of the least-burdensome principle
- implement more efficient processes and use of resources.

FDA believes the actions that we've taken and plan to take in the future will have a positive impact on the device review process by

- providing greater predictability of data requirements through guidance
- reducing unnecessary data requests through training and policy and process changes
- implementing policies to appropriately balance benefit-risk determinations
- using external experts more extensively (consistent with conflict-of-interest guidelines)
- creating incentives to conduct clinical studies first in the United States
- speeding up IDE approval decisions
- implementing the Innovation Pathway 2.0 (a priority review program to expedite development, assessment, and review of important technologies)
- instituting efficiencies in the premarket review process.

To best serve patients, both the medical device industry and FDA must have the flexibility to be innovative and entrepreneurial. CDRH must continue making critical improvements to the device program. At the same time, the medical device industry and CDRH must continue to work together to ensure that the Center receives high-quality submissions that contain the information we need to make well-informed and timely decisions.

Finally, CDRH must have adequate and stable resources to get the job done right and quickly. Timely reauthorization of MDUFA, as well as the Congressional appropriations process, is critical to achieving these goals.

Moving Forward – Reauthorization of MDUFA: For more than a year, FDA has been meeting with stakeholders and holding discussions with the medical device industry in an effort to develop a package of recommendations to reauthorize MDUFA. On February 1, we reached an agreement in principle with representatives from the medical device

industry on a set of recommendations to reauthorize MDUFA. The agreement would authorize FDA to collect \$595 million in user fees over five years, an amount that is subject to inflation increases. The President's Budget for FY 2013 recommends a MDUFA fee amount of 69.7 million. As the MDUFA III agreement moves forward, we will update this amount to reflect the new funding levels for FY 2013. The agreement strikes a careful balance between what industry agreed to pay and what FDA can accomplish with the proposed funding. We believe that it will result in greater predictability, consistency, and transparency through improvements to the review process.

Key features of the agreement include the following:

- Earlier, more transparent and more predictable interactions between FDA and applicants, both during the early product development stage as well as during the review process
- More detailed and objective criteria for determining when a premarket submission is incomplete and should not be accepted for review
- More streamlined FDA review goals that will provide better overall performance and greater predictability. This includes a commitment to provide feedback to an applicant if FDA's review extends beyond the goal date, so that the parties can discuss how to resolve any outstanding issues
- Additional resources to support guidance development, reviewer training and professional development, and an independent assessment of the pre-market review process to identify potential enhancements to efficiency and effectiveness
- More detailed quarterly and annual reporting of program performance
- A commitment between FDA and industry to reduce the total average calendar time to a decision for PMAs and 510k applications.

FDA and representatives of the medical device industry recently completed negotiating the final details of the agreement, and the Administration is reviewing the draft package of proposed recommendations. When this review is completed, FDA will present that package to Congressional committees and will seek public comment on the proposed recommendations, which will include a public meeting. FDA will then consider the public's views and comments, revise the proposed recommendations as necessary, and transmit final MDUFA reauthorization recommendations to Congress.

As we work with all interested stakeholders and Congress toward reauthorization of MDUFA in order to provide adequate and stable funding for the program, we will also be moving forward with the ongoing CDRH program improvements, focusing on smart regulation that will facilitate device innovation. As these new policies and processes continue to be implemented, we expect to see notable improvements in the consistency, transparency, and predictability of the medical device premarket review programs.

C. Tobacco Product User Fees

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) into law. This legislation granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products, and it authorized the agency to collect user fees from manufacturers and importers of tobacco products to pay for new FDA tobacco regulation activities. The legislation specified the total dollar amount to be collected each year, and directed the manner in which the fees would be assessed among classes of tobacco products, and among companies within each class.

Since 2009, FDA successfully has stood up the Center for Tobacco Products (CTP). CTP has used the user fees prescribed in the statute to hire Center leadership and to enable those leaders to initiate the scientific, educational, enforcement and regulatory activities needed to accomplish the public health goals of the Tobacco Control Act. By the end of FY 2011, the Center had a staffing level of over 230 FTEs, and it anticipates meeting projected staffing goals in FY 2013.

Importantly, since 2009, CTP already has advanced the public health significantly by:

- Enforcing a ban on cigarettes with characterizing flavors, other than menthol, such as cherry and chocolate;
- Issuing and enforcing regulations that restrict youth access to cigarettes and smokeless tobacco;
- Enforcing the prohibition on misleading advertising claims, including those that misleadingly imply products are safer;
- Enforcing requirements for the new smokeless tobacco warnings that better communicate health risks; and
- Issuing new cigarette health warnings that will promote better understanding of the dangers of smoking.

In addition, CTP has:

- Established a world-class testing laboratory with expertise and capacity to analyze tobacco products and increase our understanding the health risks of these products.
- Supported innovative research on the impact of altering nicotine levels in tobacco products to assess how such changes could affect the way people might use tobacco products.

- Dramatically increased regulatory science capabilities, along with the National Institutes of Health, via the launch of the first-ever sustained, longitudinal study to understand patterns of tobacco use and how it changes over time in youth and adults, including vulnerable populations.
- Protected millions of youth by awarding nearly \$33 million to 37 states and the District of Columbia for conducting retail inspections to ensure that tobacco retailers comply with the law's requirements, such as not selling cigarettes and smokeless tobacco products to minors.
- Conducted more than 40,000 retail inspections under these State contracts, resulting in over 2,000 warning letters for violations. Further, FDA has started issuing Civil Money Penalties for continued violations; and
- Issued guidance to industry to help them meet their obligations under the law with respect to substantial equivalence and new tobacco product applications.

The FY 2013 budget request for CTP is \$505,000,000, an increase of \$28,000,000 above the FY 2012 enacted budget. The amount requested is specifically authorized in the Tobacco Control Act and comprised entirely of tobacco user fees. FY 2013 priorities include strong measures to prevent youth from starting to use tobacco, reduce product harms, and encourage current users to quit.

In an effort to prevent youth from starting to use tobacco products (*i.e.*, initiation), CTP plans to:

- Deem all products that meet the definition of tobacco product to be subject to FDA's tobacco product authorities;
- Launch a series of comprehensive, science-based public education campaigns, targeting youth and young adults, to educate about the dangers of tobacco products; and
- Continue to expand the State Retail Enforcement Program, awarding additional contracts toward the goal of contracting with every state and U.S. territory to assist with FDA tobacco retail inspections.

In an effort to reduce harm from tobacco products, CTP plans to:

- Enact a new rule that requires testing and reporting to FDA about harmful and potentially harmful constituents and subsequently use the data to educate the public about the health risks of these constituents;
- Continue research to support development of tobacco product standards to reduce the addictiveness of current products; and

- Continue research to support the development of tobacco product standards to reduce toxic, cancer-causing elements in tobacco products and tobacco smoke.

Finally, in an effort to encourage tobacco users to quit, CTP plans to work to ensure that tobacco product marketing is neither false nor misleading.

D. New User Fees for Generics and Biosimilars

In addition to recommending the reauthorization of PDUFA and MDUFA, the FY 2013 Budget recommends new user fee programs to support review and related activities for generic drugs and biosimilars. The proposed user fee programs for generic drugs and biosimilars are modeled on the successful PDUFA program but are tailored to reflect the unique challenges and needs associated with regulating generic drugs and biosimilars.

1. Generic Drug User Fees

As a result of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments, America's generic drug industry has been developing, manufacturing, and marketing – and FDA has been reviewing and approving – lower-cost versions of brand-name drugs for more than 25 years. This legislation and the industry it fostered are a true public health success.

Last year, approximately 78 percent of the more than three billion new and refilled prescriptions dispensed in the United States were filled with generics, yet those drugs accounted for only 25 percent of prescription drug spending. In the last decade alone, generic drugs have provided more than \$931 billion in savings to the nation's health care system.

This success, however, also has come to represent a significant regulatory challenge, and delays in approvals of generic drugs have emerged as a major concern for the generics industry, FDA, consumers, and payers alike. Unlike the brand manufacturers who pay fees under PDUFA, the generic industry does not currently pay a user fee to support FDA activities related to its applications. During the past several years, despite actions by this Subcommittee to increase funding for generic drugs, FDA resources have not kept pace with the ever increasing number of Abbreviated New Drug Applications (ANDA) and other submissions related to generic drugs.

The number of generic drug submissions sent annually to FDA has grown rapidly, reaching another record high this year, including nearly 1,000 ANDAs. The current backlog of pending applications is estimated to be more than 2,500. The current median time to approval is approximately 31 months, although this includes time that the application is with the sponsor to address FDA questions about the application.

The regulatory challenge of ensuring safe, high-quality generic drugs includes inspecting manufacturing facilities, where the challenge is not just one of numbers but also of geography. To keep pace with the growth of the generic drug industry, FDA has had to

conduct more inspections as the number of facilities supporting those applications has also increased, with the greatest increase coming from foreign facilities, including those that manufacture Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs).

The number of foreign manufacturers greatly exceeds the number found in the United States, and both API and FDF manufacturers must be inspected for FDA to approve a generic drug application. The generic industry is also experiencing significant growth in India and China, a trend that will likely continue. Foreign inspections represent a significant challenge and require significant resources.

The generic drug user fee agreement is designed to address these regulatory challenges in an affordable manner. The annual fee total proposed represents less than one half of 1 percent of generic drug sales. This modest cost is expected to be offset by benefits received by the industry, as faster review times will bring products to market sooner. The result will also be more savings for patients, health care systems, and the government.

Overview of the Proposed Generic Drug User Fee Proposal: The Generic Drug User Fee Act (GDUFA) proposal submitted to Congress in January 2012 is aimed at putting FDA's generic drugs program on a firm financial footing and providing the additional resources necessary to ensure timely access to safe, high-quality, affordable generic drugs. With the proposed user fee resources, FDA will enhance the generic drug review process and increase FDA's capacity to conduct reviews of Abbreviated New Drug Applications (ANDAs) and associated Drug Master Files (DMFs) with greater efficiency and transparency. FDA will conduct additional pre-approval, bioequivalence, and post-market surveillance inspections to verify manufacturing compliance with Current Good Manufacturing Practices (CGMP) for generic drug products. The FY 2013 user fee estimate for GDUFA is \$299 million.

The proposal focuses on quality, access, and transparency. Quality means ensuring that companies, foreign or domestic, that participate in the U.S. generic drug system are held to the same consistent high-quality standards and that their facilities are inspected biennially, using a risk-based approach, with foreign and domestic inspection frequency parity.

Access means expediting the availability of low-cost, high-quality generic drugs by bringing greater predictability and timeliness to the review of ANDAs, amendments, and supplements. Transparency means requiring the identification of facilities involved in the manufacture of generic drugs and associated APIs, and improving FDA's communications and feedback with industry to expedite product access and enhance FDA's ability to protect Americans in our complex global supply environment.

The additional resources called for under the agreement will provide FDA with the ability to perform critical program functions that could not otherwise occur. With the adoption of user fees and the associated savings in development time, the overall expense of bringing a generic product to market is expected to decline. The program is expected to provide significant value to small companies and first-time entrants to the generic market.

In particular, these companies will benefit significantly from the certainty associated with performance review metrics that offer the potential to dramatically reduce the time needed to commercialize a generic drug, when compared to pre-GDUFA review times.

GDUFA Program Funding and Metrics: If enacted as negotiated, the program would provide FDA with additional funding for all aspects of the generic drug program in the amount of \$299 million per year, for five years, adjusted annually for inflation. With those additional user fee funds, FDA agrees to undertake a series of immediate program enhancements and performance goals. Many performance metrics and efficiency enhancements are set forth in the negotiated documents. The proposed goals, many of which will be phased in, include:

- **New Applications:** FDA will review and act on 90 percent of complete, unamended electronic ANDAs within 10 months after the date of submission.
- **Backlog:** FDA will review and act on 90 percent of all ANDAs, ANDA amendments, and ANDA prior-approval supplements pending on October 1, 2012, by the end of FY 2017.
- **Inspections:** FDA will conduct risk-adjusted biennial Current Good Manufacturing Practice (CGMP) inspections of generic API and generic FDF manufacturers with the goal of achieving parity of inspection frequency between foreign and domestic firms in FY 2017.

Under the program, fees will derive from two primary sources: generic drug-related submissions and generic drug-related facilities. In the first year of the program, there would also be a fee assessed for applications that are pending on October 1, 2012, the so-called “backlog.”

Like PDUFA, individual fee amounts would be set annually, with the total annual user fee revenue target specified in statute. Overall, 70 percent of the user fee revenue will be generated by facility fees and 30 percent by ANDA application, prior approval supplement and Drug Master File fees. In the first year that ratio will be slightly different because of the one-time backlog fee. The revenue from facilities is split, with 80 percent provided by the FDF manufacturers and 20 percent by API manufacturers, a ratio recommended by the generics industry.

As in all of FDA’s other medical product user fee programs, under the proposed generic drug user fee program, user fee funding will supplement appropriated funding to ensure sufficient resources for FDA’s generic drug review program, and guarantees are in place to ensure that the user fees supplement annual appropriations.

2. Biosimilars User Fees

A successful biosimilars review program within FDA will spark the development of a new segment of the biotechnology industry in the United States. The Biologics Price Competition and Innovation Act (BPCI Act) of 2009 established a new abbreviated

approval pathway for biological products shown to be “biosimilar to” or shown to be “interchangeable with” an FDA-licensed biological product. With this new abbreviated approval pathway, a biosimilar biologic can be approved by demonstrating, among other things, that it is highly similar to a reference biological product already licensed by FDA.

Developing a biosimilar is expected to be less risky, less costly, and less time-consuming than developing the reference biological product manufactured by an innovator company. Therefore, approved biosimilars are expected to be less expensive. This program will provide significant benefits for patients, making available more affordable treatments that clinicians will know that are biosimilar or that are interchangeable. The development of this new market segment will expand the opportunities for technical innovation and job growth.

Biosimilar Fee Program Funding and Metrics: The FY 2013 estimate for biosimilar user fees is \$20.2 million. The proposed biosimilars user fee program for FY 2013 to 2017 addresses many of the top priorities identified by public and industry stakeholders and the most important challenges identified by FDA. The proposed biosimilars user fee program is similar to the PDUFA program in that it includes fees for marketing applications, manufacturing establishments, and products. However, there are some differences, because of the nascent state of the biosimilars industry in the United States. For example, there are no currently marketed biosimilar biological products. Accordingly, the recommended biosimilars user fee program includes fees for products in the development phase. This program will generate fee revenue in the near-term and enable sponsors to have meetings with FDA early in the process of developing biosimilar biological product candidates.

As in all of FDA’s medical product user fee programs, the proposed biosimilars user fee program supplements appropriated funding to ensure sufficient resources for FDA’s review programs. Under the proposed biosimilars user fee program, FDA would be authorized to spend biosimilars user fees on FDA activities related to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. This program would include activities related to biosimilar biological product development meetings and investigational new drug applications (INDs). It would also include development of the scientific, regulatory, and policy infrastructure necessary for review of biosimilar biological product applications, such as regulation and policy development related to the review of biosimilar biological product applications, and development of standards for biological products subject to review and evaluation.

Details of Proposed Biosimilar Fees: The proposed biosimilars user fee program includes biosimilar product development, marketing application, establishment, and product fees.

The initial and annual biosimilar product development fees for biosimilar biological products in development would be equal to ten percent of the fee established for a human drug application under PDUFA for that fiscal year. The sponsor would pay biosimilar product development fees each year until the sponsor submits a marketing application for

the product that is accepted for filing or discontinues participation in the biosimilar product development program for the product. The proposed marketing application fee for a biosimilar biological product is equal to the fee established for a human drug application under PDUFA, minus the cumulative amount of any biosimilar product development fees paid for the product that is the subject of the application.

Finally, the proposed establishment and product fees are equal to the establishment and product fees under PDUFA for any fiscal year because the level of effort required for FDA oversight of manufacturing and post-marketing safety activities is expected to be comparable for biosimilars and biological products under PDUFA. FDA anticipates a modest level of funding from these sources initially, because only biosimilar biological products that are approved for marketing would be subject to these fees.

Proposed Biosimilar Performance Goals and Procedures: The proposed performance goals for biosimilars are similar to the PDUFA performance goals. They include performance goals for application review, first-cycle review, proprietary name review, major dispute resolution, clinical holds, and special protocol assessments. The proposal also includes goals for new types of development-phase meetings with associated time frames for timely review of data and feedback.

E. Implementing the FDA Food Safety Modernization Act

Food Safety remains a critical program area for FDA. FDA's FY 2013 proposal for food safety aims to advance the vision of a strong, reliable food safety system that Congress enacted in the landmark FDA Food Safety Modernization Act of 2011 (FSMA). The FY2013 budget proposal builds on the food safety increases that the subcommittee appropriated for FY 2011 and FY 2012, and calls for novel user fee revenue to allow FDA to establish a prevention-focused domestic and import food safety system. (These efforts will include leveraging the valuable work of FDA's food safety partners in foreign state, local, tribal, and territorial governments.)

Congress' Vision for FSMA: Passed in response to a series of outbreaks and contamination incidents involving both domestic and imported food that revealed serious weaknesses in the nation's system of food protection, FSMA set out a vision for a modern food safety system that shifts the focus to preventing food safety problems rather than relying primarily on reacting to problems after they occur. It was enacted with broad consumer and industry support and reflects a shared vision that all Americans will benefit from a modernized food safety system that reduces foodborne illness, strengthens public confidence in food safety, and minimizes costly disruptions of the food supply.

Implementing Congress' vision for a strengthened food safety system represents a dramatic expansion of FDA's workload. The statute calls for: food safety standards for produce; comprehensive implementation of preventive controls across all food and feed facilities; new inspection frequency mandates for food facilities; an entirely new import oversight system and mandated presence overseas; and a mandate to build capacity of states and foreign government to achieve harmonization and leverage resources. These

elements are visionary, but the simple truth is that FDA cannot meaningfully deliver on these mandates without sufficient funding.

FDA is redeploying current resources and pursuing efficiencies to implement FSMA, but in a constrained budget environment, it is appropriate for industries that directly benefit from FDA activities to pay moderate fees to fund some of FDA's critical new responsibilities enacted in FSMA. We look forward to working with Congress to ensure that there are sufficient and appropriate user fee resources for FDA to implement the requirements of the Food Safety Modernization Act.

FSMA's direction to FDA – essentially to build a modern new food safety system that can work more effectively to prevent food safety problems and meet the challenges of today's global food system – reflects a recognition of the food safety realities in America, including the rising volume of food imports and the high costs of foodborne illness.

The Rising Volume of Food Imports: The statistics on our food supply provide some insight into what prompted Congress to act. On the rising volume of food imports, FDA regulates more than \$450 billion of domestic and imported foods. An estimated 15 percent of the U.S. food supply is imported, including 50 percent of fresh fruits, 20 percent of fresh vegetables, and 80 percent of seafood. These imports originate from more than 250,000 foreign establishments in 200 countries each year. As a nation, we enjoy the benefits of – but are simultaneously put at risk by -- a global food supply.

The Cost of Foodborne Illness: In addition to the globalization challenge, the costs of foodborne illness are significant: Outbreaks caused by contamination in the food and feed supply impose costs on consumers, the food and feed industries, and the health care system. A 2012 study using an enhanced cost-of-illness model estimated that the aggregated cost of foodborne illness is \$77.7 billion per year. The average cost per case of foodborne illness is \$1,626. Outbreaks of foodborne illness and contamination events have a substantial impact on public health – 48 million foodborne illnesses occur every year resulting in 128,000 hospitalizations and 3,000 deaths.

In June 2011, the U.S. Department of Agriculture (USDA) Economic Research Service (ERS) estimated that the annual economic cost of foodborne illness and premature death caused by Salmonella is \$2.7 billion. The annual estimated cost of illness caused by E. coli O157 is \$489 million. These estimates include medical costs due to illness, the cost of time lost from work due to nonfatal illness, and the cost of premature death. Reducing foodborne illness by just 10 percent would keep 5 million Americans from getting sick each year. Preventing a single fatal case of E. coli O157 infection would save an estimated \$7 million.

Strategic Plan: As the subcommittee directed in the conference agreement to accompany our FY 2012 appropriation, FDA has issued a strategic plan for food safety. Known as the Food and Veterinary Medicine Strategic Plan, this plan contains FDA's strategy for food safety and preventing foodborne illness. The plan targets foodborne illnesses of unknown origins as well as illness that can be specifically attributed to known sources.

The Food and Veterinary Medicine Strategic Plan is based on goals including:

- Improving food safety effectiveness and efficiency at all levels of the food and feed supply chain
- Establishing science-based preventive control standards across the farm-to-table continuum;
- Achieving high rates of compliance with preventive controls standards domestically and internationally; and
- Strengthening scientific leadership, capacity, and partnership to support public health and animal health food safety decision making.

FY 2013 Food Establishment Registration Fee: To address the challenges of globalization and the high costs of foodborne illness, to implement FSMA, and to advance the goals of the Food and Veterinary Medicine Strategic Plan, FDA is proposing a new food facility registration user fee of \$220.2 million for FY 2013. The fee will support:

- establishing new, effective, and comprehensive food safety standards
- establishing a new program for import safety
- increasing the number and efficiency of inspections
- launching an integrated national food safety system with states and localities
- expanding research activities, which will include improved data collection and risk analysis
- improving FDA's capability to conduct risk-based decision-making.

These fees will allow FDA to reduce the risk of illness associated with food and feed, decrease the frequency and severity of food- and feed-borne illness outbreaks, reduce instances of contamination; and greatly diminish the burden on American businesses and the U.S. economy due to foodborne illness events. Without sufficient and reliable fee revenue, we can expect the unacceptably high human toll of foodborne illness to continue, with the resulting disruptions to the food system and the economic burdens to the food industry that result from foodborne illness outbreaks.

Fee revenue would provide a modest share of total resources required for FSMA implementation and FDA's other food safety activities, but is essential to meet the statutory mandates; enable investments in training, IT, and other areas that will enhance FDA's efficiency; and secure FDA's base funding. These proposed user fee investments are quite modest compared to the economic value of the nation's food and feed supplies

and the costs that the public, industry, government, and the health care system experience during an outbreak. FDA is engaging with the food industry and other food safety stakeholders to develop a workable fee structure that will have broad support within the food industry, other stakeholders and Congress.

Major Pathogens Responsible for Foodborne Illness: Finally, the conference agreement on the FY 2012 budget also directed FDA to link its budget request for food safety to actions that will attack the known and the unknown sources of foodborne illness. FDA has embraced this approach across all components of the FY 2013 budget relating to food safety – the FDA business case papers, performance tables, and center-by-center narratives. Specifically, the FY 2013 budget includes more than 125 references to the top seven causes of foodborne illness.

F. Other New User Fee Proposals

Cosmetics User Fee: The proposed cosmetic user fee of \$18.7 million will strengthen FDA efforts to protect public health by preventing harm to consumers, ensuring the safety of cosmetics and removing unsafe cosmetics from the market. With this fee revenue, FDA will develop necessary guidance and standards for industry. The fee revenue will also allow FDA to identify research gaps, such as gaps related to the safety of novel ingredients used in cosmetics.

Medical Product Reinspection User Fee: The FDA Food Safety Modernization Act, which Congress enacted in December 2010, authorized fees for reinspections of food and feed establishments. FDA is proposing to expand this fee authority to medical product establishments. With this change, medical product establishments will pay the full cost of reinspections and associated follow-up work. FDA will impose the user fee when FDA reinspects facilities due to a failure to meet Good Manufacturing Practices (GMPs) or other important FDA requirements. The FY 2013 estimate for Medical Product Reinspection user fees is \$14.7 million.

Food Contact Notification User Fee: FDA has statutory responsibility for the safety of all food contact substances in the United States. The Food Contact Notification (FCN) program supports applications for innovative food contact substances that help mitigate microbial food contamination and provide consumers with more healthful and safe food choices. The proposed user fees of \$4.9 million will support FDA efforts to increase the availability of safe food contact substances, to prevent unsafe food contact substances from reaching the market and to apply the most modern regulatory science to the review of food contact substances.

International Courier Use Fee: For FY 2013, FDA is proposing a new International Courier User Fee of \$5.6 million. The proposed fee will support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the increased cost of its international courier activities through user fees.

CONCLUSION: THE PROMISE AND THE CHALLENGE

The resources in this budget will allow FDA to perform its fundamental public health responsibilities in new and more efficient ways. Our budget also supports industry efforts to innovate and bring new products to market that will benefit American patients and consumers and strengthen our economy.

It is fitting that today is International Rare Disease Day. The difficulties in promoting the development of safe and effective therapies for diseases afflicting small populations highlights both the accomplishments we are now delivering to the American people and the public health challenges facing FDA.

Rare diseases often appear early in life, and about 30 percent of children with rare diseases die before the age of 5. By some estimates, there are 7,000 rare diseases afflicting about 25 million Americans. For these Americans, today – and every day – is Rare Disease Day.

Because of the small numbers of patients who suffer from each disease, FDA often allows drug sponsors to use non-traditional approaches to establishing safety and effectiveness. For example, FDA approved Voraxaze (glucarpidase) just last month, to treat patients with toxic methotrexate levels in their blood due to kidney failure. Voraxaze was approved based on data in 22 patients from a single clinical trial. Prior to the approval of Voraxaze, there were no effective therapies for the treatment of toxic methotrexate levels in patients with renal failure.

Similarly, less than a month ago, FDA approved Kalydeco (ivacaftor) to treat patients age 6 or older with Cystic Fibrosis (CF) and who have a specific genetic defect (G551D mutation). The G551D mutation occurs in approximately 4 percent of patients with CF, or approximately 1,200 patients in the United States. There is no cure for CF, and despite progress in the treatment of the disease, most patients with CF do not live beyond their mid-30's. FDA granted Ivacaftor Priority Review status, and approved the drug in approximately half of the six-month Priority Review period. Ivacaftor will be the first medicine that targets the underlying cause of CF.

Although these successes are encouraging, much work remains. Less than five percent of the 7,000 orphan diseases are treatable today. We recognize our vital role in bringing new therapies and new hope to patients who suffer from rare diseases, which is why FDA made drugs to treat rare diseases one of our priorities for the reauthorization of the Prescription Drug User Fee Act.

Much work remains ... not just for orphan drugs, but for all FDA-regulated products. The challenges of promoting innovation while assuring safety will only increase in the coming years, along with exciting opportunities to improve public health through new cures and a safer food supply.

My goal with this proposed FY 2013 budget is to position FDA to seize these opportunities. The resources in this budget will allow FDA to perform its core public health responsibilities in new and more efficient ways, to address these and the many other challenges at the heart of our mission. This budget also supports industry efforts to innovate and bring new products to market that will benefit American patients and consumers and strengthen our economy.

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

CHINA-FTES

Mr. KINGSTON. Thank you, Dr. Hamburg. I want to ask you first about China in terms of that increase.

How many FTEs will you have for drug inspection and how many for food? And do you know of the \$10 million how much is for salary and how much of it is for construction?

Dr. HAMBURG. Well, that money is going to be divided between drugs and foods. A little bit more will be going to drugs, and it will be to enable us to put more inspectors in China. We have three offices, actually, in China at the present time, in Shanghai, Beijing and Wanjo. This will enable us to strengthen our in-country capacity for inspections.

It will also enable us to add several more people to do risk analytics and really assess how best to target the various commodities coming in from China in terms of both our inspections and our work with industry and Chinese regulatory authorities to really enhance understanding of our standards and expectations, and try to ensure that the products coming from China meet our standards for safety and integrity of the supply chain.

With respect to the exact numbers, you know, perhaps we better submit those to the record in terms of the total number.

CHINA

There is no construction funding within the \$10 million. All of the funding will support the 19 FTE for this initiative and also provide essential China Initiative program support, including securing and outfitting office space for the FTEs.

There would be 16 new inspectors in China and three people in the U.S. to help develop our risk analytics and program activities, but we do have other inspections going on in China.

Mr. KINGSTON. Will they be looking at normal legal drugs as well as potential counterfeit?

Dr. HAMBURG. Well, we will be fulfilling our responsibility in terms of inspecting the facilities and working with the manufacturers of FDA approved commodities, including drugs and medical devices, but we will also be strengthening our activities that focus on our deep concerns about adulterated and substandard products and counterfeit products that may be arising from many parts of the world, as well as domestically, and represent a huge and growing area of concern.

COUNTERFEIT DRUGS

Mr. KINGSTON. Many of the counterfeit drugs come from that area of the world. Correct?

Dr. HAMBURG. Counterfeits actually come from many different places. We have had problems with adulterated goods from China that have received a lot of prominence, and, you know, carried a high burden of disease, even death, with them.

HEPARIN

I am sure you remember the Heparin contamination of a blood thinner, Heparin, that occurred back in 2008. That originated in China with what appears to have been an intentional adulteration of the crude Heparin product. In the food arena there was mel-

amine contamination of both dairy products and pet food, which caused considerable disease and disruption here, as well as great damage in China with over 100 kids dying from contaminated infant formula.

Mr. KINGSTON. With the pressure on making sure that the drugs are right, will you have enough payroll, enough resources for food inspection as well?

Dr. HAMBURG. Well, we are trying to balance, you know, important needs. And, of course, our activities internationally, including in China, are broader than just this one request, of course.

Mr. KINGSTON. Yes.

IMPORTS

Dr. HAMBURG. And this request is really building, strengthening and extending our capability. But we are focused very much on both medical products, drugs, devices and food, because both are areas where the volume of imports is increasing dramatically; and where we know there are real vulnerabilities, we have seen real world problems and where our projections of future demands only suggests more and more needs.

So we have really a number of strategies to address it: inspection, closer collaboration with our regulatory partners, more information sharing, closer work with industry, who of course have huge interest in assuring safety of the supply chain, and many more activities, including border screening, which remains a part of our focus, a very important part. But we need to push our activities to prevent problems further back in the supply chain, closer to the source.

Mr. KINGSTON. One of the things you may know is Congress has had a pay freeze since 2008; and, often what we do to members carries on to staff, and then it makes it hard to keep really talented staff, regardless of the fact that they are mostly ideologically driven to work here. But I would imagine at FDA, you could lose some of your top-rated scientists to other opportunities if you are not paying them sufficiently, and I know you do have a .5 percent co-adjustment in there.

And I have run out of time, but that is a concern of ours. We want to make sure you have the best and the brightest coming out of America's universities and staying, in terms of a career, because I think you are in a unique position that you have got people who can walk out any time as we do, and often for higher salary. But I am out of time and we will—

Dr. HAMBURG. Well, I appreciate your comments and you are right on target.

Mr. KINGSTON. Well, thank you.

Mr. Farr.

PLAN B

Mr. FARR. Thank you, Mr. Chairman. I was very disturbed that HHS Secretary Sibelius overturned the considered decision of FDA to approve the sale of Plan B: One Step—An Emergency Contraceptive, an over-counter contraceptive to teenagers younger than 17.

When the New York Times reported that half of all pregnancies are unplanned and more than 40 percent of children are born to

unwed mothers, 1.2 abortions are performed every year involving one out of every 50 women of reproductive age. Do we really need unplanned pregnancies, children born to unwed mothers or abortions? It seems to me the secretary's decision harkens back to the Bush years when such decisions were often political footballs and not based on good science.

I want to plug you and your agency for your courage in issuing a statement following the secretary's decision that defended the work of FDA. That certainly would not have happened in the previous Administration. I am curious now. Where do you see this going? You anticipate the manufacturer submitting a revised application with additional data that might address the issues in the secretary's memorandum? And may we someday see a contraceptive device?

I mean if contraceptives are contraceptives, and it seems to me that we should not be having these age barriers for women that are of reproductive age, and you understand that better than anybody. But I want to know why we cannot get there.

Dr. HAMBURG. Well, let me begin by saying that FDA is committed to making science-based decisions and careful review of all available data, whatever product we are reviewing and whatever the area of FDA focus and activity. With respect to Plan B it remains an open application and the company is making decisions about whether it wants to continue to pursue the application for over-the-counter availability for females of reproductive age and, of course, if they want to pursue the application further, we will work closely with them.

Mr. FARR. Do you think there is any indication that they are trying to do that?

Dr. HAMBURG. You know. I think that they are sort of assessing the situation and will, I am sure, be letting us know how they want to proceed.

Mr. FARR. What do they have to do? Do they have to just address the issues that were raised in the secretary's statement?

Dr. HAMBURG. There would have to be a determination about what kind of additional data would, you know, be important to address the gaps that were identified by the secretary and how that data could be collected and put together a package.

Mr. FARR. But you reviewed that type of data, because you did not have those restrictions on your recommendation. Is that it?

Dr. HAMBURG. Well, when our FDA reviewers looked at the submitted data and the available broader experience with this product, which has been on the market as a prescription drug since 1999 and has been used in many countries around the world, both as a prescription drug and over-the-counter drug. The assessment was that it was safe and effective for its indicated use and with respect to the requirements for an over-the-counter drug; that individuals could use it without the intervention of a learned professional; could understand the recommendations, use it properly; and, also that the condition was one that they could make their own assessment without that learned professional intervention to assess whether or not they were appropriate in terms of target population for that.

PLAN B—OVER THE COUNTER

Mr. FARR. Do you think that there will be pressure on those countries or shopping in those countries that allowed it to be an over-the-counter drug, mail order?

Dr. HAMBURG. It is currently available to females of all reproductive ages by prescription; and, the question was whether for the younger ages it would move to being over-the-counter.

Mr. FARR. Yeah.

Dr. HAMBURG. So it is still available to——

Mr. FARR. And what countries have it over-the-counter?

Dr. HAMBURG. Well, you know, there is a long list that have it available either over the counter, beyond the counter or prescription. Different countries have slightly different criterias and practices, so there is not a one-to-one correlation; but, we would be happy to provide you with more information on this.

PLAN B

Although FDA does not compile such data, we estimate from other sources that a dedicated levonorgestrel emergency contraceptive product—*sometimes known as the morning after pill*—can be purchased in more than 140 countries. In approximately 62 countries, emergency contraception is available over-the-counter, that is, without a prescription. The details of how nonprescription drugs are provided vary from country to country, and may even vary from pharmacy to pharmacy. For example, in some countries nonprescription availability means that the medication is kept behind the pharmacy counter and may be dispensed by a pharmacist without a doctor's prescription. In other settings, the product is available for the consumer to take from the general pharmacy shelf but it cannot be sold in a store without a pharmacist on the premises. In another setting, the product could be marketed for general retail sale. This is a general description of the availability of dedicated levonorgestrel emergency contraceptive pills, but FDA does not have access to all of the specific ways these products are marketed in all of the countries where it is sold without a prescription.

We note that the question refers to Plan B. Plan B is a brand name for a dedicated levonorgestrel emergency contraceptive product and is only sold in 3 countries under that name.

Mr. FARR. Because I was just thinking this is going to encourage mail orders, if it is Canada, Mexico, or other countries where people are accustomed to getting mail-order drugs. We would lose that market. Anyway, that is interesting. My time is up.

Mr. KINGSTON. Mrs. Lummis.

GLAUCOMA—EYELASHES

Mrs. LUMMIS. Well, thank you, Mr. Chairman.

Dr. Hamburg, welcome. I am going to start with something fun this morning while I am waiting for my caffeine to kick in, rather than something really serious about food, and I want to tell you a story.

My mother is in her mid-80s and she has glaucoma. And like most people in their 80s who have been on this drug for a very long time, she has eyelashes that are just unbelievable. They are enormous. And one day I was commenting, "How can that be?" Well, as it turns out, there is something in glaucoma drugs that also causes eyelashes to grow very long and very thick, and I know that the FDA has allowed certain companies to market.

PGAS

They are called PGAs: Prostaglandin analogs, as a prescription drug. And then market them with the intent of growing very long eyelashes. Well, as it happens, there are companies who are marketing those same PGAs in products that are not approved by the FDA. And here is one of them here. It is a little eyelash growing applicator with mascara, but the problem is that it can actually mask the symptoms of glaucoma if somebody goes to an eye doctor and is tested for glaucoma.

And being one of the people who is subject to glaucoma because of heritability, I am curious about these kinds of things. So when a company uses an FDA approved drug without FDA approval and without marketing it as an FDA approved drug, how can you enforce—both through an intellectual property rights protection, because you have approved a process and people have gone through these extensive approval processes—and avoid the public health risk of having companies like this market it, quite frankly, without FDA approval?

Dr. HAMBURG. Well, you raise a very complex set of issues that actually cut across many areas of FDA activity and regulatory legal frameworks. Cosmetics are under one part of the FDA and set of legal regulatory requirements and drugs another; but, as you point out, sometimes they do intersect. And the issue about FDA approved products versus non-approved and their use in the marketplace is another area of considerable challenge.

OFF-LABEL USES

With respect to FDA approved drugs, we approved them for safety and efficacy for a given indication. We do not regulate the practice of medicine, and physicians can use drugs in what is called an off-label manner to treat patients that they think that medically it is indicated. However, companies cannot market drugs for those off-label uses, and so that is an important distinction.

Now, that being a cosmetic, that may or may not have a drug in it. If there is something that truly has an FDA approved drug as a component, then we need to look at that as it is no longer strictly a cosmetic. It is a drug. And, as you point out, there is an FDA-approved product for growing eyelashes, but I am not aware—and we appreciate you doing some of our leg work for us to identify products that we may need to look at more closely.

COSMETICS—USER FEE

But your question also speaks to the fact that cosmetics are increasingly complex in terms of their composition. And that one of the things in the FY 2013 budget is a proposed user fee for cosmetics to allow us to strengthen the program, both to enhance our research and analytics of products, such as what you have identified, as well as to better understand who is out there making what, where the products come from, et cetera.

Mrs. LUMMIS. Well, I understand that Representative Blackburn has communicated with the agency about this very situation; and, so, I will probably be joining her in hoping that an enforcement action will be forthcoming.

Now, let me switch to imported food. Oh. My time is up. So, Mr. Chairman, I will wait until a second round.

Mr. KINGSTON. Thank you.

Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman, and I too presume we are going to have several rounds.

So, thank you so much for being here, Commissioner and Mr. Cochran, Mr. McGarey. It is a pleasure to see you. Two questions I have right now should not come as any surprise. I have a third question for this round if I can get it in. If not, I will——

Dr. HAMBURG. I will try to give short answers.

MENU LABELING

Ms. DELAURO. Thank you. What can you tell me about the status of implementing the menu labeling provisions of the Mail Act? As you know, it would require chain restaurants with at least 20 U.S. locations to post calorie content on menu items.

I continue to strongly oppose carving out any exemption to the menu labeling requirement for movie theaters or grocery stores, but it clearly would go against what was the legislative intent. What is the status of the proposed rule? What can we do to avoid any exemptions for the calorie posting requirement that are clearly not in accord with congressional intent?

Dr. HAMBURG. Well, we have been deeply involved in that issue, as I think you know, and have put forward as part of notice and comment rulemaking several documents for public comment. We have gotten a lot of response and we now have been reviewing the thousands of comments and have now a rule that is in administrative review and we expect to be coming forward with the final rule in the not too distant future.

It has been complex. How you define a restaurant-like establishments in our modern environment has been challenging; and, we have gotten a lot of differing opinions that we have been trying to analyze and reconcile.

Ms. DELAURO. In the not too distant future? Are we talking the next several months or the end of this year?

Dr. HAMBURG. You know, I would like to give you a more precise date. It has moved out of the FDA and is in the review process; and, you know, I suspect there will be some back and forth. But I think that, you know, we would like to do it in a timely way.

Ms. DELAURO. I think I just might do a survey of movie theaters in my own community. I mentioned this yesterday at a hearing. We are now serving hotdogs, nachos with cheese, soda, popcorn, in addition to the candy that has always been served. So the folks have gotten into the food business. So to be exempt, I think, would be a mistake in terms of legislative intent, and I hope you will just focus in on what the legislative intent is of the effort.

TANNING BEDS

Now, where do you stand on the reclassification of tanning beds and when can we expect to see movement from the agency? We had been exchanging letters. March 2010 the FDA convened an advisory committee. There were clear recommendations there. Last

year, the subcommittee included report language urging the agency to act on the recommendations in a timely manner.

The House Energy and Commerce Committee released a report earlier this year, highlighting the misleading advertising and false claims that are enabled by the current FDA classification of the devices. They are in the same category as band-aids and tongue depressors. So we have not seen any proposed regulations on reclassification announcement for the agency. Can you tell us why it is taking such a lengthy time, since the advisory committee meeting, to address this known carcinogen?

Dr. HAMBURG. Well, this has taken a long time, and I know your deep and abiding interest and concern about this. As you know, we have had a series of activities, including seeking public input and expert advice from advisory committees, and we have gotten recommendations in some key areas as to how to proceed, including labeling issues and classification of these devices.

With respect to classification of devices, that would require rule-making, which is a lengthy process, and that is something of concern to us. How long it can take and if there might be other mechanisms to address some of these as we would move forward, eventually.

Ms. DELAURO. But, when?

Dr. HAMBURG. But, you know, again, we hope that by the end of this year we will have taken definitive action.

Ms. DELAURO. Because in the meantime, there are many young women who continue to do this and are continuing to deal with very serious illness and potential death as a result of that.

Dr. HAMBURG. It has taken too long.

Ms. DELAURO. Much too long, much too long. I will address the third question I have for this round, and I will just ask you if you could get back to our office, because you will not have enough time to do that. And that is with regard to FDA information technology and, I guess, my particular concern.

IT SYSTEMS

I will just get to the question, but we will lay it out as are the IT systems in the various FDA centers and offices capable of quickly exchanging high level information, efficiently and effectively across the agency between headquarters and the field offices on a regular basis? Have you had any data conversion problems when exchanging data across the agency?

At what point will the agency achieve 100 percent electronic submissions in each of its centers? What technology and staff are and will be needed to achieve this? Looking ahead, how will the agency improve on the multiple weaknesses noted by the HHS OIG in December 2011?

Thank you very much, and I look forward to subsequent remarks.

Dr. HAMBURG. And we will submit a full response to you.

FDA IT SYSTEMS

Yes, the FDA I.T. systems are capable of quickly exchanging high level information across FDA. As a result of various initiatives completed and underway, FDA continues to improve its ability to exchange information efficiently and effectively. The data center modernization completed 2011 provided an advanced computing in-

frastructure that is secure, scalable, and reliable that enables interoperability across the FDA not previously known. FDA is now in the position to move forward with modernization of software systems. Additionally, in October 2011, FDA implemented enhancements to the Center Views or CV module, improving the productivity of FDA Domestic and Import Reviewers, Investigators, and Consumer Safety Officers by providing improved and efficient access to FDA data. CV provides the capability to search various Center data sources, eliminating the need to directly access Center legacy systems when retrieving product and firm information and provides a comprehensive product data set to aid FDA personnel in regulatory decision making.

FDA faces the challenging need to consistently and uniquely identify specific firms and facilities that process FDA-regulated products. FDA processes more than 20 million import transactions per year that relate to FDA-regulated products. The data coming from Customs to identify parties are neither unique nor consistent, creating duplicate records in our databases that do not link to the information we maintain on business entities. It is labor-intensive to match entities to our information so we can make informed decisions for import purposes. Therefore, FDA is in the process of implementing Dun & Bradstreet's DUNS number as our universal business identifier for linkage and facility identification. This will provide global recognition and identification of each specific business entity at a single location with a unique DUNS number. It will also allow the potential to link information from any source such as FDA, other government agencies, and international regulatory authorities to the correct business entity.

Mr. KINGSTON. Mr. Latham.

Mr. LATHAM. Thank you, Mr. Chairman. And, welcome and thank you very much for the opportunity to visit yesterday afternoon and to work around our schedules and everything. I appreciate that.

Dr. HAMBURG. I would note I left my purse behind, and Congressman Latham made sure that it was watched over safely until I came back to get it. So thank you very much.

Mr. LATHAM. Well, there was not much in it, so—

[Laughter.]

USER FEES

Mr. LATHAM. Yeah. We got whatever was valuable. Anyway, that is fine. The question in your budget there, the question brought to us, I think, by your budget is the total \$4.49 Billion, 17 percent increase over last year. And 98 percent of those increases come from user fees.

The user fees people paid, generally expect to have inspections or some benefit and return from that; however, you are proposing fees, a registration fee for food facilities. And I have got a list here of facilities that will be dramatically affected by those types of fees, just basically because they exist, and with no benefit, really, for them or for the public.

I just wonder how do you justify the tax that amounts to \$220 million next year alone? The industry, the food industry really has very slim profit margins, high labor costs and other inputs, and the consumer is going to be the person that ends up paying the bill on this. How do you justify that, and do you have a vehicle to authorize these types of payments or taxes?

Dr. HAMBURG. Well, first, with respect to is this user fee really needed, I would argue, emphatically yes. Food safety is of the utmost importance to both consumers and to the food industry. We know that although we have one of the safest food supplies in the world, that we still have very real vulnerabilities with some 300 deaths a year, 128,000 hospitalizations, one in six people getting sick.

And a recent industry study showed that there is a pretty dramatic lack of consumer confidence in the safety of the food supply. And I think the food industry wants to address that as well: additional dollars to help us strengthen and extend our food safety program, especially in the world of globalized food supplies with some 50, 60 percent of fresh food and produce coming from overseas, and 80 percent of seafood coming overseas—vulnerable commodities subject to potential contamination and the growing complexity of our own domestic food supplies.

I think that this investment is well worth it to help prevent problems from happening and prevent unnecessary health costs to consumers, cost to our healthcare system, and cost to both the reputation and health of this important sector of our economy.

So I think it is a wise investment that will pay off dividends down the road that will be dramatic. With respect to the process, we need to be engaged with the food industry to talk about what the shape of an agreement might look like, to talk about their goals and objectives, their concerns and needs, and to align that with what we can offer.

Mr. LATHAM. Has anybody introduced legislation for this?

FSMA

Dr. HAMBURG. Well, as you may recall in the Food Safety Modernization Act, there was discussion about some kind of a fee, and it was passed in the House bill.

Mr. LATHAM. The discussion was passed? Well, I mean, you know, there is no vehicle.

Dr. HAMBURG. That was included in the House bill but not on the Senate side; but, just as we have done successfully with two new user fees in the generic drug area and a similar area, we need—

Mr. LATHAM. But this is not a user fee; this is just an existence fee. I mean, if you exist, you have to pay it. There is no benefit.

Dr. HAMBURG. Well, in that component in the other user fees, as well as facility registration fee.

Mr. LATHAM. We gave you an additional \$40 million last year, and by your own report you say that you are able to accomplish all the inspections, both domestically and internationally.

Dr. HAMBURG. We are making progress.

Mr. LATHAM. Well, that is what you are saying—not my words. But I just do not understand what vehicle you are going to use to authorize this fee. I mean just because you breathe air, this is another tax just because you are there.

Dr. HAMBURG. Well, with respect to program support for food safety, I think that most of the examinations of our food safety budget would say we are dramatically under-funded even now. And CBO, when looking at the cost of implementing the Food Safety Modernization Act, you know, definitely defined a level of funding that would represent a larger dollar amount than we currently have.

Mr. LATHAM. Your own statement says you have accomplished this with the appropriated funds last year.

Dr. HAMBURG. Well, but I think we are making progress on that.

Mr. LATHAM. It says you have announced that you met the statutory mandate to inspect 600 foreign facilities and expect to meet

the statutory mandate for both domestic and foreign inspections again this year with appropriated funds.

Dr. HAMBURG. We are making decisions about how we target resources, but there are gaps in our program and we see looming needs that are under-addressed. So I do think this is a real concern for the nation. We know that there are problems in our food supply and that they will grow if we do not put the programs in place to address them.

Mr. LATHAM. Thank you.

Mr. KINGSTON. Mr. Bishop.

GEORGIA

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

Welcome, Dr. Hamburg, again. I have continued to have conversations with my home state's agricultural commissioner, Commissioner Black, regarding the current and potential role that the state of Georgia can play in food safety, specifically with the inspection of food that is grown within our state. I have raised this issue with you in the past and I continue to be concerned that, particularly, if the FDA's plans for new user fees do not work out as they have not in the past, that alternative plans will have to be made in terms of under girding our overall inspection capacity and resources.

Should not we be expanding the states' roles in food inspection, particularly given the reality of austere budget reductions where the federal inspection footprint is already largely dependent on state partners? Is there a way, or how can we more effectively support state inspection services, especially in the area of training assistance to the states? Do you have any thoughts where we might be able to build on existing synergies and maybe create new ones?

Dr. HAMBURG. Well, you are absolutely correct that food safety has to be a partnership and working with states and localities is the critical component of that. As we moved to implement the Food Safety Modernization Act, Congress in its wisdom did put an emphasis on really developing a national, integrated, food safety program. And our work to actually help support state food safety programs, and inspectional capacities is part of that. So it is very much a part of our work plan, a part of our emphasis, and we see it as essential to success.

Mr. BISHOP. Okay. Thank you. As a result of the Food Safety Modernization bill exporters to the U.S., as well as domestic importers, should be facing closer scrutiny of their food safety controls, including requirements that the imported foods be inspected and subjected to the same standards that are in place for U.S. foods.

Particularly, the FDA now has authority to block foods from facilities of countries that refuse FDA inspections. Have there been any issues with our foreign partners in this regard, and has FDA been blocked from inspecting any foreign facilities? And, what issues do you anticipate coming as we move forward?

Dr. HAMBURG. Well, given the globalization of our food supply, we do feel strongly that we have to have parity of standards, whether the food is coming from another country or being grown and produced domestically. We have been very, very appreciative

of the new authorities given to us in the Food Safety Modernization Act to act internationally, and we have on a couple of occasions used that authority that you identified to refuse importation of a product if the company overseas has not allowed us to go in and inspect the facility.

BACKUP PLAN—FSMA

Mr. BISHOP. Several obviously proposed the President to include it and Congress did not. Given the mandates that the Food Safety Modernization bill, particularly inspection activity, what is the back-up plan since the likelihood of proposed user fees becoming law on a scale of 1 to 10 is probably zero. And of the 250,000 registered foreign facilities, how many of them are located in China? And do we have a sense of the number of facilities that are not registered in China or elsewhere, particularly in South America and Latin America?

Dr. HAMBURG. Well, food products are coming into this country from around the world, some 200 countries and about 250,000 facilities that we know about coming into many different ports of entry into this country as well. So it is a huge challenge. It is a challenge that has grown dramatically in recent years, and that we anticipate will continue to grow.

Clearly, we will never have the resources to be able to inspect all of the facilities in the sort of traditional way that was envisioned for the FDA back in 1938 when the Food, Drug and Cosmetic Act was first put into place. And we need new strategies and we are actively working to implement those. And those include strengthening our ability to do risk-based identification of products as they enter our borders and we have a new IT base, computer-based program called "Predict," that is at our ports of entry to help us identify a number of different contributory factors.

Mr. BISHOP. You want to decrease your IT budget, though. Are you not?

Dr. HAMBURG. No. Let me just—we need to strengthen and have put in place a program to target our resources in a risk-based way as food comes into the country, but clearly have to push back. We are increasing our numbers of inspections.

We are trying to increase the efficiency of those inspections as well. But, importantly, we are working—

Mr. KINGSTON. The gentleman's time has expired and we would end the 45-second courtesy as well, which is what everybody has been getting, by the way.

Dr. HAMBURG. I apologize. It is such an important topic.

Mr. KINGSTON. Mr. Nunnelee. I think we are going in the order of arrival.

Mrs. LUMMIS. Oh. I guess I was really late today. Sorry. [Laughter.]

Mr. KINGSTON. Mr. Nunnelee was here and left, so I am not sure if he qualifies or not, but he did beat you.

Mrs. LUMMIS. Today he beat me.

Mr. KINGSTON. Yes.

DRUG SHORTAGES

Mr. NUNNELEE. All right. Thank you, Dr. Hamburg.

I was glad to hear your testimony. You addressed the topic of drug shortages, something I have been interested in. Just a couple weeks ago, I met with the Mississippi Society for Anesthesiologists, and that was the primary topic that was on their mind. So I have got several questions.

We will get as deep into them as we can in this five minutes, and then we will come back. Start with how do you define a drug shortage; and, if there are therapeutic alternatives, do you still declare a shortage?

Dr. HAMBURG. Well, a shortage reflects when the demand exceeds the capacity and we are constantly working with healthcare providers, patients and others, to identify looming or potential shortages as well as of course when there actually is a gap in availability of drug period. And when there are potential shortages or disruptions in supply, or a full inability to get access to a drug, we are actively engaged in the process of identifying alternative strategies so the patients can get the medical products that they need.

And we do that by working with manufacturers that may no longer be able to produce or produce less because of manufacturing issues or quality concerns. We try to identify other products that can substitute. We sometimes try to get new manufacturers on board to produce a given product. And in some instances we will identify a product that is available in another country, but not an FDA approved product, and expedite a review, including an inspection, so that we can bring that product in for a targeted use to address the shortage.

Mr. NUNNELEE. All right. So based on what you just said, I take it a shortage may not necessarily involve the inability to get the drug. You are monitoring it, and when demand exceeds capacity, you start working with all the available tools that you just described.

Dr. HAMBURG. Right. I mean our ability to be as effective as possible depends on as early notification of an emerging or evolving problem as possible.

Mr. NUNNELEE. So do you find overall are the shortages of drugs increasing? Decreasing? Is it about the same? Where are we?

Dr. HAMBURG. Shortages have dramatically increased in recent years, and of course it is of enormous concern to American patients and their families and to us at the FDA. We had about 250 shortages last year. We were able to prevent about 195. But, back in 2006, I think there were 61 shortages. So there has been a steady increase, and they are mainly in a couple of key areas of therapeutics: Cancer drugs, anesthesia drugs, as you noted, pain drugs, in some instances certain kinds of emergency response medications. Mainly, the shortages have been in the area of what we call sterile, injectable drugs.

Mr. NUNNELEE. So the companies, are they required to notify you in any way, and do you need any additional tools to deal with the issue of shortages?

Dr. HAMBURG. At the present time, companies that are the sole manufacturer of a medically necessary drug are required by law to notify the FDA six months before they discontinue production. We have asked manufacturers to broaden their reporting, and we sent out a letter at the end of October, early November, asking for vol-

untary notification of impending shortages or disruptions in the supply chain. And, actually, we have been very heartened by the response.

The number of reports coming in to us has increased six-fold; and, since that letter went out, it has been four months and we have been able to prevent 114 shortages. So, early notification really matters. There is legislation being considered by Congress to address the problem of drug shortages, including broadened requirements for early notification, and we think that would be of real value.

Mr. NUNNELEE. All right. Thank you. Thank you, Mr. Chairman.

GENERIC DRUG USER FEES

Mr. KINGSTON. Mrs. Emerson.

Mrs. EMERSON. Thanks, Mr. Chairman. Hi, Dr. Hamburg. Thanks for coming today.

I have got one short question and then a series of questions on the generic drug user fee I would like to ask you, but the first one has to do with the possibility of labeling foods derived from biotech manufacturing, because there are a lot of organizations, and even some of my colleagues who believe that we really need to have you all begin labeling all of those foods derived from biotech.

And, you know, I do not know the reason. Some say it is opinion polls. I do not know. Is there any scientific evidence that would suggest that you all reconsidered the policy that you have, for labeling purposes, of biotech?

Dr. HAMBURG. Well, certainly, the issue about labeling of genetically engineered foods is one that comes up on a regular basis, and one I know is of great concern to many consumers. As I understand it, our statutory framework really defines when FDA would put a label on something, and it really is when there is a material difference in the food product in terms of, you know, its composition, its nutritional character, how it behaves in certain contexts, such as oil for frying, whatever. But it has to be a real material change and not the process.

Mrs. EMERSON. Well, I guess I just want to say based on—I think you all made some statements about that in 2010. I just want to encourage you all to stand by your science-based labeling policy, and hopefully public opinion will not sway you in the opposite direction.

All right. Let us get on to the generic drug user fee, just because this five minutes goes too fast. So, in reviewing the performance metrics from the generic drug user fee agreement, one thing that does stand out to me is the lack of performance goals for approval of generic drugs until the third year of the agreement. And, I just wonder. Is the lack of goals for the first two years designed to help you all work through the current backlog of abbreviated new drug applications, or what?

Dr. HAMBURG. Well, the goals and objectives of the generic drug user, the agreement, were worked out very carefully with industry fully at the table. And I think what you were noting about the real, measurable performance goals kicking in a little bit later reflects the realities of needing to gear up a program; to hire on more people and train them and get them out in the field doing inspections,

which is a big part of the generic drug user fee program, as well as doing the reviews.

But, that does not mean that work does not start on a day-to-day basis addressing critical issues in the generic drug user program, while that hiring and training is going on, including addressing the backlog. That is a critical area of focus, a priority, both addressing the backlog and decreasing the timeframe for review. And that will be going forward, and we are committed to clearing the backlog.

Mrs. EMERSON. Okay. So you basically said between you and the industry that you were going to hire the 900 new employees in the next few years, 25 percent of whom will be hired in 2013, 50 percent in 2014, and 25 percent in 2015. So, I mean, have you determined yet what percent of those people might be dedicated strictly to trying to resolve the drug backlogs? Is there a formula?

Dr. HAMBURG. There is a work plan that is being implemented in terms of what will be required even as we are waiting for the user fees to actually be authorized, and there is a major focus on clearing the backlog. I am not sure that I will accurately recall the percentage of FTEs that will be dedicated to that, but we can get you the anticipated breakdown of our—

FTEs FOR DRUG BACKLOG

Over the five-year period of GDUFA, there will be a significant period of time when both backlog applications and newly submitted applications are being reviewed simultaneously. Enacting GDUFA will provide the resources necessary to complete the review of the backlog applications. As the backlog is reduced, those same human resources will be applied to reducing overall review times and achieving the review and inspection goals as negotiated with industry and outlined in the GDUFA goals letter.

Mrs. EMERSON. Okay. I would appreciate that. So, let's just say that if you all do get an increase in your level of funding under the new—let me move over to PDUFA for just a second.

Dr. HAMBURG. Okay.

PDUFA

Mrs. EMERSON. If you get an increased level of funding under PDUFA, can we expect to see an increased rate of approvals for generics for the outside of that program?

Dr. HAMBURG. Because we will be approving more novel drugs through PDUFA—

Mrs. EMERSON. Yes.

Dr. HAMBURG [continuing]. There will be more generics? I think, you know, these programs are synergistic and more innovation and approval of new, molecular entities through PDUFA and new biologics does have an impact on availability of generics down the road.

Mrs. EMERSON. Right.

Dr. HAMBURG. So, yes, I think that as we strengthen all of these programs, and as we work with industry and academia to make our pipeline of innovation more robust, it will reap benefits for generics. And, of course, we do now have a bio similars regulatory pathway and a user fee agreement that we are hoping will be reauthorized for that. So there is a lot to look forward to.

Mrs. EMERSON. Thank you. Thank you, Mr. Chairman.

Mr. KINGSTON. The gentlewoman's time has expired. We will begin round two, and I would want to start off with where we are right now on PDUFA.

As I understand it, you have signed-off on the letter of goals stated in PDUFA 5. Is that what it is?

Dr. HAMBURG. Correct. That is correct.

Mr. KINGSTON. And I think the committee members should really focus on the importance of the PDUFA reauthorization, because if it is not reauthorized this fall, then you would have to lay off employees, and we would have a lot of delays in terms of these approvals.

PDUFA's significance has brought drug approval time from the time the new molecular entity is developed to market—it was 26 years, or as long as 26 years, in the 1980s, and now it is 13 years and in many cases less. So it is something we all need to be aware of.

MEDICAL DEVICES

Now, on the medical device side, I understand you have agreed in principle to the goals, but it is not as far down the road. When does that get dropped and you are in agreement and what is in between you and saying that you are all on one page?

Dr. HAMBURG. You know, the medical device negotiations were more complicated and took longer. And we did not need our original goal to get a completed package up to the Hill in mid-January. But, as far as the package dollars and identification of the critical performance goals and measures, you know, we really are there.

But, you know, Congress did lay out a process that involves a period of public comment and of public meeting before moving it up to all of you. And so we are moving forward and we will be getting it to the Hill as soon as we can; and, we expect that it will be part of the whole package that is considered by all of you, and hopefully passed.

Mr. KINGSTON. Well, we would encourage you to keep pushing on that, because we know how important it is to consumers. Now, one of the things that we have heard—just complaints from various medical device or pharmaceutical scientists—is lack of transparency and communication between FDA scientists and people who are developing these. What have you done to address that?

Dr. HAMBURG. Well, it is really an important issue, and we know from experience that the ability to have early and continuing communication between a sponsor and the FDA, you know, really does make a difference in terms of being able to move the review swiftly and surely, and to really identify areas of concern.

On the medical device side, it has been a huge area of focus over the last year and a half or so within the medical device program. You know. We have taken very seriously the concerns we have heard from industry about the need for greater clarity, consistency and predictability of that program, have looked inward to see how we can improve both business processes and how can we strengthen the science—the expertise that we have—the access to outside experts, and the scientific framework for decisionmaking, as well, to give both more transparency to what we expect in terms of data and why the appropriateness of our request for data and the proc-

ess. And so we put forward actually, in January of 2011, a series of recommendations—25, that we were committed to, initiatives to completing during that fiscal year or that calendar year, I apologize. We were successful in actually completing about 75 percent of those activities and are working on the others. MDUFA, the user fee agreement, reflects continuing emphasis on these issues about more coordination, communication, enhancing predictability, as well as streamlining and modernizing that.

Mr. KINGSTON. Well, I think what our concern is, that so many of these medical device and pharmaceutical companies are international now. That this is one thing that America has great pride in, in its innovation, and we do not want to lose that marketplace—

Dr. HAMBURG. Absolutely.

Mr. KINGSTON [continuing]. To European competitors. So not only is consumer safety very, very paramount to us, but the side part is, these are really important American jobs, high paid people, high skilled folks and we do not want to lose them to markets—

Dr. HAMBURG. Absolutely.

Mr. KINGSTON [continuing]. That may be a little more transparent or approval systems that are more efficient. Number one, we are all in agreement on safety comes first, but we also want to make sure we keep our competitive edge, and I know I am out of time.

Mr. Farr.

DRUG USER FEES

Mr. FARR. Well, thank you Mr. Chairman. I want to follow-up on Mr. Latham and Mr. Bishop and Ms. Emerson's discussion about fees. I mean the drug fees have been around for about 20 years and there is a whole marketing system out there.

The new responsibility you have is under the Food Safety Modernization Act, entire new responsibility. You requested about \$955 million in order to do it. Congress, by the end of this year, is going to cut you over \$100 million and the assumption is that under the new food establishment registration fee, that you might be able to gain about \$200 million.

You were cut last year. If you are cut again this year and if the \$200 million is not authorized because politically it does not look like it is going anywhere, how are you going to carry out your responsibility? Who is going to get hurt?

SALINAS VALLEY

As you saw, in the Salinas Valley and Pajaro Valley, we grow the largest amount of fresh vegetables anywhere in the world and a lot of that is regulated under the Food Safety Modernization Act. So what is it going to mean to the producers if you do not have the money to carry out your responsibilities?

Dr. HAMBURG. Well, it is an enormous concern. As I outlined earlier, you know, there are real world impacts on people and on producers of not having the appropriate food safety programs in place. We have an enormous opportunity now to really transform our food

safety system into one that focuses on prevention, one that recognizes the globalized world we live in.

Mr. FARR. If you do not get the money——

Dr. HAMBURG. And if we do not get the money, we will see more foodborne outbreaks. We will not be able to work with companies to put in place the kind of systems that we know make a difference in terms of preventing problems before they happen. We know that we will have increasing problems with food imports that do not meet our standards and cannot be adequately screened for, and so to me, you know, this is a situation where we know that problems are going to happen. We have an opportunity to get in front of the problem and address them.

We are not, as a nation, putting the resources into food safety that I think are really necessary. You look at our current budget, and to be frank, if you look at how much every American is paying for the activities of FDA around food safety, it is about \$3.50 a year. I think, you know, what we provide in terms of benefits is worth more than that, and you look at the benefits of what we do to industry and I think it is worth quite a lot in terms of helping them to avoid preventable costs in terms of recalls, damage that persists in terms of consumer confidence in their products. We know that when there is a limited outbreak, maybe a contamination of spinach, that it has reverberations for the whole spinach industry, not just that one producer.

So I think that it is a common good. It is one where the government and industry should help contribute to the kinds of programs that we know make a difference.

Mr. FARR. Perhaps you could provide for the committee, you know, in writing what your priority will be if you do not get the \$200 million in fees and if Congress cuts what you have requested even more.

So we added a little bit last year, but I am really worried that you have a mandate that you cannot fulfill without adequate funding and it is not going to be there. So how do you prioritize what you will have to do and what food products will be affected by that prioritization?

COUNTERMEASURES

I also would like to address countermeasures. It is something that we do not think a lot about, but you have the responsibility for preparing for the worst of worst in any kind of a major disaster, whether it would be nuclear or an outbreak of disease and having enough drugs to counter it, and I have two questions there. One is how are we coming and, two, how are children covered?

So much of countermeasure planning just gets prepared for adults, but will we have the ability to also know what the impact would be on children and have the drugs available for them?

I guess underlying all that is that with a lot of these preparations, you cannot have human samples. You cannot go and expose people to radiation and then see what the impact is. So how do you test for all these things that you are going to have to do in the responsibility of the CBRN? I cannot remember exactly what all those——

Dr. HAMBURG. Chemical, biological, radiological, and nuclear.

Mr. FARR. Nuclear. And are we on target to be prepared?

Dr. HAMBURG. Well, this is, you know, such an important issue and obviously the FDA piece is part of a broader national strategy to make sure that we have adequate preparedness against deliberate and nationally occurring threats.

Mr. KINGSTON. It is a very serious response. Let's—

Dr. HAMBURG. Okay. Okay, very good.

Mr. KINGSTON. In fact, I tell you what, how long would it take you to answer the question because if it is going to be a long time and if we could have unanimous consent to—

Dr. HAMBURG. Well, I am not good at short answers—

Mr. KINGSTON [continuing]. Yield to the gentleman.

Dr. HAMBURG [continuing]. As you have noticed, but I will try to be, you know, more targeted in my answer and take just a minute and a half.

Mr. KINGSTON. Without objection?

Mr. FARR. That is pretty good for all these diseases. I mean—

Mr. KINGSTON. Try to do it in a minute.

Dr. HAMBURG. Yes. Okay. You know, thanks to money that you have given us in recent years, we have a program in place now that both looks at how can we take targeted action to help move in key areas such as children and pregnant women or problems like acute radiation syndrome, to move opportunities that may exist in terms of science and technology development into products that people really need.

What is the science base that also needs to be developed because as you point out, it is much harder to study a problem when you do not have a population to test it in, and so we have to develop new models, both animal models and computer simulations and other kinds of models, and really understand underlying mechanisms of disease so we can target things better.

So we have a program that is also looking at how do we build the regulatory science and doing it with the best minds wherever they are, in academia and industry as well and in other parts of government, including DoD and Homeland Security and elsewhere, and also looking at the legal regulatory framework for some of this because we have to be more flexible. We cannot apply exactly the same standards and approaches when you are dealing with unknown threats and so we have to develop new models like the animal role model, which is not the way we standardly review and approve a drug, but in these instances, where you do not have the clinical population for study, we have to.

We have three-tiered program and we are making progress and we are addressing important issues of science, important issues of threat, and important subpopulations in terms of their unique needs.

Mr. KINGSTON. All right. Mr. Latham.

REGISTRATION TAX

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

Just going back to the registration tax that you are talking about, I have a letter here from a list of groups in opposition to it. I did not know there were even some of these groups or did not realize existed, but you have got the American Fruit and Vegetable

Processors and Growers Coalition, California League of Food Processors.

Are you aware that, you know, this proposal was made last year and rejected also during the debate of the Food Safety Modernization Act, that this was debated and rejected? Why don't you just ask for more money—

Dr. HAMBURG. Well—

Mr. LATHAM [continuing]. Rather than do something you know is not going to happen?

Dr. HAMBURG [continuing]. You know, at the end of the day, what I am committed to is trying to have a program that works and makes a difference. I do believe, as I said, that it is not inappropriate for industry to contribute to our program.

Mr. LATHAM. But this has nothing to do with food safety. It is just another tax to consumers—

Dr. HAMBURG. Well, I think—

Mr. LATHAM. It is a food tax.

Dr. HAMBURG [continuing]. These are monies that would directly go to strengthening—

Mr. LATHAM. Ask for—

Dr. HAMBURG [continuing]. The program and we do know, as Chairman Kingston noted, that in the drug area, the user fees enabled us to take a program that was struggling—

Mr. LATHAM. This is not a user fee. This is not a user fee. It is a food tax—

Dr. HAMBURG. Well, I think—

Mr. LATHAM [continuing]. That consumers will pay.

Dr. HAMBURG [continuing]. You know, that is a debate that I will let others pursue, but from my perspective—

Mr. LATHAM. Is it an inspection fee?

Dr. HAMBURG. It would be an establishment—

Mr. LATHAM. It is a registration—

Dr. HAMBURG [continuing]. Registration fee and—

Mr. LATHAM. It has nothing to do with inspections.

Dr. HAMBURG [continuing]. An establishment registration fee is embedded in other user fees as well and I think it is, you know, to my way of thinking, an appropriate cost of doing business in terms of the need to have the kinds of programs in place that will help to strengthen food safety and reduce the burden of preventable illness and disease on people and preventable cost in—

Mr. LATHAM. How do we know the money would go to that—

Dr. HAMBURG. Well, we, I am sure would—

Mr. LATHAM [continuing]. Because it is not designated towards that fund.

Dr. HAMBURG. Well, what we need to do is really sit down with industry, with the people that support user fees and the people that do not to—

Mr. LATHAM. It is not a user fee.

Dr. HAMBURG [continuing]. End this discussion about how it would be—

Mr. LATHAM. It is an existence fee.

Dr. HAMBURG [continuing]. Targeted.

Mr. LATHAM. If you exist, you pay it. It is not anything to do with food safety or inspections or anything else. Why don't you just ask for the appropriation rather—

Dr. HAMBURG. Well, if you were to give us the appropriation, I would be—

Mr. LATHAM. Well—

Dr. HAMBURG [continuing]. Happy to have that too.

Mr. LATHAM [continuing]. But I mean be straightforward because you know this is never going to happen and you are not unique. Okay. I have been here with the Clinton Administration, the Bush Administration, now in this and they all do the same thing and it does not happen. So I just want some honesty in budgeting maybe.

FSMA

Dr. HAMBURG. Well, you know, the concern for me is having the adequate resources to do our job and I think, you know, we need to be creative and flexible and work in partnership to achieve the goals of the Food Safety Modernization Act and to ensure the safety, quality, and wholesomeness of our nation's food supply and that is what we are trying to achieve through this effort.

Mr. LATHAM. If this maybe did that and it was applied to that rather than just give you \$220 million to spend wherever you want, and it is not—there is nothing ties this to what you are talking about.

Dr. HAMBURG. Well, we would tie it to what we are talking about and—

Mr. LATHAM. Trust you. Trust. Okay.

Dr. HAMBURG [continuing]. In the negotiations with industry, we would spell out goals, objectives, and metrics to hold us accountable.

Mr. LATHAM. But you are aware it has twice been rejected by Congress?

Dr. HAMBURG. I am concerned about that. [Laughter.]

Mr. LATHAM. Can you say, "Yes, I understand it has been rejected twice"?

Dr. HAMBURG. Yes.

Mr. LATHAM. Okay. Thank you.

I do not know how much time we have, but in the medical device user fee agreement that you and the industry kind of come to agreement on, there is an independent assessment of agencies pre-market review program and I think it is probably a very excellent mechanism to make improvements that will make your process more timely and efficient, clear, consistent.

What would your feeling be about doing that as far as the user fee programs with prescription drugs and generics and biosimilars?

Dr. HAMBURG. You know, we are very open to scrutiny. We do believe that these programs should be as transparent as possible. We believe that we should be accountable for the use of our resources and that, you know, we want to get honest feedback about how we can strengthen and improve our programs, how we can, you know, streamline our business processes, how we can apply science in ways that enable us to be more efficient and effective.

So, you know, we have really been putting a lot of time and effort in the medical device area and others trying to get, in informal and formal ways, input and, you know, we have sought out the advice of expert organizations like the Institute of Medicine and the National Academy of Sciences to look at our 510(k) process and we have also, you know, brought in McKenzie to work with us as well.

Mr. LATHAM. Thank you for that brief answer.

Mr. KINGSTON. Ms. DeLauro.

Ms. DELAURO. Thank you, Mr. Chairman.

Addressed for the gentleman from Iowa, I do not know if he would vote to increase budget authority. That would be the answer to this question of the money that we need here.

Secondly, it is my understanding that the drug companies do pay a registration fee as well. Is that accurate? So that this is not something new. I say that to clarify except that I think that we are looking at user fees as a percentage of the total FDA budget would go from 35 percent in 2012 to 44 percent in 2013. I believe that this is an abdication of congressional responsibility and what our job is to do is to fund an agency who has regulatory authority over food, over drugs, over tobacco, over cosmetics, and over a whole variety of programs, but we want to play around the edges here.

My concern with user fees is that what happens is, is that what the user fees do is drive the work that is being done by the agency because the Congress fails in its responsibility to make the necessary investments.

USER FEES

I counted 12 current authorized user fees programs in the 2013 request. Before we even look at new fee programs, I really am concerned about how these user fees fill budget authority, that void. This is about the tail wagging the dog, an industry who continues to have more and more control over what needs to be strong, scientific public health mission of this agency without outside influence.

Now, we have spoken about user fees several times, that before those of us in the Congress ever see a user fee proposal, the agency appears to have drafted principals, agreements, and letters with industry to consumers, and patient safety advocates have equal representation in those agreement negotiations. Do they have a voice at this table when these user fees are being put together?

Dr. HAMBURG. Well, in the user fee—

Ms. DELAURO. I need a short answer because I got to get to food safety on this. [Laughter.]

Dr. HAMBURG [continuing]. We did include part of the user fee process, PDUFA and MDUFA, involved stakeholder engagement, public meetings, discussions, publication of minutes of those meetings on the website, and we found that input very, very useful and it did help shape some of our—some of the components. Particularly in PDUFA there is a focus on patient reported outcome measures and benefit-risk that very much—

FSMA

Ms. DELAURO. Because I want to get to food safety because, quite frankly, I am appalled at the amount of money that is in this budget for food safety and I would get you the budget authority. I will provide you with the budget authority.

You say in page 25 of your testimony that the simple truth is that the FDA cannot meaningfully deliver on FSMA, the Food Safety Modernization Act, mandates without sufficient funding.

The question has been asked, but I want an answer and you can do it in writing, the implications because those fees are not going to be approved. You have a very good understanding of what is happening here this morning. So without that, where do you go?

I will posit these two statements. CBO estimated that the FDA will need over \$400 million to implement FSMA. Do you agree, yes or no, with that estimate?

Dr. HAMBURG. We have a somewhat different estimate.

Ms. DELAURO. Well, then you give us your estimate of what it would take to implement this program to ensure the safety of our food, and there are predictions last year that the FDA would need to hire thousands of new inspectors to implement FSMA. Again, is that true? Please get back to me on whether or not that is the case.

FSMA COSTS

In enacting the FDA Food Safety Modernization Act—FSMA, Congress gave FDA an opportunity to modernize the food safety system. In order to take full advantage of that opportunity, FDA needs adequate resources to properly implement FSMA. For FY 2011, FDA received a budget increase related to FSMA of \$61 million. In FY 2012, FDA received a budget increase devoted to FSMA of \$39 million. In FY 2013, the President's Budget recommends food facility registration user fee increases for FSMA implementation of approximately \$220 million. FDA believes that the requested increase of \$220 million to implement FSMA in FY 2013 would provide for substantial progress in building the science-based, prevention-oriented and efficient food safety system mandated by Congress.

FDA is not aware of the origin of the estimate that we would need thousands of new inspectors to implement the FDA Food Safety Modernization Act. The FDA FY 2013 Budget includes funding to hire 273 staff members to implement FSMA.

CHINA EXPORTS

I want to address the China exports for a second because I—this is—from my point of view, we are in such deep trouble going into these efforts without the kinds of resources that you need and what I find here is that in the testimony, I was really shocked to read that some of the money, this limited amount of money, and my colleague, Mr. Farr, was right about CFSAN. We are \$10 million below where we were in the last go-round. There is really no money to implement the Food Safety Modernization Act. There is this piece of change with regard to China and what we are going to do with a portion of that money is to strengthen their regulatory capacity in order to deal with this—with the issue of food safety and the drugs.

You laid out where everything is coming from. Food and Water Watch wrote, I think a year ago or last summer, China's food supply is polluted with agrichemicals, veterinary medicines, intentional chemical adulteration of food processing factors. Their farmers and fish farmers often use dangerous levels of pesticides, herbi-

cides, fungicides, including banned chemicals. The chemicals can remain on foods after harvesting and processing.

We have such limited resources. Why is it that unlike other countries we trade with, that they cannot invest in a regulatory capacity and what Chinese law requires as to the safety of food and drug exports and that we are going to continue—we are going to subsidize what they are going to do to put a regulatory system in place when we do not have the resources to deal with the imports coming in from them and 80 percent of seafood is coming from China today. How do we handle this without the resources that you need in order to be able to ensure the safety of our food supply?

My time is limited, but I will tell you this, Mr. Chairman.

Mr. KINGSTON. Actually, it is out. [Laughter.]

Mr. KINGSTON. But what—

Ms. DELAURO. That is fine and I understand the five minutes and everybody abides by the five minutes, but if this committee does not take the responsibility of providing resources for one of the most significant areas of the budget that we have responsibility from, then we abdicate our responsibility and I would wish that the budget would have come up with an enormous number for food safety and then let this committee deliberate as to what should happen with it instead of a paltry amount of money to deal with such an important issue in our budget.

And I will lay out those questions for you. You can get back to me, but it is unconscionable that we have a budget at this amount for such an issue.

Thank you, Mr. Chairman.

Mr. KINGSTON. Thank you. We will have another round also.

Mrs. Lummis.

FEE STRUCTURE

Mrs. LUMMIS. Thank you, Mr. Chairman. And perhaps we have sufficiently flogged this, but if indeed a fee structure does occur, can you tell me will it be a flat fee or a fee based on risk or size of the company?

Dr. HAMBURG. It would most likely be a fee that would very much reflect a number of important factors, including size of the company, levels of production, et cetera, but what we would hope to be doing is what we have done with the successful user fees in drugs and devices where we sit at the table with representatives of industry who are charged to represent the concerns of the range of different kinds of components of the food system and really identify what are our goals, what are the needs, where are the gaps, how can we best address them, and really make a plan for how these important and necessary dollars would be utilized to strengthen food safety domestically and internationally and to benefit both consumers and industry.

Mrs. LUMMIS. Okay. Well, thanks, Dr. Hamburg.

I am going to change subjects just a little bit, but this is an adjunct to what we have been discussing all along. I do hear from people that America is at risk of losing jobs to other countries, especially European countries, because we are developing fabulous technology here in the United States with regard to medical devices, but that Europe is now surpassing us in terms of the speed

with which it can approve these medical devices, thereby encouraging the movement of jobs offshore to create those medical devices in Europe because of the time lag that we are having.

So I really do want to encourage us to concentrate on ramping up a robust approval process for medical devices, and at the same time since, you know, we started this discussion with the complexity that I appreciate with regard to medical device and drug approval and cosmetics and other non-ingestible food items, I would pose this question. Is it time for Congress to consider having a drug administration and taking the food safety component over to the Department of Agriculture? The reason being, we do have some duplication.

GAO REPORT—EGGS

The GAO report mentioned that the FDA makes sure that chicken eggs are safe, wholesome, and properly labeled, while the Department of Ag is responsible for the safety of eggs processed into egg products. I would have thought it would be just exactly the opposite where you have the Department of Ag working with the raw product, the egg itself, and the FDA working with the processed product. Well, that tells me that over time this system has evolved in some fairly irrational ways and it—to me it is starting to make more sense as we see the Department of Ag evolving into a food and nutrition agency as opposed to an agriculture agency, we are going to see over time the phase out of direct payments to agriculture and it is time for that, quite frankly. Even as an ag producer, I admit that, but maybe what we should be doing while we are watching the transition of the Department of Agriculture from something that is focused on farmers and ranchers to something that is focused on food safety and the consumption of food, food nutrition programs for the hungry or less fortunate, perhaps this whole food safety component should be transferred over to the future of the Department of Ag and so you can really concentrate where we need these highly technically skilled physicians and medical engineers to deal with these extraordinarily complex issues related to drugs, medical devices, and related components.

You do not have to comment on that today because I know that is beyond the scope of this hearing, but, you know, based on what I am hearing, I just think we are trying to pound a square peg into a round hole, that we are dealing with an archaic system and that you need to be unleashed in terms of the extraordinary skills associated with drug and medical devices and concentrate our Department of Agriculture on things like ensuring that eggs are safe, wholesome, and properly labeled.

And, Mr. Chairman, I yield back. Thank you for my editorial opportunity.

Mr. KINGSTON. Well, thank you for getting in nearly under the five minutes. That was a first for all of us. [Laughter.]

Mr. KINGSTON. Mr. Bishop.

TOMATO RECALL

Mr. BISHOP. Thank you very much.

Dr. Hamburg, I want to be provincial once again. Tomato farmers in South Georgia and North Florida continue to tell me that

they are still reeling from the FDA's tomato salmonella recall from a couple of years ago, and of course in Georgia alone, tomato growers lost over \$14 million from tomatoes that were grown and in some cases that had already been harvested, but could not be sold because consumers were told to stop buying tomatoes on the recommendation of the FDA and the CDC.

It is estimated that growers nationwide lost about \$125 million from the false indictment of tomatoes from our own government when the actual culprit were peppers from someplace else, and of course our growers still have not recovered, and of course under the Food Safety Modernization Act, which was signed into law last December, it authorizes payments to producers that were harmed by future government decisions, which ultimately prove to be incorrect or ill-founded.

Is there a way that we can find some assistance for the Georgia growers and Florida growers who were badly, badly hurt by the ill-fated indictment by the government in terms of the losses two years ago?

Dr. HAMBURG. You know, I think with respect to the particular instance that you are describing, you know, I would rather have people that are closer to the issues get back to you directly about, you know, what the opportunities would be.

I do want to underscore the importance of bringing the best science to bear in the area of food safety and outbreak investigation, how important that is that we continue to strengthen our tools so that we can rapidly identify the source of foodborne disease—

Mr. BISHOP. Of course.

Dr. HAMBURG [continuing]. And address it in a targeted way and also to work, as the Food Safety Modernization Act mandates us to do, to try to ensure that systems are in place to prevent problems from happening in the first place.

So I think that, you know, the situation you are describing and the broad repercussions of foodborne disease and the intended and unintended consequences on industry and on consumers, of course, you know, really matters and I understand the concerns that you are raising and, you know, I hope that going forward we can have programs that really are as effective and efficient as possible at preventing problems and identifying the source as expeditiously as possible.

Mr. BISHOP. You are required under the food safety legislation to establish appropriate product tracing systems, to receive information that provides that—

Dr. HAMBURG. Yes.

Mr. BISHOP [continuing]. Capacity so that you can rapidly track that and I appreciate that and we want to do everything we can to help you, but what I am concerned about is the folks that have already been hurt and that are still—

Dr. HAMBURG. No, I understand that.

Mr. BISHOP [continuing]. Hurting and I think the legislation does authorize—

Dr. HAMBURG. Yes.

Mr. BISHOP [continuing]. Some payments and—

Dr. HAMBURG. Yes. You know, I do not want to give you misinformation. I am just not up to speed on the details of that aspect of the program and how it would relate to this particular situation, but I think we can provide you with some expert advice and help.

Mr. BISHOP. I would appreciate that very much and we can do that later outside—

Dr. HAMBURG. Right.

Mr. BISHOP [continuing]. The hearing context, but I would look forward to setting that up and doing it.

[The information follows:]

PAYMENTS TO PRODUCE GROWERS / AUTHORITY

Section 206 of the FDA Food Safety Modernization Act contains provisions that relate to the consideration of mechanisms to compensate for recall-related losses. The text of section 206 appears below:

e) GAO Review—

(1) In general.—Not later than 90 days after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that—

(A) identifies State and local agencies with the authority to require the mandatory recall of food, and evaluates use of such authority with regard to frequency, effectiveness, and appropriateness, including consideration of any new or existing mechanisms available to compensate persons for general and specific recall-related costs when a recall is subsequently determined by the relevant authority to have been an error;

(B) identifies Federal agencies, other than the Department of Health and Human Services, with mandatory recall authority and examines use of that authority with regard to frequency, effectiveness, and appropriateness, including any new or existing mechanisms available to compensate persons for general and specific recall-related costs when a recall is subsequently determined by the relevant agency to have been an error;

(C) considers models for farmer restitution implemented in other nations in cases of erroneous recalls; and

(D) makes recommendations to the Secretary regarding use of the authority under section 423 of the Federal Food, Drug, and Cosmetic Act (as added by this section) to protect the public health while seeking to minimize unnecessary economic costs.

(2) Effect of review.—If the Comptroller General of the United States finds, after the review conducted under paragraph (1), that the mechanisms described in such paragraph do not exist or are inadequate, then, not later than 90 days after the conclusion of such review, the Secretary 165a 75 340 1C4 of Agriculture shall conduct a study of the feasibility of implementing a farmer indemnification program to provide restitution to agricultural producers for losses sustained as a result of a mandatory recall of an agricultural commodity by a Federal or State regulatory agency that is subsequently determined to be in error. The Secretary of Agriculture shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report that describes the results of the study, including any recommendations.

FOOD LABELING

I want to talk a little bit about food labeling, biotechnical foods. During the past year, there has been significant concern raised by some food safety advocates that there need to be some specific labeling requirements for food that is connected or derived from biotech research and development. In 2010, the FDA reiterated its authority and its policy when it stated that the method of food production does not in and of itself result in a material change that requires labeling and the finding quote was that, “The FDA has no basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way or that a class—foods de-

veloped by the new techniques present any or any greater safety concern than foods developed by traditional plant breeding.”

Is this still the FDA’s position on this matter?

Dr. HAMBURG. That is and I believe it is actually the legal regulatory framework for FDA. I had a brief discussion about this with Congresswoman Emerson earlier. You know, I certainly understand, you know, the concerns that consumers are raising about desire to know, but FDA labeling is undertaken under certain specified circumstances and, you know, you outlined it there.

Mr. BISHOP. I think my time is up.

Mr. KINGSTON. That has never stopped everyone else. [Laughter.]

Mr. BISHOP. Well, very quickly—

SODIUM

Mr. KINGSTON. All right. We are on the last round, so we start getting a little more flexible here.

Okay. And you do not need to answer this now, but you and I have had some correspondence about sodium intake and one of the questions is about low intake and I wanted to just bring to your attention a McMaster University study that was printed and published in the Journal of American Medical Association and it said, “While higher intake of sodium was associated with increased risk of stroke, heart attack, and other cardiovascular events, low intake was associated with an increase of cardiovascular death and hospitalization for congestive heart failure,” and as you know, salt always is getting a mixed review.

I just wanted to bring that up and I would like your response to it, which we can get—well, I will just follow-up with—

Dr. HAMBURG. Okay.

Mr. KINGSTON [continuing]. More detail.

SODIUM

FDA is at the beginning stages of a literature review process with support from the Centers for Disease Control and the National Institute of Health to assess recent studies on sodium intake to evaluate their relevance to sodium reduction efforts in the general population. As part of our scientific assessment, we intend to consider a significant number of recent studies with potential relevance to the health effects of reduced sodium intake. One of these is the McMaster study (O’Donnell et al., 2011) that you refer to in your question. Each study will be reviewed to determine what scientific conclusions can be drawn based on the study design and analysis. We will weigh that information in the context of the existing body of scientific literature to ensure that our understanding of the health effects of sodium reduction is appropriately informed by current science. We look forward to analyzing the significance of the McMaster study as part of that review, and we regret that we are not currently able to provide you with our assessment. We appreciate your calling it to our attention, however.

The other thing, just getting back to MDUFA and PDUFA a minute, last year the California Health Institute released a report that said that the review for a 510(k), that is medical device, has been slowed by 43 percent and that complex premarket approval has—that process time has lengthened by 75 percent and then also last year, Price Waterhouse released its medical technology innovation scorecard, which I guess is an annual event—

Dr. HAMBURG. Yes.

MEDICAL DEVICE INNOVATION

Mr. KINGSTON [continuing]. But they compare our medical device innovation, the U.S., China, Germany, France, UK, Brazil, India, Israel, and Japan, and found that the U.S. environment for approval was deteriorating because of unpredictability and inconsistency, and I am concerned about that, but I am also aware that those score reviews did not happen necessarily under your watch or any procedures in which you were able to have influence.

So realizing from my previous question and knowing that you are already working on PDUFA and MDUFA, I am hoping that we are moving in the right direction. But even with all the systems in place, there is a concern that I see not just in FDA, but in our society in general, that we are risk adverse and, you know, we do need to be bold and Mr. Farr had mentioned earlier about the vaccines for a chem-bio attack. They cannot have the high standards because we have to move quickly on those than we would on some of the other pharmaceutical normal type things.

I am going to check the box. I might want you to react to these things just to be aware of these scorecards internationally because that does hurt our competitiveness and jobs and getting the stuff to people, but on the risk adverse culture of our society today and maybe growing in FDA, do you feel that we are being aggressive enough and in the right direction/right balance?

Dr. HAMBURG. Well, there is so many components of your question that I want to respond to, but let me first say with respect to standards, I did not mean to imply that we would have lower standards for the review and approval of a vaccine or other product—

Mr. KINGSTON. Well, if I could—

Dr. HAMBURG [continuing]. In terms of safety and efficacy, but more flexibility in terms of the data that we would use to make those decisions or the—under emergency or unusual conditions move a drug that was not fully approved out into—

Mr. KINGSTON. Yes. But if you will pause a minute, I think people need to realize a shoe with a stone in it is better than no shoe at all and if we had an anthrax attack and we do not have the perfect drug and it is only 50 percent, then that is better than nothing at all. And so to me, it is a different world than the normal drugs that we would take for cancer or whatever, and it sounds, you know, loose to say that, but it is a different world and so—

Dr. HAMBURG. Well, I think we always have to be thinking about risks and benefits for the intended use, but I do want to say that sometimes something that is new is not necessarily better and what we would not want to do would be to put something out there that we did not know would offer benefit because that actually might interfere with using another product that would offer benefit. So I think, you know, it is a complex equation and, you know, we try to be flexible in terms of how we assess risks and benefits and how we make products available to people who need them under a range of different conditions.

RISK BENEFIT

Going to the risk adverse question, I think, you know, that there is always a pendulum that goes back and forth and it is a societal question in many ways about, you know, how we balance risks and benefits, but I think that we are trying very hard, you know, in a science-based, data driven way to really try to identify what are the risks and benefits, to get input from the range of stakeholders to help us think about the framework for balancing those risks and benefits, and part of actually the PDUFA process in a formal way and on the device side, they have put out guidance addressing this, we are really trying to systematize and formalize and make more transparent how we think about risks and benefits because I think it really matters both so that we are serving the public responsibly and also so that the developers and manufacturers of medical products can work more effectively with us and respond to the directions that we are going.

It is critically important and I share your concern about making sure that we really both capture all the opportunities in science and technology today in terms of translating those quickly into real world products for people that need them and I am very proud, as you are, of American preeminence in the area of life sciences research—

Mr. KINGSTON. Yes.

Dr. HAMBURG [continuing]. And preeminence in medical product production and I think that has to be a priority for us all.

Mr. KINGSTON. And those scorecards are something that have been brought to your attention?

Dr. HAMBURG. Yes, and I would say—

Mr. KINGSTON. Okay.

Dr. HAMBURG [continuing]. On the drug side, we actually are leading the world in terms of both approval of new products and speed of approval. With respect to the majority of devices, another industry study actually showed that we were equal or somewhat quicker than our European counterparts, but on the more complex devices that require more clinical safety and efficacy review, we are not as quick. But I think that, you know, there are reasons for that, that, you know, perhaps are important such as having an efficacy—

Mr. KINGSTON. Well, I know we are all rated on scorecards routinely and if we really watched every one of them, it would drive us crazy. So we do not want you to be distracted by them, but just, you know, it is—

APPROVAL PATHWAYS

Dr. HAMBURG. You know, the big picture is very important and we are working hard to streamline and modernize our approval pathways, but we also are committed to safety and efficacy of those products.

Mr. KINGSTON. Thank you.

Mr. Farr.

Mr. FARR. Thank you. Everybody red light.

Mr. KINGSTON. Not on the third round.

Mr. FARR. I want to continue on the Food Safety Modernization Act. I am sorry Mrs. Lummis is not here because I think she forgets the huge argument we had on adopting that act when Rosa DeLauro led the battle with trying to create a single food agency and the Department of Agriculture lost in that battle. So that is FDA is responsible for the Food Safety Modernization Act.

Dr. HAMBURG. And 80 percent of the food supply.

Mr. FARR. And as you know from visiting my district, the FDA is using producer information and practices to shape the implementation of the new law. As I understand, at one time your agency was going to assess the potential food safety risks by doing profiles on different crops using historical information and a transparent scientific process. I have heard now that the team is determined that the risks might be defined by cultural practice, one of them, for example, being of the use of irrigation water.

If you are going to use that as a standard, how does it apply to other crops such as those that are not on the ground, like trees and vines and crops like that?

Dr. HAMBURG. Well, I think that as we have been trying to shape this program, we have been trying to be very both responsive to real world needs and conditions and the fact that there is no one, you know, cookie cutter, one size fits all approach, you know, really looking at what are the risks and how do we target attention and resources to the risks that really matter. So, for example, you raised contaminated water, I mean it is very different if the water is directly being applied to the edible food product versus the trunk of a tree that is growing, and so our expectations and requirements would be different.

Mr. FARR. Okay. Well, that is good to hear.

Also, I am interested in how we are going to do these regulations. For example, it is Secretary Vilsack's responsibility to come out with a leafy green marketing order, like what the produce industry in California adopted. As you saw it is a very strict, almost surgical approach to harvesting crops and then inspecting water, inspecting ground, inspecting invasion into the fields, and all kinds of things. It is his call of whether that becomes a national standard, but it is also for food safety. And that is in your jurisdiction.

USDA

Is FDA going to be having dialogue with USDA? And frankly, we just passed several trade agreements and we all know that portions of those trade agreements was based on negotiation commodity by commodity. Sometimes countries overreact. For example, Mexico banned all lettuce imports—none of which was contaminated—when the U.S. had a spinach recall. I don't want to see trade wars begin from such misunderstandings. As your agency moves into this field, I think there need to be a very close working relationship with USTR and USDA and wonder whether those protocols are being established.

Dr. HAMBURG. Well, we are trying to work very closely together and formally we work through the President's food safety working group, but around, you know, these areas of food safety we also,

on a day-to-day basis, work with counterparts and government across Federal Government at the state and local level and internationally and it is getting harder, and, of course, you know, programs are fragmented in ways, you know, that are, you know, historical in nature, but not always helpful. But we are trying to identify, you know, where some of these critical overlaps occur. We are trying to synergize where we can. We all are struggling with how do we best use limited resources and do not want to duplicate effort for anybody, but also how to bring these things together.

We are driven, of course, as an agency by public health, but we believe that good public health practices, and in particular prevention, can go hand in hand with trade and other needs. But there are areas where historically there have been conflicts. There are certainly examples, as you know, where just bad science and policy has been applied to a situation and it has hurt people significantly and hurt industry, and so it is an area that we are working hard in terms of strengthening our working relationships, our sharing of information, and, you know, we do feel that what we are doing provides a benefit to everyone.

Mr. FARR. Well, I would hope also that you might be endorsing or approving protocols like the leafy green marketing orders, if there is an example where using these protocols meets your standards. Those are very important because—

Dr. HAMBURG. And it certainly is a living example of some benefits.

Mr. FARR [continuing]. That message has got to be gotten out there because producers are taking this on with the belief that the marketing order is going to be okay and it may become a national standard. I think other states are going to push back, but if it worked for California, it ought to work for the rest of the nation.

So I think you are into a whole new responsibility. This committee is the Ag Committee and FDA and the rubber hits the road here. You are going to hear a lot more comments as you heard today about fee structures and implementation of regulations as these states and districts respond to the new rules. I appreciate your clarity in helping us understand what is going to happen.

And, frankly, Mr. Chairman, we have given her incredible responsibility and we have to pay for it. We cannot just depend on some fee structure that Congress is not going to approve. As Rosa said so eloquently, we have got to give this department the money that they need to carry out the responsibilities that we have given them.

Mr. NUNNELEE. Thank you, Mr. Chairman.

DRUG SHORTAGES

Back to drug shortages, I think you helped me with a lot of the tools that you have and that are available, but I have heard allegations that when a drug moves off patent is when the—very often the shortages occur. Can you just address that issue and whether there is a disproportionate shortage of generic drugs?

Dr. HAMBURG. You know, I think that it is true that many of the drugs in shortage are generic sterile injectable drugs. It is not because they have just moved off patent, but it is in fact because these are drugs where the manufacturing has to be done right.

You want an injectable drug to be sterile, free of any microbial contaminants or particulate matter. You want it to be stable and not crystallizing in the vial, et cetera, and, you know, one of the, you know, problems in the drug shortage area definitely has to do with the fact that some of these products that have been in shortage are vulnerable to contamination. The manufacturing capacity in many instances is getting older and increasing the vulnerability and that is why working with companies closely to identify emerging problems and to make sure that ongoing commitment to quality is built in to everything that is being done is so important and, you know, we do see that the early notification makes a difference to be able to address a manufacturing issue that might result in a need to recall a product or shut down a facility and upgrade the equipment.

If we can identify the problem earlier, we can work on strategies to keep production going, but ensure safety and quality. But it is not because these are generic products. It is the nature of the product itself, the sterile injectable, that makes it especially vulnerable.

Mr. NUNNELEE. All right.

CIGARS

And then real quickly move from pharmaceuticals to cigars, make a big jump. The Tobacco Control Act charges you with the responsibility of regulating tobacco products that are marketed to children. I am concerned that in enforcing that act, which I fully support, that we are going to catch the cigar industry, which does not market its products to children, and that an overreach of government regulation is going to impact that industry.

Can you just walk me through what is the process and where are you going with regulating sale of cigars?

Dr. HAMBURG. Well, the Family Smoking Prevention and Control Act gave us a broad set of authorities in the arena of tobacco, specifically looking at issues around manufacture, marketing, and distribution. A major area of focus has been on reducing smoking, uptake of smoking in children and youth, but also focused on helping adults to either not smoke or to stop smoking and also to look at strategies to reduce harm in tobacco products.

It authorizes FDA specifically to take actions around cigarettes, roll your own tobacco, and smokeless tobacco, but also gives us the authority to more broadly address tobacco products, but through regulation in keeping with the definition of tobacco products and the law. That is where our authorities related to cigars would come in and we are actively looking at how we should exercise a broader authority around tobacco products because new tobacco products are coming into the marketplace all the time beyond cigarettes and roll your own tobacco and smokeless tobacco, and of course there is a long history of cigars in this country and others and how we are going to address issues of cigars is currently under discussion.

We will be putting forward some draft regulations. We will welcome, you know, comment and feedback. I have certainly heard already a lot of concerns coming from the cigar industry and specialty cigars and we are, you know, aware of those concerns and we will take concerns very seriously, and when we do move forward

with draft regulations, we will, you know, expect to and will welcome comments about their appropriate oversight.

Mr. NUNNELEE. Thank you.

Mr. KINGSTON. Ms. DeLauro.

Ms. DELAURO. Thank you, Mr. Chairman.

SEAFOOD

Just as a follow-on to my colleague Mr. Farr, I guess the quick question here is we do have the three new free trade agreements that were recently signed into law. We will have a Transpacific partnership FTA that is being currently negotiated and we know the great quantities of seafood that that would necessitate, but can you tell me what the agency's role is in those negotiations and how we will ensure that as we continue to import more food products, the agency has the capacity to adequately ensure their safety?

I have three short questions, but, you know, so I want—yes.

Dr. HAMBURG. Do you want me to quickly—

Ms. DELAURO. Yes. No, no, no. Go ahead and answer that.

Dr. HAMBURG. You know, I think it is very important, as we were just discussing, you know, for us to be part of discussions and we are—

Ms. DELAURO. Are you part of the negotiation of the agreement?

Dr. HAMBURG. Not in all of its elements, but we are brought in on the aspects that do involve us. For example, with the Transpacific recently, the issue of tobacco was, you know, a major concern and—

Ms. DELAURO. What about the issue of seafood?

Dr. HAMBURG. We are involved in those discussions and we, of course, are bringing a public health perspective to the table in those discussions and we think it is important and valuable voice.

Ms. DELAURO. And we already talked about the capacity issues at the moment, and this is an area I would like, you know, to take a look at as to how your capacity is going to—it will expand with this effort and how you are going to be able to deal with that.

Dr. HAMBURG. Now, I am sorry. Capacity in relation to which issue?

Ms. DELAURO. Capacity, you know, we are going to import—

Dr. HAMBURG. Just to—

Ms. DELAURO. No, no. We are going to import more food products.

Dr. HAMBURG. Oh, yes. Okay.

Ms. DELAURO. We are going to import a serious amount of food products here. How can you adequately ensure that you are going to be able to deal with that?

Dr. HAMBURG. Yes. Well, this is one of the issues that frankly keeps me up at night because it is such a huge challenge, a growing challenge, and where frankly the issues and the demands outstrip our resources. It requires that we do things very differently and we are actively engaged in developing and putting in place new programs and policies to address it. I reorganized FDA over the summer with a much stronger focus with a directorate that is focused on global regulatory affairs. We are strengthening our border screening system, as I mentioned. We are strengthening our foreign capacity and our offices around—

Ms. DELAURO. Well, but all of that requires resources.

Dr. HAMBURG. It requires resources, yes.

Ms. DELAURO. I have to go back to the fundamental issue that we talked about before. So I am going to continue to monitor what we do here in terms of the resources that are necessary in order for you to carry out free trade agreements, other kinds of responsibilities that we have asked the agency to undertake.

I have a short adjunct to this is in the foreign supplier verification rules taking a long time to get into effect. We are behind schedule there. Would you need additional staff dedicated to this issue?

TARGETING RESOURCES

Dr. HAMBURG. You know, that is one good example of how we are trying to target resources as effectively as possible in terms of that program would enable us to move certain products more quickly if we can verify that importers, you know, have a good track record and that they will be accountable for their products. It—

Ms. DELAURO. You need more staff to do that.

Dr. HAMBURG [continuing]. You know, to do that and all the other things, we do need more staff.

Ms. DELAURO. Microbiological data program, it is now in the budget for USDA, though 2013, USDA is going to eliminate this program. Secretary Vilsack was here last week, who said it more properly belonged in FDA's budget. Over 35,000 tests were performed, a range of commodities, including cantaloupes, and will the FDA absorb this program by—well, absorb this program? It is about \$4.3 million.

Dr. HAMBURG. There will not be a transfer of resources, as you know, but we will try to address—working with our colleagues at the CDC and others as well, try to address those issues in a continuing way. We also believe there are opportunities to bring new science to bear in terms of, you know, better, more efficient detection technologies and also utilize some existing epidemiologic and laboratory networks to continue to do that important work.

Ms. DELAURO. Right. I am very, very concerned that the function of this agency is going to get lost for a \$4.3 million and the good work and the data that is provided—this agency provides data to the CDC and obviously to you. As I say, 35,000 tests. USDA in 2012 intends to conduct 49,000 analyses with just this small amount of money. So my hope is that we continue to talk about this and that between agencies and the Administration, we can find the money to be able to do it.

Mr. Chairman, can I just beg your indulgence for—

Mr. KINGSTON. Yes. In fact, you just triggered another question for me. So—

REAGAN-UDALL

Ms. DELAURO. Okay, because I have to get to the floor for something, but this is Reagan-Udall. You know it is an issue that I have—an area that I have had questions about before.

The subcommittee did not include a ban on agency funds being used to support Reagan-Udall in 2012. I understand that in the absence of such a funding prohibition, the agency is required to direct

funds to the foundation, but no funding was included specifically for the foundation. Can you tell me where these funds were diverted from at the agency and how much money are we talking about?

Dr. HAMBURG. Well, we have not yet transferred any funds or made a final determination about the size of those funds. We were given a range, but we do think it is important for them to have some core support for the Reagan-Udall Foundation. I think that we have an opportunity with appropriate safeguards in terms of criteria for who they get money from and what kinds of—or who the Reagan-Udall Foundation gets money from and how it is used, but to make a real difference and to have it serve as an adjunct to the FDA mission in terms of important research, consortiums, and activities. So that money would likely come from—

Ms. DELAURO. It is going to come from agencies.

Dr. HAMBURG [continuing]. It would—

Ms. DELAURO. Where? Can you tell us where you are thinking about having this money come from?

Dr. HAMBURG. I am thinking about taking it from monies in the Office of the Commissioner.

Ms. DELAURO. And I do not know how much we are talking about. Do you have an idea of how much money we are talking about?

Dr. HAMBURG. You know, I might be wrong, but was \$500,000 to \$1.25 million.

Mr. KINGSTON. Yes, it has a cap on it.

Dr. HAMBURG. Yes.

Ms. DELAURO. Okay. Does the foundation staff have any particular FDA expertise that sets them apart from existing foundations or nonprofits? If not, should we guarantee them funds in this area of limited agency resources when other well-qualified foundations and nonprofits have to compete for federal funds?

Dr. HAMBURG. I mean Reagan-Udall Foundation is obviously a unique entity in terms of its goals and objectives of supporting the mission of FDA. It is set up in a way that is quite similar to the NIH Foundation or the CDC Foundation, but I think we have more safeguards and firewalls, Reagan-Udall Foundation has put more in place, because of the fact that FDA is a regulatory agency and really, you know, more scrutiny and transparency with respect to where the money comes from and what it is used for, but we do think that it has the potential to really benefit FDA in critical ways and in ways that I do not think—

Ms. DELAURO. We cannot get these—

Dr. HAMBURG [continuing]. Another kind of foundation could do.

Ms. DELAURO [continuing]. We cannot get these other—we cannot get these—this talent or this information from anything that currently exists? There is a uniqueness about—

Dr. HAMBURG. I think it would play a unique role. I really do.

Ms. DELAURO. Well, I would be interested to know what that unique role is. I will be very honest with you, I have never been able to figure out the uniqueness of the Reagan-Udall Foundation and how it is—you know, we are creating another effort here when there is an NIH Foundation or other places in which it seems to make—

Dr. HAMBURG. My hope, and we are starting to see this in terms of some of the projects that they are taking on, that they will really be able to do collaborative—sponsor collaborative research and other activities that really reflects critical needs and gaps in FDA knowledge or programs that is not related to any given product that would come before us, but it is related to the knowledge that we need to have modern and truly—

Ms. DELAURO. I understand that and I am all for knowledge and for—but I am wondering if the knowledge is not in already existing foundations or nonprofits to get that information rather than something that is specifically laid out that—you know, and I am not a scientist. I do not—

Dr. HAMBURG. I think they are addressing—

Ms. DELAURO [continuing]. Have the answers.

Dr. HAMBURG [continuing]. That, but I would be happy to discuss this more—

Ms. DELAURO. Great.

510K PROCESS

Dr. HAMBURG [continuing]. With you and especially as we are starting to stand up projects, you know, maybe be able to show you how there is, you know, really a unique and vital contribution.

Ms. DELAURO. And for the record, we will get a number of questions including the 510(k) process in terms of medical devices and when we are going to see something and how they relate to the IOM findings.

Dr. HAMBURG. Okay. Great.

Ms. DELAURO. Thank you very, very much.

Dr. HAMBURG. Thank you.

Ms. DELAURO. Thank you, Dr. Hamburg.

Mr. KINGSTON. Thank you, Ms. DeLauro.

And I wanted to mention one other thing on food safety because I know it is a passion of yours, Mr. Farr, but the funding on FDA food safety from 2008 to present has gone from \$508 to \$866 million, a 70 percent increase, and I know that the mission has increased, but the number of employees have gone from 2,614 to 3,684. However, while I sit here and think about some of the duplications that, you know, often pop up between federal agencies, you do have some potential duplications of what you do, what CDC does or USDA or HHS, and if there are duplications that we can identify that could be eliminated, then that money could actually be redirected to food safety and I think that would certainly be something that maybe we could talk about.

RECALLS

Ms. DELAURO. I think we can. I think one has to have a very fundamental understanding of the priority in these areas and I believe that you do and I certainly know that Mr. Farr does as well, both of you, but you have got the issue—you have got FDA recalls class I by center, you take a look at CFSAN, which has a responsibility here and therefore, when we are taking a look at the allocations in this area, we need to be thinking not just, you know, about how all these—but where the needs are and that is the point that I would make—

Mr. KINGSTON. Yes.

Ms. DELAURO [continuing]. Because I think that is a critical mission here of this agency.

Mr. KINGSTON. All right.

Well, we are adjourned 'til 2 o'clock this afternoon and we want you to come back because we know you enjoyed it. We have the IG this afternoon.

Mr. Farr, do you have any comments?

Mr. FARR. I am good.

Mr. KINGSTON. Okay. With that, we stand adjourned. Thank you.

Dr. HAMBURG. All right. Thank you very much.

FOOD AND DRUG ADMINISTRATION
QUESTIONS FOR THE RECORD
HOUSE AGRICULTURE APPROPRIATIONS SUBCOMMITTEE HEARING
FEBRUARY 29, 2012

QUESTIONS SUBMITTED BY CHAIRMAN JACK KINGSTON

Data Consolidation/IT Savings

1. Mr. Kingston: Dr. Hamburg, I know that you and your team have worked tirelessly on the President's FY 2013 request. I just want to comment on the proposal to derive \$19.7 million in data consolidation and IT savings, and then ask some questions. It appears that the food safety program takes the single largest hit of these savings -- \$7.7 million or 39 percent. It appears just from looking at the numbers that these savings were simply based on a pro-rata share of discretionary budget authority. Please tell the Committee, with some specifics, how the Foods program was able to actually come up with these savings?

Response: The savings that have been identified within the Foods Program include efficiencies gained through the consolidation of FDA's data center contract support, reducing redundant IT devices, and reevaluating planned IT infrastructure investments.

FDA has successfully reduced the number of data centers through years of data center consolidation. The remaining two primary consolidated data centers are, however, currently managed by two distinct service providers. Consolidating the operations support of the two data centers will achieve operational and process efficiencies by eliminating redundant contractor management teams, standardizing code promotion and release processes, and achieving economies of scale from the consolidation of 24/7/365 network and server operations support teams.

Additionally, FDA will reduce the number of redundant IT devices within FDA to comply with Executive Order 13589, Promoting Efficient Spending, and Executive Order 13514, Federal Leadership in Environmental, Energy, and Economic Performance. The one laptop or device policy, which will include a health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance as well as reduce helpdesk and desktop support costs.

2. Mr. Kingston: Did FDA simply calculate a pro-rata share of discretionary budget authority and then spread the savings based on those percentages?

Response: Although there is variability in redundant devices and demands on the data center across FDA program areas, there is enough consistency to allow FDA to rely on a proportional approach to achieving the savings in the FY 2013 Data Consolidation and Information Technology Savings initiative. Accordingly, FDA allocated the savings in this initiative proportionately, based on BA funding.

3. Mr. Kingston: If so, why didn't FDA calculate this spread based on total budget authority?

Response: FDA did not calculate the IT Initiative distribution based on the program level budget, because the initiative is related to budget authority.

4. Mr. Kingston: Would the FDA be willing to support a recalculation of these savings based on program level funding?

Response: To achieve the level of effort proposed in the FY 2013 budget, FDA must derive the full savings of \$19.7 million through reductions in budget authority. Therefore, FDA is unable to support a recalculation of the initiative based on the program level budget.

White Oak Consolidation

5. Mr. Kingston: According to p. 503 of the budget justifications, the White Oak consolidation includes \$17,658,000 in budget authority and \$42,000 in user fees for a total request of \$58,044,000. Please provide a detailed breakout for the \$17,658,000 increase, e.g., furniture, equipment, security, IT, telecommunications, etc.

The budget anticipates that the construction of the laboratory complex will be completed by the beginning of FY 2014. What are FDA's contingency plans if the GSA has not completed its work by then?

Response: The increase of \$17.7 million over the FY 2012 enacted budget is required for special facility-related costs for outfitting, commissioning and providing the essential equipment and infrastructure for the laboratories to be certified and operational.

I am happy to submit a breakout for the \$17.7 million increase.

[The information follows:]

Special Commissioning for equipment in Laboratory Building 52/72 and Outfitting of the Bio-Safety Level Labs.	\$6.9M
Commissioning and Outfitting Lab Support Space in Building 75.	\$3.0M
Program Changes including Outfitting the Bio-safety Health Facility.	\$4.8M
Operating the safety infrastructure at White Oak.	\$3.0M

These costs have a direct relationship to the highly specialized construction of state-of-the-art laboratories. There are unique, one-of-a-kind installations and commissioning requirements needed to ensure acceptable operation of these facilities.

GSA has scheduled completion of construction of the Laboratory Complex by December, 2013. The FDA FY 2013 funding for the special commissioning, outfitting, and safety

infrastructure is critical to make the complex operational as scheduled, and to allow FDA to use the Complex to protect the safety of drugs, vaccines and other biologics. While GSA and FDA fully expect to meet the construction completion date of December, 2013, in the event of unforeseen delays, FDA may have to activate certain contingency plans such as negotiation and extension of existing leases.

GSA Rent

6. Mr. Kingston: Commissioner Hamburg, the competition for financial resources is tight. One area I would like to discuss with you is GSA Rent and Other Rent and Related Activities. Do you know how much rent FDA has paid to GSA from FY 2008 to FY 2012? \$862.8 million dollars, and in total, will be over a billion dollars by the end of fiscal year 2013. Does the FDA ever question the bill that GSA submits? Please provide a breakout of GSA rent by center, field, and headquarters for fiscal years 2010, 2011, and estimates for 2012.

Response: FDA carefully reviews GSA's rent bills. GSA's bills are submitted monthly, on a building by building basis. FDA reviews these monthly bills, building by building, to compare GSA's charges with our actual tenancy, with each lease, and with the agreed-upon rate in each Occupancy Agreement. When FDA identifies a discrepancy, we immediately contact the responsible GSA Realty Specialist or GSA management to correct the discrepancy.

I am happy to provide a breakout of GSA rent by center, field, and headquarters for fiscal years 2010, 2011, and estimates for 2012.

[The information follows:]

FDA GSA RENT BY CENTER
FY 2010 - 2012
(Program Level Dollars in 000s)

Center	FY 2010 Actual	FY 2011 Actual	FY 2012 Enacted
Office of Regulatory Affairs (ORA) Field	\$59,059	\$60,372	\$67,824
Center for Biologics Evaluation and Research (CBER)	\$7,211	\$8,439	\$9,672
Center for Drug Evaluation and Research (CDER)	\$35,497	\$34,953	\$39,370
Center for Devices and Radiological Health (CDRH)	\$23,336	\$22,847	\$25,294
Center for Food Safety and Applied Nutrition (CFSAN)	\$17,775	\$17,825	\$19,158
Center for Tobacco Products (CTP)	\$3,645	\$3,818	\$3,924
Center for Veterinary Medicine (CVM)	\$7,005	\$6,835	\$7,230
National Center for Toxicological Research (NCTR)	\$26	\$50	\$61
FDA Headquarters	\$24,155	\$22,980	\$32,939
TOTAL	\$177,709	\$178,119	\$205,472

Inspections in China

7. Mr. Kingston: The FDA is proposing an increase of \$10 million and 10 FTEs for increased inspections in China. How many FTEs will be devoted to drug inspections and how much to food inspections?

Response: The FDA is proposing an increase of \$10 million for 16 FTEs for inspections in China: 9 FTEs for drug inspections and 7 FTEs for food inspections. The increase will also support 3 FTE in the U.S. to help develop our risk analytics and program activities.

Mr. Kingston: What else besides salary and benefits are built into this proposal?

Response: Locally-employed staff, travel, relocation, building, and administrative costs are also integrated.

Mr. Kingston: Does FDA plan to hire permanent staff that will be located in country?

Response: Yes, there is a plan to hire staff that will be located in country. The response to the first part of this question on FTEs also addresses this question.

Sodium Intake

8. Mr. Kingston: Last November, I sent you a letter asking you to review several studies that found increased medical issues resulting from low sodium diets – particularly in children and in diabetics. On Dec. 16 you responded to my letter on the studies suggesting that you would review these studies and consider them in the light of the full body of sodium research. You further stated, “Our understanding of the current scientific consensus does not support the view that modest reductions in sodium intake will lead to significantly greater risk of death.”

I leave it to you to determine the efficacy of the newly published studies, but I would appreciate you conveying your reviews and findings to me and my staff. In addition, I would ask that you also review the McMaster University study that suggests that both high and low levels of salt intake may put people with heart disease or diabetes at increased risk of cardiovascular complications.

The study, published in the *Journal of the American Medical Association (JAMA)* *JAMA. 2011;306(20):2229- 2238.doi:10.1001* found that moderate salt intake was associated with the lowest risk of cardiovascular events, while a higher intake of sodium was associated with an increased risk of stroke, heart attack and other cardiovascular events and a low intake was associated with an increased risk of cardiovascular death and hospitalization for congestive heart failure. The low intake level, however, that was identified as a concern was almost twice the level of the current Dietary Guidelines for Americans (DGA). In other words, these researchers found evidence in direct contradiction to the statement in your letter, i.e. reductions in sodium intake led to increased risk of cardiovascular death and hospitalization for congestive heart failure.

My concern, and the issue I hope you can address in your review, is that the low consumption level triggering the concern was at a level much higher than the current recommendations by FDA to the American public.

Response: FDA is at the beginning stages of a literature review process with support from the Centers for Disease Control and Prevention and the National Institutes of Health to assess recent studies on sodium intake to evaluate their relevance to sodium reduction efforts in the general population. As part of our scientific assessment, we intend to consider a significant number of recent studies with potential relevance to the health effects of reduced sodium intake. We are including in the literature review the studies you informed us of last November, as well as the McMaster study--O'Donnell et al., 2011--that you recently noted. Each study will be reviewed to determine what scientific conclusions can be drawn based on the study design and analysis. We will weigh that information in the context of the existing body of scientific literature to ensure that our understanding of the health effects of sodium reduction is appropriately informed by current science. We look forward to analyzing the significance of the studies that you pointed out as part of the literature review. We regret that we are not currently able to provide you with our assessment.

Food and Veterinary Medicine Strategic Plan

9. Mr. Kingston: FDA's budget justification indicates that the Food and Veterinary Medicine (FVM) Strategic Plan, "places high priority on the prevention of food borne illness of unknown origins and illness that can be specifically attributed to known sources." Under the five sub-programs related to achieving the goals of this strategic plan three of these sub-programs allow FDA to address known and unknown sources of illness from the farm-to-table continuum. Which of the three subprograms allow FDA to address known and unknown sources of illness, and more importantly, how does the plan allow FDA to address unknown sources of illness?

Please provide, for the record, the FY 2012 allocation to each sub-program in the FVM strategic plan.

The justification also indicates that FDA had some approvals of new preventive controls such as new applications of irradiation in food, and new chemical antimicrobial treatments. Can you tell us what these applications and treatments are, and what the results are for food safety?

Response: The three sub-programs which allow FDA to address known and unknown sources of foodborne illness are *Prioritizing Prevention*, *Strengthening Surveillance and Enforcement* and *Improving Response and Recovery*. *Prioritizing Prevention* resources will allow FDA to establish a science-based, prevention-focused food safety system through standard-setting, industry outreach, and consumer education. Information gained from the risk analysis, regulatory science, enforcement, and response activities of *Strengthening Surveillance and Enforcement* and *Improving Response and Recovery* will

enable FDA to monitor the nation's food supply, identify the most significant foodborne contaminants, whether biological or chemical, evaluate the effectiveness of FDA controls for those contaminants, and take action to mitigate incidents of foodborne illness and contamination. The risk analysis component of *Strengthening Surveillance and Enforcement* and response activities under *Improving Response and Recovery* will afford the agency an opportunity to gather more information on unknown sources of foodborne illness as we analyze agents and vehicles in outbreaks of foodborne illness.

Response: I am happy to provide the following for the record.

[The information follows:]

Foods Program	
Sub-programs	FY 2012 Amount
Prioritizing Prevention	\$ 242,395,000.00
Strengthening Surveillance and Enforcement - A. Strengthening Surveillance	\$ 433,800,000.00
Strengthening Surveillance and Enforcement - B. Strengthening Enforcement	\$ 216,767,000.00
Improving Response and Recovery	\$ 77,441,000.00
Nutrition & Labeling Strategies for Better Health	\$ 18,270,000.00
Reinventing Cosmetics Safety	\$ 11,286,000.00
Total	\$ 999,959,000.00

Regarding new approvals of preventive controls, FDA expanded the permitted use of irradiation as a treatment to reduce foodborne pathogens in iceberg lettuce and spinach. This irradiation provides producers with an additional tool to reduce levels of pathogens such as *E. coli* and *Salmonella* on these leafy greens. FDA also published guidance for manufacturers on microbiological considerations in preparing submissions for antimicrobial food additives. We issued several other authorizations for antimicrobial ingredients for fresh produce and for use in wash water during the processing of meat and poultry.

Pay Cost

10. Mr. Kingston: The Obama Administration proposed a .5 percent pay increase for Federal employees. The FDA is not seeking additional appropriations to cover this increase, but what is the cost to the FDA for a .5 percent increase for all Federal employees? How will FDA absorb this cost?

Response: The FDA cost of the FY 2013 1.6 percent pay raise for Commission corps employees is \$1.502 million. The FDA cost of the FY 2013 .05 percent pay raise for civilian federal employees is \$4.463 million. The FDA total will be \$5.965 million which we will absorb by generating savings across FDA programs. For example, in some cases, FDA programs will not replace non-essential professional staff that retire or leave FDA. This will produce savings that can be redeployed to pay the cost of the civilian pay raise.

Center for Tobacco Products

11. Mr. Kingston: The Center for Tobacco Products is fully funded through user fees. The FY 2012 level is \$477 million, and the budget request assumes collections of \$505 million. How many FTEs are currently employed at CTP?

Response: As of the end of February 2012, CTP has 326 FTE.

12. Mr. Kingston: How much did CTP spend on salaries and related expenses in FY 2011? How much does CTP expect to spend on salaries and related expenses in FY 2012? FY 2013?

Response: In FY 2011, CTP spent \$33,035,400 on salaries and related expenses. During FY 2012 and FY 2013, CTP expects to spend approximately \$64,006,450 and \$66,574,170, respectively, on salaries and related expenses.

13. Mr. Kingston: How much did CTP spend on grants to states and localities in FY 2011? How much does CTP expect to spend on grants to states and localities in FY 2012? 2013?

Response: CTP did not award any grants to states and localities during FY 2011. However, FDA awarded contracts totaling \$24.5 million to 15 states in FY 2011 to enforce the Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents and other regulations issued pursuant to the Tobacco Control Act. To date, during FY 2012, CTP has awarded contracts, totaling \$33 million to 37 states and the District of Columbia to help ensure retailer compliance. CTP expects to spend \$40 million on contracts that will include additional states, U.S. territories, and tribal nations during FY 2013.

14. Mr. Kingston: In FY 2011 CTP collected \$421.4 million in user fees; however, only \$135.7 million was actually spent in that year. What did CTP do with the unobligated balances?

Response: It is important to note that FDA anticipated and planned to carry over tobacco industry user fees during CTP's start-up phase, which is one of the reasons Congress had the foresight to make the tobacco user fees available as "no year" funds. CTP has retained these unobligated balances to fulfill the requirements established by Congress under the Family Smoking Prevention and Tobacco Control Act. CTP plans full use of unexpended balances, and will depend on those carryover funds to build the scientific base for tobacco product regulation, to enforce the law, and to launch FDA's science-based public health education program about the contents and dangers of tobacco products.

Since CTP was established in August of 2009, the agency has used tobacco user fees to establish the regulatory framework and staffing foundation necessary for tobacco product regulation. During this start-up period, all statutory obligations were met and recruitment and hiring has proceeded as projected.

It is also important to remember that since tobacco industry user fees are collected at the end of each quarter, the fourth quarter collections will not be available for obligation until the first quarter of the following fiscal year. Therefore, there will always be a carry-over balance equal to at least the fourth quarter projected collections. Because the user fees are the only funds available for tobacco regulation, this carry-over balance ensures operating funds for the subsequent fiscal year.

During the remainder of FY 2012, CTP plans to use the carry-over funds and the user fees collected in the current fiscal year to continue hiring staff and investing in the scientific, educational, and enforcement programs required to implement the Tobacco Control Act.

15. Mr. Kingston: How is CTP ensuring that its activities are not duplicative of the Department of Health and Human Services efforts from funding that was provided by Prevention and Wellness Fund contained in the American Recovery and Reinvestment Act of 2009 and section 4002 of the Patient Protection and Affordable Care Act (the Prevention and Public Health Fund)?

Response: The Tobacco Control Act authorizes the FDA to collect quarterly fees from the tobacco industry. These fees are to be available only for the purposes of paying the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products. Furthermore, the Act specifies that these tobacco user fees are the only funds authorized to be made available for tobacco regulation and public health authorities including research, compliance and enforcement, and science-based public education campaigns addressing the dangers of tobacco use.

FDA has put a comprehensive financial stewardship and accounting plan in place to ensure that tobacco user fees only support its statutory and regulatory authorities. Although many agencies and offices in HHS, including FDA, are working together to address the significant public health concerns created by the use of tobacco products, FDA does not provide cessation services or engage in community-based tobacco prevention activities that are funded by the Prevention and Wellness Fund section of the American Recovery and Reinvestment Act of 2009 or the Prevention and Public Health Fund authorized by the Patient Protection and Affordable Care Act. FDA works closely with other HHS components to ensure the various tobacco programs are coordinated and are not duplicative.

16. Mr. Kingston: Reports indicate that in November of 2011, CTP issued Requests for Proposals (RFPs) for an anti-smoking media campaign totaling approximately \$600 million. What is the status of these RFPs? How many entities responded to these RFPs? Has CTP entered into any binding agreements with respondents to these RFPs? If so, with whom, for what amounts, and what is the duration of the agreements?

Response: FDA has released two RFPs and the proposal application periods have closed for public education and communication pursuant to FDA responsibilities outlined in the Family Smoking Prevention and Tobacco Control Act. One of the RFPs was reserved for small business and the other is a full and open competition. FDA received 25 proposals in response to the small business RFP. FDA received seventeen proposals in response to the full and open competition. FDA anticipates that the total estimate for a five-year performance period for these contracts is \$600 million. FDA is reviewing these proposals, and these contracts will be awarded in FY 2012. Once awarded, these contracts will allow FDA to implement its authorities to conduct science-based public health awareness campaigns, targeting youth and young adults, to educate them on the composition of tobacco products and the risks the products pose to themselves and others.

17. Mr. Kingston: In order to minimize the 2009 increase in the federal excise tax on certain tobacco products, some tobacco manufacturers have been selling cigarette tobacco in packaging mislabeled as "pipe tobacco." To make it easier for consumers to buy and use this tobacco, commercial-scale roll-your-own cigarette manufacturing machines are proliferating around the country. What actions is CTP taking to enforce the Family Smoking Prevention and Tobacco Control Act regarding misbranding and regulation of tobacco product manufacturers?

Response: FDA is aware of retail establishments selling consumers pipe tobacco for use in roll-your-own cigarette machines and is gathering more information about this practice to determine the appropriate regulatory response.

18. Mr. Kingston: Reports indicate that since March 22, 2011, CTP received over 3,100 substantial equivalence reports (SE Reports) from tobacco manufacturers. CTP mandated this deadline to address existing, modified and new tobacco products. Even though CTP's budget more than doubled from \$235,000,000 in fiscal year 2011 to \$477,000,000 in fiscal year 2012, including the addition of 216 FTE positions, manufacturers report that they have received no substantive responses to their submissions. Please confirm the number of pending premarket product applications and the number that have been acted upon by the CTP.

Response: FDA has received 3,304 substantial equivalence reports and responded to 3,270 of the submitters whether their product falls under the jurisdictional authority of the CTP. FDA has not received any premarket tobacco product applications.

19. Mr. Kingston: There is a growing body of evidence that suggests some tobacco products are less harmful than others. Is the agency currently working to understand tobacco-related harm reduction and the opportunities it may present from a public health impact perspective?

Response: Yes, FDA is actively engaged in learning whether some tobacco products are less harmful than others. For example, it is important to understand more about products sold or distributed for use to reduce harm or tobacco related disease associated with other commercially marketed tobacco products, termed modified risk tobacco products. When reviewing applications for modified risk tobacco products, under the statutory public health standard FDA must take into account the relative risk to individual users and the impact of the modified risk tobacco products on initiation and relapse among non-users, and any impact on cessation among current users.

On December 14, 2011, the Institute of Medicine provided FDA with a report on the scientific standards for Studies on Modified Risk Tobacco Products. The report provided twelve findings and recommendations under the categories of Range of Evidence, addressing the quality of evidence or design and integration of studies, and credibility of evidence or governance of studies. FDA is presently evaluating the Institute's report and its impact on FDA's regulatory activities.

FDA met seven times with individual tobacco products manufacturers or groups of manufacturers to discuss the science behind the entire portfolio of products they manufacture, including smoked and smokeless products. FDA also met three times with manufacturers of dissolvable tobacco products to discuss the product science, individual risk, and population health impact of these specific products. FDA has recently completed a series of Tobacco Product Scientific Advisory Committee meetings on the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. Based on statutory requirements, FDA has a deadline of April 1, 2012, and has issued a notice in the Unified Agenda indicating the Agency's intention to issue guidance or regulations on the scientific standards expected

to support submissions by tobacco manufacturers proposing to market modified risk tobacco products. In addition, FDA has recently made its research priorities public, which include studies of the diversity of tobacco products, reducing addiction, and modified risk tobacco products.

20. Mr. Kingston: Does CTP have a plan to address the backlog of SE Reports? If so, please describe such plan, including the anticipated date that the backlog will be cleared.

Response: FDA has received a total of 3,304 substantial equivalence reports. Products with reports received on or before March 22, 2011, can remain on the market until FDA finds that they are "not substantially equivalent." FDA has carried out an initial jurisdictional review on 3,270 of the substantial equivalence reports it has received and provided information to 3,270 submitters about whether their product falls under the current jurisdictional authority of the CTP.

FDA has performed an initial Completeness Review on 61 substantial equivalence reports received since July 5, 2011. FDA has sent 61 Advice and Information letters to those parties that submitted reports that FDA believes are missing information. These letters ask that the parties either provide clarification or submit the missing information to facilitate FDA's review. FDA has received responses from 32 of the submitters and is proceeding with substantial equivalence evaluation on these reports. FDA has agreed to work on a case-by-case basis with those who submitted reports on or before March 22, 2011, to help them provide the information needed so that a determination of substantial equivalence or not substantial equivalence can be made.

FDA is developing final policies and procedures about the timeframe for responding to substantial equivalence reports. Submission of substantial equivalence reports is new to both FDA and tobacco product manufacturers. The optimal time it might take for various tobacco manufacturers to develop substantial equivalence reports and respond to FDA requests for additional information is not yet known. Thus, FDA will base final policies on this experience.

21. Mr. Kingston: Reports indicate that CTP is planning to expand its regulatory authority over certain sectors of the tobacco industry. Does CTP believe this is a prudent allocation of scarce resources while a backlog with SE Reports persists and the use of mislabeled "pipe tobacco" and RYO cigarette machines proliferates?

Response: The Tobacco Control Act provided FDA with immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Act also authorizes FDA to deem, by regulation, other tobacco products to be subject to Chapter IX of the Food, Drug, and Cosmetic Act or FD&C Act. FDA has publicly announced its intention to deem all products that meet the statutory definition of tobacco product to be subject to the FD&C Act. Deeming would ensure that all tobacco products are subject to FDA's tobacco control authority, which will help to address existing regulatory gaps. FDA is confident that it has adequate resources to effectively apply the FD&C Act and related rules to these other tobacco products without interfering with its

ability to complete its other regulatory activities related to tobacco product applications or other regulatory submissions.

Reagan-Udall Foundation

22. Mr. Kingston: 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) was established under section 770 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 379dd. The purpose of the RUF is to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. Section 770 directs FDA to provide annual support to the RUF.

FDA is currently working with the Reagan-Udall Foundation on two partnerships. The first partnership relates to making cancer chemotherapy safer. Tyrosine Kinase Inhibitors, also known as TKIs, are a class of anti-cancer drug that can have significant adverse effects on the heart. This study examines how existing data bases containing information about these adverse effects could be used together to identify the causes of this cardiotoxicity and how it might be avoided or ameliorated. The objectives of research are to create a publicly accessible database of genes and pathways associated with TKI cardiotoxicity, identify the main physiologic pathways involved, and develop a predictive model to be placed in the public domain.

The second partnership relates to facilitating the development of multi-drug regimens for tuberculosis, also referred to as TB. Developing new therapies for multi-drug resistant TB is difficult in part because there are no reliable methods for testing several drugs together, and in part because of the global nature of this disease and the need for community involvement in testing. The RUF is a partner in the Critical Path to TB Regimens project, a global initiative launched by the Bill and Melinda Gates Foundation and other foundations, to accelerate the development of new TB multidrug regimens. The RUF component of this work addresses collaborative development and validation of reliable methods for testing multi-drug combinations.

The public health benefits of these partnerships are potentially enormous and broad-based. In addition to the benefits of having more effective TB therapies and safer chemotherapy, all scientific information will be in the public domain, and thus be available to support future research. Further, the results of the TB research are likely to be applicable in other diseases where multi-drug regimens are used, such as cancer and AIDS, and the results of the TKI work may apply to adverse effects on other organ systems.

This work addresses scientific hurdles specific to the development of FDA-regulated products, not basic science or translational research. There is no other foundation whose mission encompasses the scientific work that is at the heart of FDA's mission.

Pathway to Global Product Safety and Quality

23. Mr. Kingston: Provide the Committee with a current update on the activities and plans on the Pathway initiative.

Response: I am happy to provide a summary of current activities and plans for the Pathway Initiative. FDA is working on developing procedures to facilitate more comprehensive and systematic information-sharing mechanisms and the coordinated deployment of its resources.

FDA is also implementing model inspection programs with key foreign counterparts such as the European Medicines Agency, also known as the EMA. These inspection programs foster mutual confidence between regulators and permit greater strategic use of resources.

FDA exchanges inspection findings with foreign regulatory counterparts with whom it has confidentiality arrangements. One initiative with the European Commission allows EMA and FDA reduces inspections of firms in Europe and allows FDA to shift its inspection resources to other regions, thereby promoting wider global inspection coverage.

FDA is identifying mechanisms to conduct more sophisticated risk assessments. For example FDA is working with regulatory partners to craft a process for regular, systematic information exchanges that will provide ongoing input into FDA's risk modeling efforts, and ultimately, the deploy FDA resources to achieve greater public health impacts.

FDA is examining the potential to establish a globally accepted unique facility identifier to encourage regular information sharing.

FDA is exploring the broader use of confidentiality arrangements and cooperative arrangements to allow greater information-sharing among trusted foreign regulatory counterparts. Currently, FDA has established confidentiality commitments with 44 foreign counterpart agencies and with 4 units of the World Health Organization, permitting the exchange of non-public information.

FDA is finding more efficient and expansive ways to gather intelligence that supports the FDA mission, identify potential compliance signals, and work to proactively identify product vulnerabilities.

Finally, FDA foreign offices and posts are making strides working with their foreign counterparts to ensure that applicable standards are met for products destined for the United States, addressing the concerns and capabilities of exporting industries, and assessing local economic developments and natural events that may affect the quality and availability of food and medical products bound to the United States.

24. Mr. Kingston: How has the work that FDA has done on this allowed FDA to better prepare the agency for challenges as you look 5 or 10 years out?

Response: In the decade ahead, FDA anticipates a phenomenal growth in the import sector and increased risks from counterfeiting and other fraud. FDA recognizes that relying solely on inspections at production facilities and ports of entry is no longer sufficient to protect American consumers.

To achieve the necessary transformation to appropriately battle the regulatory challenges posed by globalization, the FDA has developed an international operating model, the "Global Product Pathway Initiative". In the early stages of implementing this multi-year long initiative, FDA has embraced a wide variety of strategies to increase international engagement.

FDA also recognizes that it must level the playing field by treating manufacturers in equivalent ways, regardless of their location. Additionally, new user fee legislation will play an important role in the expedition of the drug approval process, under the extra resource stresses the Agency is facing due to globalization's challenges.

FDA is focused on planning risk-based inspections, and seeks to rely on information provided by trusted counterparts to identify. FDA is amenable to accepting third party inspection results and is working towards establishing an audit infrastructure to verify the integrity of the information it receives from public and private third parties.

25. Mr. Kingston: Has the FDA completed its action plan for the initiative? If so, please provide a copy of that plan for the record. If not, when does the FDA plan to complete such a plan?

Response: We are in the evaluation stage of our process and we do not have a completion date for an action plan at this time.

26. Mr. Kingston: What operational changes has FDA made in recent years to deal with the growth in imported products? Please be specific.

Response: To better protect the U.S. public, FDA is using a variety of global engagement strategies to strengthen its global regulatory capacity.

FDA's 13 international offices and posts build strong, sustained partnerships with their counterparts abroad, serve as a portal for other countries to FDA, collect and leverage local and regional knowledge, and provide a platform for inspection of foreign facilities.

FDA is working strategically with a range of countries to develop and harmonize science-based regulatory standards, provide information, and develop tools and scientific exchange programs that contribute to building or strengthening regulatory capacity.

To make the most of its resources for monitoring and inspecting imported products, FDA is developing innovative strategies to take advantage of the latest developments in science, engineering, and information technology. FDA fully deployed PREDICT in 2011, replacing the legacy screening tool with a more dynamic and comprehensive assessment that uses information from a wide variety of sources, including open source intelligence. This allows FDA to better focus its operational resources through a more risk-based approach.

FDA's development of an Import Operations Strategic Plan looks at all facets of FDA's import process to streamline, improve, and clarify import processes wherever appropriate.

Working with partners in the U.S., FDA helps monitor and respond to global public health challenges. FDA participates in the Border Interagency Executive Council which is, a forum for interagency coordination working on three areas benefitting federal agencies and the trade community, such as information sharing, electronic transmission of documents, and trusted partnership programs. FDA also participates in the Commercial Targeting and Analysis Center which provides streamlined communication between agencies, enhancing federal efforts to address import safety issues. Participating agencies share knowledge, experience, and best practices for effective enforcement of our Nation's laws. FDA is also actively involved in workgroups and the Interagency Policy Committee that are further developing opportunities to coordinate and leverage actions under the National Strategy for Global Supply Chain Security to strengthen global supply chains.

27. Mr. Kingston: The importation of FDA regulated products has significantly grown over the last several years. According to FDA, food product imports have grown an average of 10 percent per year, pharmaceutical products have grown nearly 13 percent per year, and medical devices have grown at over 20 percent per year. What does FDA see as the main driver in the significant growth of imported medical devices?

Response: The medical device industry is like other FDA-regulated sectors, using the ever-increasing global economy to meet its business needs. These manufacturers and producers face intense pressure to lower costs and improve productivity, fueling a cycle in which the quest for efficiency leads to increased production abroad and higher volumes of imported products to regulate. Over the next decade, FDA will transform itself from a domestic agency operating in a globalized world to a global agency prepared for a regulatory environment in which product safety and quality know no borders.

28. Mr. Kingston: Has the FDA established a framework and approach for broader data sharing and the use of third parties? If so, please provide that information for the record

Response: Currently FDA is engaged in rulemaking to implement the accredited third-party auditor provision of the FDA Food Safety Modernization Act (Section 307), which will establish a framework for the use of accredited third-party audits for food safety in certain situations. In January 2009, FDA issued guidance on voluntary third-party certification for food and animal feed, which provided our recommendations on, among other things, attributes and measures to ensure the competency and independence of third-party auditors (also known as certification bodies). We also conducted a pilot of third-party certification in the aquacultured shrimp industry to inform us about the opportunities and challenges FDA would face in administering a third-party certification program.

FDA is also exploring the broader use of confidentiality arrangements to allow greater information-sharing among trusted foreign regulatory counterparts. Currently, FDA has established confidentiality commitments with 44 foreign counterpart agencies in 21 countries and with 4 units of the World Health Organization (WHO), permitting the exchange of non-public information. These types of arrangements and information-sharing activities foster mutual reliance, help to leverage knowledge and resources and expand intelligence gathering.

FDA is making strides in working with its foreign counterparts. For example, FDA is currently working with Health Canada to enhance technical collaboration, mutual recognition of standards, and work sharing. Potential outcomes include reducing unnecessary duplicative costs for manufacturers of pharmaceutical products, streamlining regulatory decision-making, and minimizing delays in bringing medical products to the marketplace through collaboration.

29. Mr. Kingston: Provide the Committee with an update on how FDA is working with foreign counterparts to create coalitions of regulators.

Response: FDA is working with its foreign counterparts to assemble global coalitions of regulators dedicated to strengthening the product safety net around the world, developing global data information systems in which regulators can share real-time information and resources; expanding its intelligence gathering capabilities; and effectively leveraging the combined efforts of government, industry, and public- and private-sector third parties.

For example, FDA co-hosted the inaugural International Tobacco Regulators' Conference with the World Health Organization's Tobacco Free Initiative. The conference included officials from 22 countries. At the conference's conclusion, the participating regulators established an informal information-sharing network.

FDA participated in the inaugural meeting of the International Medical Device Regulators Forum. This forum is a regulator-led effort to exchange relevant post-market

safety information on medical devices with global distribution, implement a uniform device identification system, develop a medical device single audit program, and create a list of international standards used for medical device regulation.

FDA and the World Health Organization are collaborating to support a worldwide exchange of information and expertise in matters concerning resistance of foodborne pathogens and disease to anti-microbial treatments, also known as AMR. Rapid access to AMR data worldwide will strengthen AMR decisions making and help build capacity for laboratory-based AMR surveillance in developing regions.

FDA was recently admitted as a member of The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme which supports the global product safety net that FDA seeks to enhance.

FDA established and strengthened bilateral relationships with trusted counterparts to assist in global regulatory efforts through information-sharing confidentiality arrangements, and the establishment of collaborative pilot programs that allow the FDA to share inspection reports, share information on clinical trials, and conduct parallel evaluations of relevant development and manufacturing data components. Ultimately, these programs are intended to promote mutual reliance and shared information.

FDA Transparency

30. Mr. Kingston: Please provide the Committee with an update on the current status of the FDA Transparency initiative that was begun in fiscal year 2010.

Response: Commissioner Dr. Margaret Hamburg launched the FDA Transparency Initiative to make available more useful, user-friendly information about Agency activities and decision-making.

Phase 1: In 2010, FDA launched *FDA Basics*, an online resource that provides user-friendly information about Agency work. To date, it has received 1.3 million views and 3,200 public comments.

Phase 2: Relates to proactive disclosure and how to make information about Agency activities more transparent and user-friendly, while protecting confidential information.

The following information is now available:

- Office of Regulatory Affairs Annual Field Workplans (from FY01).
- Filer evaluation outcomes for importers or third parties working on behalf of importers.
- Basic information about inspected entities, inspection dates, FDA-regulated products involved, and final inspection classifications.

- The most common objectionable conditions or practices observed during FDA inspections.
- A searchable database for major product recalls, supporting industry efforts to enable consumers to identify products subject to recall.
- Expanded online posting of untitled letters and, for companies who corrected violations cited in warning letters, official “close-out” notices.

Additionally, in January 2012 FDA released a report announcing an exploratory program to investigate ways to increase access to Agency compliance and enforcement data.

Phase 3: Addresses ways FDA can become more transparent to the regulated industry to foster a more efficient regulatory process.

Actions taken under Phase 3:

- Launched *FDA Basics for Industry* to provide information about FDA’s regulatory process. To date, it has been viewed over 500,000 times.
- Posted online external presentations given by FDA employees at events the Agency sponsored or co-sponsored.
- Formed a cross-Agency working group to identify best practices for improving the transparency and efficiency of FDA guidance development processes. (Report issued December 2011).
- Created an alert system to allow the public to receive e-mails when an Import Alert is issued or updated.

FDA Food Safety Modernization Act (FSMA)

31. Mr. Kingston: What is the current status, including cost-benefit analysis, of each proposed rule, regulation, policy guidance, etc. related to FSMA? Also, provide a comprehensive description of each rule, regulation or policy guidance related to FSMA.

Response: To respond to your question, we are providing the following document which details the status of the guidance documents and regulations required under FSMA. Any cost-benefit analysis is done concurrent with the proposed or final regulation, thus the status of the relevant regulation also reflects the status of the cost-benefit-analysis.

Title I - Improving Capacity to Prevent Food Safety Problems				
Section	Subject	Document Type	Description	Status
101	Inspections of Records	Rulemaking	<i>Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements:</i> FDA issued this interim final rule to amend FDA's regulation on the record availability requirements to be consistent with the amendments to the Federal Food, Drug, and Cosmetic Act - FD&C Act - made by the FDA Food Safety Modernization Act - FSMA -. The FSMA amendment expands FDA's former records access authority beyond records relating to the specific suspect article of food to records relating to any other article of food that the Secretary of Health and Human Services - the Secretary - reasonably believes is likely to be affected in a similar manner. Additionally, the FSMA amendment permits FDA to access records relating to articles of food for which the Secretary believes that there is a reasonable probability that the use of or exposure to the article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.	The interim final rule published February 2012.
101	Inspections of Records	Guidance	<i>Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food; Edition 5:</i> This guidance updates a previous guidance of the same title and contains current information pertaining to the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States under the FD&C Act, as amended by FSMA. It is intended to provide individuals in the human and animal food industries with an updated overview of FDA's access to records. It provides practical information by answering common questions that cover a range of topics, including who is subject to records requirements, the scope of records retention and availability requirements, and the consequences of failing to establish and maintain required records or failing to make required records available to FDA.	Guidance published in February 2012.
101	Inspections of Records	Guidance	<i>Draft Guidance for Industry: FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act:</i> The draft guidance is intended for the regulated food industry and FDA personnel. This draft guidance provides updated information pertaining to FDA's authority to access and copy records under sections 414(a) and 704(a)(1)(B) of the FD&C Act, as amended by section 101 of FSMA.	Guidance published in February 2012.

Title I - Improving Capacity to Prevent Food Safety Problems				
Section	Subject	Document Type	Description	Status
102	Registration of Food Facilities	Guidance	<i>Guidance for Industry: What You Need to Know About Registration of Food Facilities:</i> The purpose of this guidance document is to clarify the circumstances under which facilities are required to register with FDA and the new requirement for biennial registration renewal.	Under development.
103	Hazard Analysis and Risk-Based Preventive Controls	Rulemaking	<i>Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food:</i> The rule modernizes FDA's requirements for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food and adds requirements for domestic and foreign facilities that are required to register under the FD&C Act to establish and implement hazard analysis and risk-based preventive controls for human food.	The proposed rule, including the cost-benefit analysis, is in review.
103	Hazard Analysis and Risk-Based Preventive Controls	Rulemaking	<i>Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Animals:</i> FDA is proposing regulations to establish current Good Manufacturing Practice in manufacturing, processing, packing, and holding of animal food. FDA is also proposing regulations to establish and implement Hazard Analysis and Risk-Based Preventive Controls for Food for animals.	The proposed rule, including the cost-benefit analysis, is in review.
103	Hazard Analysis and Risk-Based Preventive Controls	Guidance	<i>Small Entity Compliance Guide: Preventive Controls Regulation for Human Food:</i> After the issuance of the final Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food regulation, FDA intends to issue a small entity compliance policy guide, setting forth in plain language, the requirements and to assist small entities in complying with the hazard analysis and other required activities.	Will be developed in conjunction with the final rulemaking.
103	Hazard Analysis and Risk-Based Preventive Controls	Guidance	<i>Small Entity Compliance Guide: Preventive Controls Regulation for Animal Food:</i> After the issuance of the final Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Animals Human Food regulation, FDA intends to issue a small entity compliance policy guide, setting forth in plain language, the requirements and to assist small entities in complying with the hazard analysis and other required activities.	Will be developed in conjunction with the final rulemaking.
103	Hazard Analysis and Risk-Based Preventive Controls	Guidance	<i>Guidance on Hazard Analysis and Preventive Controls:</i> FDA will develop guidance that will explain the requirements of the two proposed preventive controls with respect to the various components of the food safety plan, including how to perform a hazard analysis and determine appropriate preventive controls. A description of procedures will be accompanied by supplemental Q&As.	Under development.
103	Hazard Analysis and	Guidance	<i>Guidance for Industry on Fish and Fishery Products Hazards and Controls,</i>	Guidance published in

Title I - Improving Capacity to Prevent Food Safety Problems				
Section	Subject	Document Type	Description	Status
	Risk-Based Preventive Controls		<i>Fourth Edition:</i> The updated guidance supports and complements FDA's regulations for the safe and sanitary processing and importing of fish and fishery products using hazard analysis and critical control point - HACCP - methods.	April 2011.
104	Performance Standards	Guidance	<i>Most Significant Foodborne Contaminants:</i> The agency, in coordination with the U.S. Department of Agriculture - USDA -, will review and evaluate relevant health data and other relevant information, including toxicological and epidemiological studies and analyses, current Good Manufacturing Practices issued by the Secretary relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee, to determine the most significant foodborne contaminants.	Under development.
104	Performance Standards	Guidance	<i>Hazard Analysis and Preventive Controls Guidance: Contaminant Specific:</i> Based on review and evaluation, and when appropriate to reduce the risk of serious illness or death to humans or animals, or to prevent adulteration of the food under section 402 of the FD&C Act, or to prevent the spread by food of communicable disease, the agency shall issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations. There will be separate guidance documents for human food and animal food.	Under development.
105	Standards for Produce Safety	Rulemaking	<i>Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption:</i> FDA is proposing to establish science-based minimum standards for the safe production and harvesting of fruits and vegetables that minimize the risk of serious adverse health consequences or death.	The proposed rule, including the cost-benefit analysis, is in review.
105	Standards for Produce Safety	Guidance	<i>Good Agricultural Practices:</i> This guidance will represent the current thinking of FDA and USDA on a number of microbial food safety hazards and on good agricultural and management practices common to the growing, harvesting, packing, holding, and transport of most fresh fruits and vegetables.	Under development.
105	Standards for Produce Safety	Guidance	<i>Small Entity Compliance Guide: Produce Safety Regulation:</i> After the issuance of regulations for standards for produce safety, FDA intends to issue a small entity compliance policy guide setting forth in plain language the requirements of the regulation and to assist small entities in complying with standards for safe production and harvesting and other required activities.	Will be developed in conjunction with the final rulemaking.
106	Protection Against Intentional	Rulemaking	The agency intends to promulgate regulations to protect against the intentional adulteration of food. The proposed regulation will specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific	Under development.

Title I - Improving Capacity to Prevent Food Safety Problems				
Section	Subject	Document Type	Description	Status
	Adulteration Protection Against Intentional Adulteration		vulnerable points. The agency intends to issue a guidance document related to the protection against the intentional adulteration of food, including mitigation strategies or measures to guard against such adulteration.	
106		Guidance		Under development .
111	Sanitary Transportation of Food	Rulemaking	The agency intends to promulgate regulations that will require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices, prescribed by the Secretary, to ensure that food is not transported under conditions that may render the food adulterated.	Under development.
113	New Dietary Ingredients	Guidance	<i>Draft Guidance: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues:</i> This draft guidance is intended to assist industry in deciding when a premarket safety notification for a dietary supplement containing a new dietary ingredient - NDI - is necessary and in preparing premarket safety notifications (also referred to as "NDI notifications"). The draft guidance addresses in question and answer format what qualifies as a NDI, when a NDI notification is necessary, the procedures for submitting a NDI notification, the types of data and information that FDA recommends manufacturers and distributors consider when they evaluate the safety of a dietary supplement containing a NDI, and what should be included in a NDI notification. In addition, the guidance contains questions and answers about parts of the dietary supplement definition that can affect whether a particular substance may be marketed as a dietary ingredient in a dietary supplement.	Guidance issued in July 2011.

Title II - Improving Capacity to Detect and Respond to Food Safety Problems				
Section	Subject	Document Type	Description	Status
204	Enhancing Tracking and Tracing of Food and Recordkeeping	Rulemaking	FDA plans to propose regulations to establish additional recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that are designated as high-risk. This will assist in rapidly and effectively identifying recipients of a food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences.	Under development.
204	Enhancing Tracking and Tracing of Food and Recordkeeping	Small Entity Compliance Guide	After promulgation of a final rule that establishes additional recordkeeping requirements for facilities that manufacture, process, pack or hold foods that are designated as high-risk, the agency intends to issue a small entity compliance guide. The small entity compliance guide will set forth, in plain language, the requirements of the regulation in order to assist small entities, including farms and small businesses, in complying with recordkeeping requirements.	Will be developed in conjunction with the final rulemaking.
207	Administrative Detention of Food	Rulemaking	<i>Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption:</i> FDA issued this interim final rule to change the criteria for ordering administrative detention of human or animal food. Under the new criteria, FDA can order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. This will further help FDA prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply.	The interim final rule published in May 2011.
207	Administrative Detention of Food	Guidance	<i>Guidance for Industry: What You Need to Know About Administrative Detention of Foods:</i> FDA announced the availability of a guidance for industry entitled, "What You Need to Know About Administrative Detention of Foods," which replaced the guidance of the same title issued in November 2004. The guidance represents the Agency's current thinking on its authority to order the administrative detention of human or animal foods.	Published in October 2011.
211	Improving the Reportable Food Registry	Rulemaking	The Reportable Food Registry amendments are aimed at improving consumer awareness of recalled foods they may possess and increase store management awareness of the need to remove reportable/recalled food products from grocery store shelves. Fruits and vegetables that are raw agricultural commodities will be exempt from these requirements.	Under development.

Title III - Improving the Safety of Imported Food				Status
Section	Subject	Document Type	Description	
301	Foreign Supplier Verification Program	Rulemaking	<i>Foreign Supplier Verification Programs - FSVPs - for Importers of Food for Humans and Animals:</i> FDA is proposing to require that importers perform risk-based verification activities to verify that the food imported is produced in compliance with risk-based preventive control and food safety requirements, as applicable, and is not adulterated or misbranded with respect to major food allergens.	The proposed rule, including the cost-benefit analysis, is in review.
301	Foreign Supplier Verification Program	Guidance	The draft guidance will explain in greater detail certain aspects of the FSVP requirements, which should assist importers in understanding their responsibilities under the FSVP regulations. The draft guidance also will provide recommendations for actions that importers should take to comply with various aspects of the FSVP requirements.	Under development.
302	Voluntary Qualified Importer Program	Guidance	<i>Guidance for Importers on the Voluntary Qualified Importer Program - VQIP -:</i> The agency intends to establish a program to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in the VQIP.	Under development.
304	Prior Notice of Imported Food Shipments	Rulemaking	<i>Information Required in Prior Notice of Imported Food:</i> FDA issued this interim final rule to require an additional element of information in a prior notice of imported food. This change requires a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry. The new information can help FDA make better informed decisions in managing the potential risks of imported food into the United States.	The interim final rule published in May 2011.
307	Accreditation of Third-Party Auditors	Rulemaking	FDA intends to amend its regulations to provide for the accreditation of third-party certification bodies to conduct food safety audits of foreign food entities, including foreign food facilities, and to issue food, facility, and process certifications, pursuant to FSMA. Use of accredited third-party certification bodies and food, process, and facility certifications, will help FDA prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply.	Under development.
307	Accreditation of Third-Party Auditors	Guidance	The draft guidance will explain in greater detail aspects of the requirements for the recognition of accreditation bodies that accredit third-party auditors to, among other things, issue certifications for purposes of the import certification for food.	Under development.

32. Mr. Kingston: How many FSMA rules and regulations have been finalized? Which ones?

Response: FDA has issued three interim final rules under the FDA Food Safety Modernization Act. In May 2011, FDA issued the interim final rule on *Criteria Used to Order Administrative Detention of food for Human or Animal Consumption*, which allows FDA to order an administrative detention if there is reason to believe that an article of food is adulterated or misbranded. FDA also issued the interim final rule on *Information Required in Prior Notice of Imported Food*, which requires a person submitting prior notice of imported food to report the name of any country to which the article has been refused entry. Finally, in February 2012 we issued the interim final rule on *Establishment, Maintenance, and Availability of Records*, which expands FDA's records access.

33. Mr. Kingston: Does the FDA have adequate staffing to draft and finalize rules and regulations required under FSMA?

Response: To augment the current staff that are working tirelessly to meet the challenge of the numerous provisions of the FDA Food Safety Modernization Act, we are using FY 2012 resources to hire additional staff to work on FSMA regulation and guidance documents.

34. Mr. Kingston: What is FDA's goal for finalizing all rules and regulations required by FSMA?

Response: The numerous provisions of the FDA Food Safety Modernization Act or FSMA, present FDA with a unique opportunity to improve food safety. This also represents an enormous challenge to develop and issue more than 50 regulations, guidance documents, and reports under very tight timeframes. FDA is committed to issuing all of the rules and regulations in FSMA and is prioritizing its work by concentrating first on the rulemakings that will form the foundation of the preventive controls framework envisioned in FSMA.

35. Mr. Kingston: Has FDA shifted resources to focus on the new law? If so, how has the shift allowed FDA to better carry out its mission under the new law? What is the FDA no longer doing that it may have been doing pre-FSMA?

Response: FDA is committed to directing its current base resources as fully as possible to implement the FDA Food Safety Modernization Act, or FSMA, while maintaining statutorily required programs, such as nutrition labeling, food additives and food contact substances, infant formula, dietary supplements, cosmetics, color additives, and food animal drugs and residues. FSMA is now the organizing framework for most FDA food safety activities, which allows FDA to carry out its food safety mission by focusing on developing and issuing the regulations establishing the preventive controls framework,

deploying our food safety experts on guidance development and technical assistance in support of the new FSMA rules, developing prevention-oriented compliance strategies including training programs, building capacity for a national integrated food safety system, and establishing an enhanced import oversight program. These are related to activities that FDA was pursuing before FSMA was enacted by Congress. In light of FSMA, we have shifted the focus of these activities, but there is no specific activity that we are no longer doing.

36. Mr. Kingston: Provide a current update on the \$39,000,000 food safety increase that the Congress provided to FDA in fiscal year 2012. Include a copy of the spend plan that accompanied this increase, and any modifications to that plan since it was submitted.

Response: FDA very much appreciates the food safety increase that we received in fiscal year 2012 and is allocating it for implementation of the FDA Food Safety Modernization Act according to the spend plan that we submitted previously. There have been no modifications to the 2012 plan, which we have included as requested. [The information follows]

FY 2012 Transforming Food Safety Increases

Report on Funding Allocations, Outputs and Performance

Budget Authority -- Dollars in Thousands

A. Transforming Food Safety (TFS) Priority	B. Center/ Field Allocation	C. FTE	D. FDA Activity	E. FDA Performance	F. Public Health Benefit
Preventive Controls on Farms (Produce Safety Standards - FSMA Section 105) CFSAN	\$4,400	17	Establish protective and practical standards for key risk factors to enhance produce safety and protect the health of consumers Develop practical, risk-based preventive controls for produce farms and appropriate controls for small scale, organic, and sustainable agriculture operations	Clear a proposed or final rule, covering topics such as preventive controls for produce safety through the agency. These rules will help industry identify and implement preventive controls as required by the FDA Food Safety Modernization Act of 2011.	This initiative will allow FDA to: • reduce the number of foodborne illnesses associated with consuming produce, particularly illnesses from Salmonella and E. coli O157:H7. • identify and address sources of risk in the food safety system
Preventive Controls for Food and Feed					

FY 2012 Transforming Food Safety Increases Report on Funding Allocations, Outputs and Performance

Budget Authority -- Dollars in Thousands

A. Transforming Food Safety (TFS) Priority	B. Center/F ield Allocatio n	C. FT E	D. FDA Activity	E. FDA Performance	F. Public Health Benefit
Processing (FFSMA Sections 101, 103, 104, 110, 204, 405) CFSAN	\$9,600	38	Develop and issue guidance and standards necessary for a prevention-oriented food safety system designed to protect consumers Develop uniform hazard analysis and risk-based controls guidance to ensure proper implementation of preventive controls guidance and standards Develop performance standards for food hazards Validate the effectiveness of widely used process controls to provide industry and FDA with a better understanding of successful food safety processes Engage in extensive outreach, dialogue, and other efforts with the food industry to ensure FDA standards and guidance are protective and practical Conduct economic analyses to inform development of new standards and guidance	Clear two proposed or final rules, covering topics such as preventive controls for food processing, through the agency. These rules will help industry identify and implement preventive controls as required by the FDA Food Safety Modernization Act of 2011	This initiative will allow FDA to: • reduce the number of foodborne illnesses associated with foods, particularly illnesses from Salmonella, E. coli O157:H7, and Listeria. • identify and address sources of risk in the food - safety system
Integrated Food Safety System					

FY 2012 Transforming Food Safety Increases Report on Funding Allocations, Outputs and Performance

Budget Authority – Dollars in Thousands

A. Transforming Food Safety (TFS) Priority	B. Center/Field Allocation	C. FTE	D. FDA Activity	E. FDA Performance	F. Public Health Benefit
(FFSMA Sections 202, 204, 205, 209, 210) ORA	\$12,680	12	FDA will continue to develop and implement an integrated national food safety system (IFSS) built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply through food safety inspections and the sharing of analytical findings that states may collect. Activities will include: ● Provide funding to our regulatory and public health partners in the form of state grants, cooperative agreements or inter-agency agreements ● Improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application and enforcement of food safety laws and standards ● Upgrade IT systems to allow for the acceptance of FDA, state, and foreign data to support the move	Hire Field state liaisons to assist with the implementation of Manufactured Food Regulatory Program Standards (4 FTE) Hire a National Work Plan Manager and National Work Plan Analysts to assist ORA with its movement to national standards (3 FTE) Hire Official Establishment Inventory Coordinators for the field (4 FTE) Hire IT Support Specialist to support the integration of state and FDA data towards a national workplan (1 FTE)	Funding the IFSS portion of the Initiative will allow FDA to: ● Improve foodborne illness surveillance and reduce the risk of foodborne illnesses to consumers ● Identify sources of risk in food safety systems ● Improve industry compliance with food safety standards ● Reduce time to detect and respond to outbreaks that could cause injuries or illness to consumers ● Build a formal system of collaboration between our

FY 2012 Transforming Food Safety Increases

Report on Funding Allocations, Outputs and Performance

Budget Authority -- Dollars in Thousands

A. Transforming Food Safety (TFS) Priority	B. Center/ Field Allocation	C. FTE	D. FDA Activity	E. FDA Performance	F. Public Health Benefit
			towards a national workplan Evaluate system improvements needed to accommodate requirements under the Importer Accountability Verification Program		regulatory and public health partners to ensure consistent oversight, application and enforcement of food safety laws and standards
Import Oversight (FFSMA Sections 201, 211, 301-308)					
ORA	\$10,406	42	Funding these import oversight activities will provide a greater level of assurance regarding importers and imported products, support globalization response and put additional emphasis on working with foreign regulators, thus expanding overall coverage of the foreign industry beyond what FDA could do on its own by conducting additional foreign inspections. ORA will conduct the following activities: Implement the Importer Accountability Verification	By FY 2014, once the new employees are fully trained, ORA would be able to conduct 731 import verification inspections. By FY 2015, once the new employees are fully trained, ORA would be able to conduct 127 assessments or audits.	The number of substandard products entering the United States will decrease, reducing the number of illnesses and injuries to consumers and contributing to decreased health care costs and decreased economic impact from foodborne outbreaks.

FY 2012 Transforming Food Safety Increases Report on Funding Allocations, Outputs and Performance Budget Authority -- Dollars in Thousands					
A. Transforming Food Safety (TFS) Priority	B. Center/ Field Allocation	C. FTE	D. FDA Activity	E. FDA Performance	F. Public Health Benefit
			Program and conduct import verification inspections in support of both the Foreign Supplier Verification Program (FSVP) and the Voluntary Qualified Importer Program (VQIP) (22 FTE) Conduct performance assessments and audits for the third party certification recognition and accreditation program (15 FTE) Increase ORA capacity to support foreign inspections and activities (3 FTE) Perform periodic audits of the Foreign Food Safety System Comparability Program (2 FTE)		
Rent Activities	\$1,914		Pay GSA Rent and Other Rent and Rent-Related costs for the facilities that support Food Safety activities		Funding these rent activities will reduce the need for FDA to redirect resources from core, mission-critical public health activities to pay rent costs.
Total	\$39,000	109			

37. Mr. Kingston: What was the direct appropriation for food safety activities in fiscal year 2008, and what was the direct appropriation in fiscal year 2012?

Response: The budget authority appropriation for food safety activities in fiscal year 2008 was \$694,807,000 and the fiscal year 2012 amount was \$1,144,707,000.

38. Mr. Kingston: How many FTE did the fiscal year 2008 direct appropriation for food safety activities support, and how many FTE did the fiscal year 2012 appropriation support?

Response: The fiscal year 2008 budget authority appropriation supported approximately 3,262 FTE and the fiscal year 2012 appropriation supports approximately 4,550 FTE.

39. Mr. Kingston: The FDA recently released an interim rule that will allow the FDA access to records beyond those related to suspect foods if FDA believes that these other products may be similarly affected. The rule will take effect on March 1, 2012. FDA stated that costs will be negligible. What records are businesses required to produce prior to the interim rule, and what records will they be required to produce under the interim rule?

Response: The interim final rule, *Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements*, amends the existing regulation, 21 CFR 1.361, on the availability of records to be consistent with the language of the FD&C Act as amended by section 101 of the FDA Food Safety Modernization Act, or FSMA. The FSMA amendments expand FDA's former records access authority beyond records relating to the specific suspect article of food to include records relating to any other article of food that the Secretary of Health and Human Services reasonably believes is likely to be affected in a similar manner. In addition, the FSMA amendments permit FDA to access records relating to articles of food for which there is a reasonable probability that the use of, or exposure to, the article of food, and any other article of food that is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.

Since the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188), firms have been required to make and keep certain records. The interim final rule does not mandate additional creation or maintenance of records. When FDA requests records access, FDA can access the relevant records already made and kept by businesses. The FSMA amendments expanded the scope of records that FDA may request, but businesses do not have to make or keep additional records to respond to a specific records request. FDA anticipates costs to be negligible because businesses routinely keep the records to which FDA now has access and are familiar with the procedures for responding to a request for records access.

40. Mr. Kingston: How will this improve food safety?

Response: FDA believes this will improve food safety by allowing FDA timely access to a broader range of records that can assist in foodborne illness outbreak investigations and thus enhance FDA's response to such events, including more rapid removal of potentially contaminated product from distribution.

GAO/OIG Reports

41. Mr. Kingston: Please provide a listing of all GAO reports conducted on FDA programs and activities in fiscal year 2010 and fiscal year 2011.

Response: I am happy to provide the following list of GAO Reports.

FY 2010

- Herbal Dietary Supplements, GAO-10-662T, May 26, 2010
- Border Security, GAO-10-694, July 19, 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, 2010
- Medical Devices: FDA Should Enhance Its Oversight of Recalls, GAO 11-468, June 14, 2011
- Pediatric Research: Products Studied under Two Related Laws, but Improved Tracking Needed by FDA., GAO-11-457, May 31, 2011
- Antibiotic Resistance: Data Gaps Will Remain Despite HHS Taking Steps to Improve Monitoring, GAO-11-406, June 1, 2011
- DHS and HHS Medical Counter Measures – Hill briefing on Dec. 10, 2010
- Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims, GAO-11-102, January 14, 2011
- Influenza Vaccine: Federal Investments in Alternative Technologies and Challenges to Development and Licensure, GAO-11-435, June 27, 2011
- Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water, GAO-11-346, August 8, 2011
- Food Irradiation: FDA Could Improve Its Documentation and Communication of Key Decisions on Food Irradiation Petitions, GAO 10-309R, March 18, 2010
- Intellectual Property: Observations on Efforts to Quantify the Economic Effects of Counterfeit and Pirated Goods, GAO 10-423, March 12, 2010
- Food and Drug Administration: Response to Heparin Contamination Helped Protect Public Health; Controls That Were Needed for Working with External Entities Were Recently Added, GAO-11-95, October 29, 2010
- Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed, GAO-10-961, October 28, 2010

- Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources. GAO-11-286, May 16, 2011
- Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated Into Future Planning (GAO-11-632), June 27, 2011
- Additional Strategic Planning Needed to Guide HHS's Efforts to Establish Electronic Situational Awareness Capabilities, GAO-11-199, December 17, 2010
- FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters, GAO-11-607, September 8, 2011
- Homeland Security: Actions Needed to Improve Response to Potential Terrorist Attacks and Natural Disasters Affecting Food and Agriculture, GAO-11-652, September 13, 2011
- Illicit Tobacco--Various Schemes Are Used to Evade Taxes and Fees, GAO-11-313, March 7, 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, March 18, 2011
- Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals GAO-11-801, Sept. 7, 2011
- High-Containment Laboratories: Duplication of Federal Oversight Activities (ongoing study)

FY 2011

- Medical Devices: FDA Should Enhance Its Oversight of Recalls, GAO 11-468, June 14, 2011
- Pediatric Research: Products Studied under Two Related Laws, but Improved Tracking Needed by FDA., GAO-11-457, May 31, 2011
- Antibiotic Resistance: Data Gaps Will Remain Despite HHS Taking Steps to Improve Monitoring, GAO-11-406, June 1, 2011
- DHS and HHS Medical Counter Measures – Hill briefing on Dec. 10, 2010
- Influenza Vaccine: Federal Investments in Alternative Technologies and Challenges to Development and Licensure, GAO-11-435, June 27, 2011
- Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water, GAO-11-346, August 8, 2011
- Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed, GAO-10-961, October 28, 2010
- FDA's Management of the Food and Drug Administration: Response to Heparin Contamination Helped Protect Public Health; Controls That Were Needed for Working with External Entities Were Recently Added, GAO-11-95, October 29, 2010
- Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims, GAO-11-102, January 14, 2011
- Illicit Tobacco--Various Schemes Are Used to Evade Taxes and Fees. GAO-11-313, March 7, 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, March 18, 2011
- Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources. GAO-11-286, May 16, 2011
- Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated Into Future Planning (GAO-11-632), June 27, 2011
- Additional Strategic Planning Needed to Guide HHS's Efforts to Establish Electronic Situational Awareness Capabilities, GAO-11-199, December 17, 2010
- Homeland Security: Actions Needed to Improve Response to Potential Terrorist Attacks and Natural Disasters Affecting Food and Agriculture, GAO-11-652, Sept. 13, 2011
- Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals GAO-11-801, Sept. 7, 2011
- High-Containment Laboratories: Duplication of Federal Oversight Activities (ongoing)
- Antibiotics: FDA Needs to Do More to Ensure That Drug Labels Contain Up-to-Date Information, GAO 12-218, January 31, 2012
- Prescription Pain Reliever Abuse: Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness, GAO 12-115, Dec. 22, 2011
- National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources, GAO 12-121, October 26, 2011
- Preslaughter Interventions Could Reduce E. coli in Cattle, GAO-12-257, March 9, 2012
- National Cord Blood Inventory: Practices for Increasing Availability for Transplants and Related Challenges, GAO 12-23, October 7, 2011
- Funding for Nanotechnology EHS Research (ongoing)
- Pediatric Medical Devices: Provisions Support Development, but Better Data Needed for Required Reporting, GAO-12-225, December 20, 2011
- GAO Study on Tobacco Trade Tax Differentials (ongoing)
- FDA IT Modernization (ongoing)
- Drug Shortages: FDA's Ability to Respond Should Be Strengthened, GAO 12-116, December 15, 2011
- Cybersecurity Electronic Implantable Medical Devices (ongoing)
- FDA's Mandatory Food Recall Authority (ongoing)
- Use of Psychotropic Drugs for Children (ongoing)
- Foster Children: HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions, GAO 12-270T, December 14, 2011
- Medical Devices: FDA Has Met Most Performance Goals but Device Reviews Are Taking Longer, GAO-12-418, Feb 29, 2012
- FDA Review Times for Drugs (ongoing)
- USDA and FDA Pesticide Residue Monitoring and Enforcement (ongoing)

- Health Effects of Cell Phones (ongoing)
- Agencies' Implementation of FOIA (ongoing)

42. Mr. Kingston: Provide a listing of all OIG audits and investigations on FDA programs and activities in fiscal year 2010 and fiscal year 2011.

Response: I am happy to provide the following list of OIG audits and investigations.

FY 2010

- FDA's Approval Status of Drugs Paid for by Medicaid, OEI-03-08-00500, November 24, 2010
- Vulnerabilities in FDA's Oversight of State Food Facility Inspections OEI-02-09-00430, December 12, 2011
- CDRH's Policies and Procedures for Resolving Scientific Disputes (ongoing)
- CDRH Oversight of 510(k) Program (ongoing)
- Adverse Events in Hospitals: Public Disclosure of Information About Events, OEI-06-09-00360, January 5, 2010
- FDA Food Facility Registry, OEI-02-08-00060, December 14, 2009
- FDA Inspections of Domestic Food Facilities, OEI-02-08-00080, April 5, 2010
- Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials, OEI-01-08-00510, June 2010
- Review of the Food and Drug Administration's Monitoring of Imported Food Recalls, A-01-09-01500, Issued June 11, 2011.

FY 2011

- FDA's Approval Status of Drugs Paid for by Medicaid, OEI-03-08-00500, November 24, 2010
- Vulnerabilities in FDA's Oversight of State Food Facility Inspections OEI-02-09-00430, December 12, 2011
- FY 2011 Audit of FDA's Network Management Controls (ongoing)
- CDRH's Policies and Procedures for Resolving Scientific Disputes (ongoing)
- CDRH Oversight of the 510(k) Program (ongoing)
- Review of the Food and Drug Administration's Monitoring of Imported Food Recalls, A-01-09-01500, Issued June 11, 2011.
- OIG Audit of Unapproved Drugs (ongoing)
- Review of FDA's Oversight of Less-than-Effective Drugs (ongoing)
- Review of Risk Evaluation and Mitigations Strategies Program (ongoing)
- FDA's Oversight of Claims Made on Dietary Supplement Labels (ongoing)

Medical Countermeasures initiative (MCMi)

43. Mr. Kingston: If the requested funding increase is not provided for MCMi, how will FDA support the 7 FTE that are performing MCMi activities?

Response: If Congress does not appropriate the Fiscal Year 2013 increase of \$3.51 million for FDA's Medical Countermeasures Initiative, or MCMi, then the MCMi will not have base funding to support 7 FTEs that have already been hired and are conducting MCMi activities. Specifically, FDA will not have sufficient funding to support 7 FTEs that are currently performing work to enhance the review and approval process for medical countermeasures, to advance regulatory science for developing medical countermeasures, and to modernize the legal, regulatory, and policy framework for effective public health response to chemical, biological, radiological and nuclear threats and emerging infectious diseases such as pandemic influenza. As a temporary solution, if the Fiscal Year 2013 budget is not approved FDA will redirect resources committed to medical countermeasure regulatory science to pay the FTE costs of these 7 FTEs. These resources for regulatory science are not base resources, but one-time resources. Therefore, this can only be a temporary solution while the one-time resources remain available. When the one-time resources are exhausted, FDA must transfer these employees from the MCMi to other FDA programs where they will perform non-MCMi work. The result will be a diminished opportunity to maintain the momentum of this vital national security program and bring MCMs to Americans during deliberate or naturally-occurring public health emergencies.

44. Mr. Kingston: Provide a copy of the 5-year strategic plan for the MCMi for the record.

Response: I would be happy to provide that for the record.



Medical Countermeasures Initiative

Strategic Plan 2012 - 2016



US Department of Health and Human Services
Food and Drug Administration



Message from the Commissioner

The US Food and Drug Administration plays a vital role in protecting our nation from chemical, biological, radiological, and nuclear threats, and from emerging infectious diseases. It is FDA's responsibility to ensure that medical countermeasures—such as drugs, vaccines, and diagnostic tests—to counter these threats are safe, effective, and secure. FDA works closely with our partners through the US Department of Health and Human Services' Public Health Emergency Medical Countermeasures Enterprise (Enterprise) to build and sustain the medical countermeasure programs necessary to respond to a public health emergency.

In August 2010, FDA rolled out its Medical Countermeasures Initiative (MCMi), which is intended to build on existing FDA medical countermeasure programs, with a goal of refocusing and strengthening FDA activities. We developed the MCMi as part of a comprehensive, yearlong review of the Enterprise, ordered by HHS Secretary Sebelius, to assess the United States' readiness to reduce the impact of a future public health emergency and improve our nation's capacity to respond quickly and effectively to these threats as mandated by President Obama.

The MCMi is designed to address key challenges in three areas: (1) enhancing the regulatory review process for the highest priority medical countermeasures and related technologies; (2) advancing regulatory science for medical countermeasure development; and (3) modernizing our regulatory and legal framework. This document describes FDA's strategic goals and key objectives for implementing the MCMi and addressing these challenges.

Achieving our medical countermeasures mission is critical for the health and security of our nation. At FDA, we recognize that our active engagement in the Enterprise is essential to developing the next generation of medical countermeasures that will be needed to protect the nation's health and security. We recognize that achieving our mission is a long-term proposition that will require a significant and continued investment of resources and a solid commitment of our leadership to what is a broadly shared responsibility.

The dedicated professionals at FDA, and those across the Enterprise, are deeply committed to succeeding. I believe FDA is uniquely equipped and positioned to contribute to the success of this effort to significantly strengthen national and global health and security.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
December 2011



Executive Summary

Developing medical countermeasures—including drugs and biological products, medical devices, and other medical equipment—that will be needed to protect the nation from public health emergencies involving chemical, biological, radiological, nuclear (CBRN) threats and emerging infectious diseases (EID), such as pandemic influenza, is critical to advancing the health, security, and well-being of the American people.

The US Food and Drug Administration's Medical Countermeasures Initiative (MCMi), launched in August 2010, builds upon the substantial work ongoing at FDA to ensure that the nation has the necessary medical countermeasures to protect the nation from identified, high-priority CBRN and EID threats and to develop the capabilities necessary to produce medical countermeasures quickly in response to new or unanticipated threats.

The MCMi mission is to promote the development of medical countermeasures by enhancing FDA's regulatory processes and fostering the establishment of clear regulatory pathways for medical countermeasures, and to facilitate the timely access to available medical countermeasures by establishing effective regulatory policies and mechanisms.

The MCMi is based on a three pillar strategy that integrates ongoing FDA medical countermeasure efforts with new initiatives as needed:

- **Pillar I** – enhancing the regulatory review processes for the highest priority medical countermeasures and related technologies
- **Pillar II** – advancing regulatory science for medical countermeasure development and evaluation
- **Pillar III** – modernizing the legal, regulatory, and policy framework for effective public health response

This document sets forth the strategic goals and key objectives that FDA will pursue through 2016 to build and sustain the programs needed to achieve the MCMi mission. FDA's MCMi strategic goals include:

- **Goal 1:** Develop and maintain the highly qualified workforce with appropriate technical training, scientific skill, and subject-matter expertise, and improve infrastructure at FDA (e.g.,

information technology, laboratory equipment) so that the MCMi workforce has the tools required to succeed

- **Goal 2:** Build and sustain the integrated, coordinated programs necessary to ensure that the MCMi reflects medical countermeasure priorities and objectives and that MCMi programs are sufficiently resourced and aligned to fulfill MCMi program initiatives
- **Goal 3:** Engage MCMi stakeholders to foster effective collaboration, solicit input and feedback, improve program implementation, and maximize the transparency of programs and priorities
- **Goal 4:** Integrate MCMi programs to foster effective preparedness, planning, and response capabilities
- **Goal 5:** Establish and support Public Health and Security Action Teams to support development of high-priority candidate medical countermeasure products, product classes, and critical medical countermeasure technologies
- **Goal 6:** Establish and sustain a medical countermeasures regulatory science program to develop solutions to complex regulatory challenges and facilitate the incorporation of new, cutting edge science into the regulatory review process to speed product development
- **Goal 7:** Modernize the legal, regulatory, and policy environment to adequately support preparedness for and response to CBRN and EID threats with medical countermeasures.

FDA's MCMi is vital to our national security and will help protect the nation from potentially catastrophic CBRN and EID threats. Investments in the MCMi not only will create opportunities to improve overall public health, advance medical countermeasure development, and contribute to the development of products to treat other diseases and conditions, but also improve the safety, efficacy, and access to FDA-regulated medical products while reducing costs. The MCMi is clearly a timely and critical investment that will pay dividends far into the future of our nation.

CONTENTS

MESSAGE FROM THE COMMISSIONER III

EXECUTIVE SUMMARY VI

INTRODUCTION..... 1

CBRN AND EID THREATS 2

ROLE OF 21ST-CENTURY REGULATORY SCIENCE IN ADDRESSING CBRN AND EID THREATS 6

MCMi ACTION PLAN 10

MCMi STRATEGIC GOALS AND KEY OBJECTIVES 12

IMPLEMENTATION..... 21

CONCLUSION..... 21

APPENDIX A: MEDICAL COUNTERMEASURES INITIATIVE ORGANIZATION..... 23

APPENDIX B: ALIGNMENTS AND LINKAGES..... 31

APPENDIX C: SUMMARY OF MCMi STRATEGIC GOALS AND KEY OBJECTIVES..... 34

APPENDIX D: CROSSWALK OF FDA STRATEGIC GOALS AND LONG-TERM OBJECTIVES WITH MCMi STRATEGIC GOALS AND KEY OBJECTIVES..... 35

APPENDIX E: ACRONYMS..... 37

Introduction

The world faces serious threats from chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases (EIDs). These threats directly challenge national and international security, owing to the potential for massive loss of life as well as untold social, political, and economic disruption.

The US Department of Health and Human Services (HHS) has the mission to protect the US civilian population from CBRN threats and EIDs by providing leadership in the research, development, regulation, procurement, stockpiling, maintenance, deployment, and utilization of medical countermeasures.¹ HHS is pursuing a unified, integrated approach to its mission through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE or Enterprise), a coordinated, interagency partnership² that fosters the medical countermeasure programs necessary to improve public health emergency preparedness as well as to prevent and mitigate the adverse health consequences associated with CBRN threats and EIDs. The US Food and Drug Administration (FDA) is one of three primary HHS agencies included in the Enterprise. FDA supports the medical countermeasure mission by providing subject matter expertise in the areas of product development with a goal towards FDA approval³ as well as to other Enterprise activities, including ensuring timely access to medical countermeasures.

The HHS Secretary's 2010 *Enterprise Review* called on FDA to take an even more active role in fostering the development and facilitating the

¹ Medical countermeasures include qualified countermeasures as defined in section 319F-1(a)(2) of the Public Health Service Act (42 U.S.C. § 247d-6a(a)(2)); qualified pandemic or epidemic products as defined in section 319F-3(i)(7) of the Public Health Service Act (42 U.S.C. § 247d-6d(i)(7)), and security countermeasures as defined in section 319F-2(c)(1)(B) of the Public Health Service Act (42 U.S.C. § 247d-6b(c)(1)(B)).

² The Enterprise is led by the Office of the Assistant Secretary of Preparedness and Response and includes three primary HHS internal agencies: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). Key interagency partners are the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and the Department of Agriculture. See Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Management. Washington, DC: US Department of Health and Human Services. Available at <https://www.medicalcountermeasures.gov/BARDA/PHEMCE/pheemce.aspx>. Accessed April 13, 2011.

³ For purposes of this document, the term "approval" refers to FDA-approval, licensure, or clearance under sections 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

deployment of medical countermeasures.⁴ As a result, FDA launched its Medical Countermeasures Initiative (MCMi). This document presents FDA's *Medical Countermeasures Initiative Strategic Plan 2012 – 2016* and establishes the strategic goals and key objectives FDA will pursue to foster innovative, science-based regulatory oversight and to help build the critically needed scientific infrastructure and capacity to ensure that the nation has the ability to effectively develop, stockpile, deploy, use, and sustain the medical countermeasures required to protect the nation from CBRN and EID threats. The *MCMi Strategic Plan* is guided by and complements strategic- and operational-level planning for CBRN and EID threats across departments and agencies at the executive level, the White House, and the legislative branch (see Appendix B).

CBRN and EID Threats

“Over the coming years, [the United States] will continue to face a substantial threat...from terrorists attempting to acquire biological, chemical, and possibly nuclear weapons and use them to conduct large-scale attacks.”

The US intelligence community assesses that CBRN weapons and EIDs present real, substantial, and growing threats to the national security of the United States and will continue to do so for the foreseeable future.⁵

The United States faces CBRN threats from both state and non-state actors. The March 2011 unclassified annual threat assessment from the US intelligence community states that, “...many of the countries pursuing [weapons of mass destruction] programs will continue to try to improve their capabilities and level of self-sufficiency over the next decade.

Nuclear, chemical, and/or biological weapons—or the production technologies and materials necessary to produce them—also may be acquired by states that do not now have such programs. Terrorist or insurgent organizations acting alone or through middlemen may acquire nuclear, chemical, and/or biological weapons and may seek opportunistic networks as service providers.”⁶ In 2009, the US intelligence community assessed that “[o]ver the coming years, [the United States] will continue to face a substantial threat, including in the US Homeland, from terrorists

⁴ *The Public Health Emergency Medical Countermeasures Enterprise Review – Transforming the Enterprise to Meet Long-Range National Needs*. Washington, DC: US Department of Health and Human Services. August 2010. Available at: <https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf>. Accessed April 5, 2011.

⁵ Clapper, J.R. Statement for the Record on the Worldwide Threat Assessment of the US Intelligence Community for the House Senate Committee on Armed Services. *Annual Hearing to Receive Testimony on the Current and Future Worldwide Threats to the National Security of the United States*, Hearing, March 10, 2011. Available at: http://www.dni.gov/testimonies/20110310_testimony_clapper.pdf. Accessed: March 31, 2011.

⁶ *Ibid.* 5, pg. 5.

attempting to acquire biological, chemical, and possibly nuclear weapons and use them to conduct large-scale attacks.”⁷

“Traditionally biological, chemical, or nuclear weapon use by most nation states has been constrained by deterrence and diplomacy, but these constraints may be of less utility in preventing the use of these weapons by terrorist groups. Moreover... Biological and chemical materials and technologies...move easily in our globalized economy, as do the personnel with scientific expertise designing and using them.”

The US intelligence community’s 2011 threat assessment notes that “[t]raditionally biological, chemical, or nuclear weapon use by most nation states has been constrained by deterrence and diplomacy, but these constraints may be of less utility in preventing the use of these weapons by terrorist groups. Moreover, the time when only a few states had access to the most dangerous technologies is well past. Biological and chemical materials and technologies, almost always dual-use, move easily in our globalized economy, as do the personnel with scientific expertise [in] designing and using them. The latest discoveries in the life sciences also diffuse globally with astonishing rapidity.”⁸ The 2009 US intelligence community assessment stressed that “[i]n particular...the terrorist use of biological agents represents a growing threat as the barriers to obtaining many suitable starter cultures are eroding and open source technical literature and basic laboratory equipment can facilitate production.”⁹

This assessment is in alignment with myriad strategic-level threat assessments including by the National Intelligence Council, which reported in November 2008 that “[f]or those terrorist groups that are active in 2025, the diffusion of technologies and scientific knowledge will place some of the world’s most dangerous capabilities within their reach. One of our greatest concerns continues to be that terrorist or other malevolent groups might acquire and employ biological agents, or less likely, a nuclear device, to create mass casualties”¹⁰; the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism which reported in December 2008 that “terrorists are more likely to be able to obtain and use a biological weapon than a nuclear weapon”¹¹; and the National Security Council, which reported in November 2009 that “...(1) the risk [posed by biological threats] is evolving in unpredictable ways; (2) advances in the enabling technologies will continue to be globally available; and (3) the ability to exploit such

⁷ Blair, D. Testimony before the Armed Services Committee, United States Senate. *Annual Threat Assessment of the Intelligence Community*, Hearing, March 10, 2009. Available at: http://www.dni.gov/testimonies/20090310_testimony.pdf. Accessed March 31, 2011.

⁸ *Ibid.* 5, pg. 5.

⁹ *Ibid.* 7, pg. 21.

¹⁰ *Global Trends 2025: A Transformed World* (NIC 2008-003). Washington, DC: National Intelligence Council; November 2008. Available at: http://www.dni.gov/nic/PDF_2025/2025_Global_Trends_Final_Report.pdf. Accessed March 31, 2011.

¹¹ *World at Risk*. Washington, DC: Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism; December 2008. Available at: <http://documents.scribd.com/docs/15ba1nrl9aerfu0yu9qd.pdf>. Accessed March 31, 2011.

advances will become increasingly accessible to those with ill intent as the barriers of technical expertise and monetary costs decline.”¹²

“...for the foreseeable future [infectious diseases] will remain the top health-related threat to US national security...”

With respect to the threat posed by EIDs,¹³ in 2008 the National Intelligence Council assessed that although numerous infectious and noninfectious health conditions can potentially impact US strategic interests, “...for the foreseeable future [infectious diseases] will remain the top health-related threat to US national security...” and notes that the US population “...will continue to be vulnerable to [EIDs]—many of which will originate overseas (e.g., HIV/AIDS, West Nile, and dengue fever)—including a potential influenza pandemic or an outbreak of a “mystery” disease (e.g., SARS.)”¹⁴

Beyond the direct potential health effects to the US population, infectious diseases also threaten the health and well-being of the global population, can slow socioeconomic development, and disrupt domestic stability and security abroad, potentially challenging the legitimacy of governments and creating significant security risks on both regional and global levels.^{15, 16} These risks can ultimately affect the United States’ ability to protect the health of US forces and personnel, compromising our ability to deploy US assets abroad, impede our ability to coordinate US/international response efforts to global crises, and precipitate diplomatic frictions between the United States and other countries, ultimately impairing our ability to pursue US strategic objectives.^{17, 18}

“...health issues can suddenly emerge from anywhere in the globe and threaten American lives and US strategic objectives.”

Although the threats posed by CBRN agents and EIDs are significant and growing, there is considerable uncertainty associated with managing the risks posed by these threats. The 2010 annual threat assessment from the US Intelligence Community notes that the “... [2009 H1N1] influenza

¹² *National Strategy for Countering Biological Threats*. Washington, DC: White House, National Security Council. November, 2009. Available at: http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf. Accessed March 31, 2009.

¹³ Emerging infectious diseases include “newly-emerging” infectious diseases (i.e., infectious diseases that newly appear in a population that heretofore had not been recognized in humans) and “re-emerging” infectious diseases (i.e., infectious diseases that have been recognized in humans but are increasing in incidence or geographic range). See: Morens DM, Folkers GK, Fauci AS. The challenge of emerging and re-emerging infectious diseases. *Nature*. 2004 Jul 8;430(6996):242-9.

¹⁴ *Strategic Implications of Global Health* (ICA 2008-10D). Washington, DC: National Intelligence Council; December 2008. Available at: http://www.dni.gov/nic/PDF_GIF_otherprod/ICA_Global_Health_2008.pdf. Accessed March 31, 2011. Note: this study was “limited to examination of naturally occurring health phenomena, leaving the issues of bioterrorism and biowarfare for separate study”

¹⁵ *Ibid.* 5, pg. 31-32.

¹⁶ *Ibid.* 14, pg. 16.

¹⁷ *Ibid.* 5, pg. 31-32.

¹⁸ *Ibid.* 14. pg. 16.

"It is unlikely that any country will be able to detect cases early enough to prevent the spread of another new, highly transmissible virus should one emerge during the next five years..."

pandemic is the most visible reminder that health issues can suddenly emerge from anywhere in the globe and threaten American lives and US strategic objectives."¹⁹ The emergence/re-emergence of infectious diseases is the outcome of a complex and dynamic interaction among multiple factors including biological, social, demographic, geographic, ecological, political, and economic factors (e.g., microbial adaptation, human susceptibility, urbanization, climate/weather, land use, travel, commerce, poverty, war, famine).²⁰ When and where the next infectious disease will emerge or re-emerge is extremely difficult to ascertain. In March 2011, the US intelligence community assessed that "[i]t is unlikely that any country will be able to detect cases early enough to prevent the spread of another new, highly transmissible virus should one emerge during the next five years..."²¹ And CBRN threats arguably pose greater uncertainty than EIDS, owing to the potential for their intentional use. Potential adversaries of the United States who are suspected of pursuing or possessing CBRN weapons are difficult to identify and gather information on, and CBRN weapons research, development, and production is difficult to detect or discern from legitimate research and development.²² It is difficult to gain insight into the specific intentions and capabilities of declared or potential aggressors who seek to maintain secrecy so as to prevent preemptive strikes and to achieve a tactical and strategic advantage. This makes it difficult to identify in advance when, where, and how a declared or potential adversary will make a CBRN weapons breakthrough or attack the United States with CBRN weapons. In addition, the CBRN threat is continually evolving in unpredictable ways as technology advances and intelligent adversaries adjust their strategies and tactics in response to US risk-reduction initiatives and perceived US vulnerabilities. Thus, predicting the likelihood of a CBRN attack based on estimating the specific intentions and capabilities of declared or potential aggressors in a way that is both accurate and actionable is extremely challenging, and advance warning of a CBRN attack is unlikely.

¹⁹ Blair, D. Testimony before the Senate Select Committee on Intelligence, United States Senate. Annual Threat Assessment of the Intelligence Community, Hearing, February 2, 2010. Available at: http://www.dni.gov/testimonies/20100202_testimony.pdf. Accessed April 1, 2011.

²⁰ Morens DM, Folkers GK, Fauci AS. The challenge of emerging and re-emerging infectious diseases. *Nature*. 2004 Jul 8;430(6996):242-9.

²¹ *Ibid.* 5, pg. 32.

²² *The Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction - Report to the President of the United States*. Washington, DC: Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction. March 31, 2005. Available at: http://govinfo.library.unt.edu/wmd/report/wmd_report.pdf. Accessed April 4, 2011.

Role of 21st-Century Regulatory Science in Addressing CBRN and EID Threats

HHS pursues an integrated, interagency, and multinational strategy to address the challenges presented by the diverse CBRN and EID threat spectrum as articulated in the 2009 *National Health Security Strategy* (NHSS).²³ This effort is part of the US government's "whole of government" approach to protecting and improving the security of the United States, its citizens, and US allies/partners by integrating all elements of US power into addressing 21st century threats as described in the 2010 *National Security Strategy*.²⁴

The NHSS details 10 strategic objectives that "...describe what must be accomplished to address current gaps in national health security over the next four years and to sustain improvements in health security over the longer term."²⁵ One of those strategic objectives is to promote an effective medical countermeasures enterprise. Medical countermeasure programs work in conjunction with efforts to prevent the development and deployment of CBRN weapons to serve as an overall deterrent to their development and use by making it more difficult to conduct a successful CBRN attack and reducing the anticipated rewards of such an attack.²⁶ In addition, should deterrence efforts fail and a CBRN attack occur, medical countermeasure programs will help mitigate the morbidity and mortality (and attendant economic consequences) of an attack, thus fostering resilience and recovery.²⁷

²³ *National Health Security Strategy of the United States of America*. Washington, DC: US Department of Health and Human Services. December 2009. Available at: <http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf>. Accessed April 4, 2011.

²⁴ *National Security Strategy*. Washington, DC: White House. May 2010. Available at: http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf. Accessed April 4, 2011.

²⁵ *Ibid.* 23, pg. 4.

²⁶ For example, the National Strategy for Countering Biological Threats states that: "Ensuring that communities can quickly and effectively respond to large outbreaks of infectious disease in a manner that greatly reduces their impact is among the most effective ways to deter a deliberate attack..." *Ibid.* 12, pg. 6.

²⁷ "Mitigating illness and preventing death are the principal goals of [the United States'] medical countermeasure efforts" with respect to CBRN threats. See HSPD 18: Medical Countermeasures against Weapons of Mass Destruction. Washington, DC: White House. January 31, 2007. Available at: http://www.dhs.gov/xabout/laws/gc_1219175362551.shtm#1. Accessed April 4, 2011.

"...we are launching a new initiative that will give [the United States] the capacity to respond faster and more effectively to bioterrorism or an infectious disease – a plan that will counter threats at home, and strengthen public health abroad."

"...we want to create a system that can respond to any threat at any time. The kind of system that is so dependable and comprehensive that it deters potential bioterrorism attacks..."

With EIDs, medical countermeasure programs have the potential to greatly limit the resultant morbidity and mortality (and attendant economic consequences) of these types of threats to the US population, fostering resilience and recovery. Furthermore, medical countermeasures can "...help advance economic development, foster diplomacy, and improve overall health worldwide...", which can help strengthen US national security by improving the US ability to pursue strategic objectives abroad – for example by supporting humanitarian relief and medical diplomacy efforts and facilitating development among partner nations and regions.²⁸

Recognizing that CBRN and EID threats will continue to evolve in unpredictable ways and that the nation needs to continue to improve its ability to address these threats, President Obama announced in his 2010 State of the Union Address that the US government would be "...launching a new initiative that will give [the United States] the capacity to respond faster and more effectively to bioterrorism or an infectious disease—a plan that will counter threats at home, and strengthen public health abroad."²⁹ The first step in this initiative was a comprehensive review of the Enterprise. In calling for the review, HHS Secretary Sebelius noted that "[t]he ultimate goal...is a modernized countermeasure production process where we have more promising discoveries, more advanced development, more robust manufacturing, better stockpiling, and more advanced distribution practices. In other words, we want to create a system that can respond to any threat at any time. The kind of system that is so dependable and comprehensive that it deters potential bioterrorism attacks and makes our enemies say, "It's not worth the effort."³⁰

The *Enterprise Review*—released in August 2010—laid out a vision for the Enterprise that shifts from a strategy focused largely on responding to known threats to one that pursues a "... flexible capacity to produce [medical countermeasures] rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized naturally occurring emerging infectious disease."³¹ The *Enterprise Review* revealed that the current regulatory framework and the unmet need for regulatory science present real and perceived barriers for developers who are

²⁸ *Ibid.* 14, pg. 7.

²⁹ Obama, B. *Remarks by the President in State of the Union Address*. Washington, DC: White House. January 27, 2010. Available at <http://www.whitehouse.gov/the-press-office/remarks-president-state-union-address>. Accessed April 5, 2011.

³⁰ Sebelius, K. Speech before the American Medical Association Third National Congress on Health System Readiness. Washington, DC: US Department of Health and Human Services; December 1, 2009. <http://www.hhs.gov/secretary/speeches/sp20091201.html>. Accessed April 5, 2011.

³¹ *Ibid.* 4. pg. 6.

interested in developing medical countermeasures.^{32,33} Regulatory uncertainties associated with medical countermeasure development—largely driven by gaps in scientific knowledge—are among the most important challenges to medical countermeasure regulatory assessment and, thus, approval. This is especially so for novel medical countermeasures for which there may not be a clear development pathway, contributing to what developers perceive as a higher than typical risk environment for engaging in medical countermeasure development. Reducing regulatory uncertainty is one of the most important challenges that the US government must successfully address if it is to achieve the vision laid out in the *Enterprise Review*.

"FDA is critical to the success of the enterprise, as it oversees, from a regulatory standpoint, the entire evaluation process of [medical countermeasures]..."

The *Enterprise Review* recommends a series of new infrastructure initiatives and enhancements to the Enterprise that provide a strategy for transforming the medical countermeasure Enterprise.³⁴ Among the new infrastructure initiatives is "*21st-Century Regulatory Science*," which the *Enterprise Review* deems "...a lynchpin to success of the enterprise."³⁵ Indeed, the *Enterprise Review* notes that "...FDA is critical to the success of the [medical countermeasure] enterprise..." because FDA actions and guidance—from defining regulatory pathways to evaluating the safety, efficacy, quality, and manufacturing control of medical countermeasures—span the medical countermeasure lifecycle, from early development to deployment and use.³⁶ FDA evaluation of product safety and efficacy significantly affects the course of medical countermeasure development and approval. In addition, FDA involvement is crucial to developing medical countermeasures for inclusion in the Strategic National Stockpile and—should it be needed—moving quickly to authorize the circumscribed use of medical

³² *Ibid.* 4, pg. 8.

³³ The *Enterprise Review* was supported by the National Biodefense Science Board (NBSB) and the Institute of Medicine (IOM), both of whom held independent workshops to provide HHS with analyses of the challenges confronting the Enterprise and recommendations for addressing those challenges. Consistently at the forefront of the challenges identified by the NBSB and IOM was regulatory uncertainty and the NBSB and IOM both identified the need for increased involvement of the FDA in the Enterprise. See: (1) *Where are the Countermeasures? Protecting America's Health from CBRN Threats – A Report of the National Biodefense Science Board*. Washington, DC: National Biodefense Science Board. March 2010. Available at <http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/nbsb-mcmreport.pdf>. Accessed April 5, 2011; and (2) *The Public Health Emergency Medical Countermeasures Enterprise – Workshop Summary*. Washington, DC: Institute of Medicine. April 8, 2010. Available at <http://iom.edu/Reports/2010/The-Public-Health-Emergency-Medical-Countermeasures-Enterprise.aspx>. Accessed April 5, 2011.

³⁴ *Ibid.* 4, pg. 10-16. The recommended new infrastructure initiatives are 21st-Century Regulatory Science, Flexible Manufacturing and Advanced Development Core Services Partnerships, Expanding the Product Pipeline and Addressing Multiuse Potential, and an Independent Strategic Investment Firm for Innovation in Medical Countermeasures

³⁵ *Ibid.* 4, pg. 7.

³⁶ *Ibid.* 4, pg. 10.

countermeasures in an emergency—even if the product is not yet approved for that particular use.³⁷

The 21st-Century Regulatory Science initiative as described in the *Enterprise Review* will help to accelerate medical countermeasure development and enhance the probability of approval by increasing resources at FDA to do a number of things, including: (1) step up FDA's engagement in medical countermeasure development from the earliest steps in the process; (2) foster the establishment of clear, scientifically supported regulatory pathways for medical countermeasures; (3) identify and help to fill critical scientific gaps that often derail medical countermeasure development; and (4) facilitate the efficient use of available medical countermeasures by working to establish supportive legislative and regulatory policies and mechanisms. Advances in regulatory science will facilitate all of these efforts.

Advancing regulatory science and innovation—along with advancing medical countermeasures and emergency preparedness—is a cross-cutting strategic priority for FDA.³⁸ In 2010 FDA launched its Advancing Regulatory Science (ARS) Initiative, including enhanced collaboration and joint grant-making with the National Institutes of Health, to accelerate the translation of scientific breakthroughs into new, innovative medical therapies.³⁹ Regulatory science involves the focused development of new tools (or new uses for old tools), standards, and approaches to foster more efficient development of medical products and facilitate and ensure the evaluation of product safety, efficacy, quality, and performance.⁴⁰ Facilitating the development of medical countermeasures to protect against EID and CBRN threats is one of the major priorities of the FDA ARS Initiative. Anticipated outcomes of the ARS Initiative include strengthening advances in the biomedical sciences and more effectively translating cutting-edge developments in science and technology into

³⁷ Under the Project BioShield Act of 2004 [PL 108-276], the Secretary of HHS has the authority to authorize the "emergency use" of medical countermeasure in emergencies under certain terms and conditions [Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb-3)]

³⁸ *United States Food and Drug Administration Strategic Priorities 2011-2015 – Responding to the Public Health Challenges of the 21st Century*. Washington, DC: US Food and Drug Administration. April 20, 2011. Available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM252092.pdf>. Accessed April 20, 2011.

³⁹ NIH and FDA Announce Collaborative Initiative to Fast-Track Innovations to the Public [FDA – NIH News Release]. Washington, DC: US Food and Drug Administration. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm201706.htm>. Accessed April 6, 2011.

⁴⁰ Advancing Regulatory Science at FDA. Washington, DC: US Food and Drug Administration. August 2011. Available at: <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM268225.pdf>. Accessed August 19, 2011.

products; fostering prevention as well as response; and increasing the accuracy and efficiency of FDA regulatory review, which can reduce adverse events, improve access to FDA-regulated products, and reduce medical product development costs.⁴¹

MCMi Action Plan

The MCMi implements the Enterprise Review's call for a 21st-Century Regulatory Science initiative; it builds on the substantive medical countermeasures work ongoing at FDA.

FDA launched its Medical Countermeasures Initiative (MCMi) in August 2010.⁴² The MCMi implements the *Enterprise Review's* call for a 21st Century Regulatory Science initiative; it builds on the substantive medical countermeasures work ongoing at FDA and serves as a complementary, stand-alone component of FDA's overarching ARS Initiative.

The MCMi mission is to promote the development of medical countermeasures by enhancing FDA's regulatory processes and fostering the establishment of clear regulatory pathways for medical countermeasures, and to facilitate the timely access to available medical countermeasures by establishing effective regulatory policies and mechanisms.

FDA has organized the MCMi around an Action Plan built on a three pillar strategy that integrates ongoing FDA medical countermeasure efforts with new initiatives—as needed.

The Office of Counterterrorism and Emerging Threats (OCET), within FDA's Office of the Chief Scientist (OCS), provides overall strategic leadership and coordination for this agency-wide effort. OCET works in close partnership with FDA's three medical product centers— Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH)—as well as the Office of Regulatory Affairs (ORA) to coordinate the MCMi. FDA has organized the MCMi around an Action Plan built on a three-pillar strategy that integrates ongoing FDA medical countermeasure efforts with new initiatives—as needed—based on the expected outcomes and elements of the 21st-Century Regulatory Science initiative as described in the *Enterprise Review* (see Appendix A).⁴³

- **Pillar I: Enhance the Medical Countermeasure Regulatory Review Process**—Goal: to advance the development of high-priority medical

⁴¹ Advancing Regulatory Science for Public Health. Washington, DC: US Food and Drug Administration. October 2010. Available at: <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM228444.pdf>. Accessed April 6, 2011.

⁴² Hamburg, MA. *Remarks at the Medical Countermeasures Review Roll Out* [speech]. Washington, DC: US Food and Drug Administration. August 19, 2010. Available at <http://www.fda.gov/NewsEvents/Speeches/ucm226351.htm>. Accessed April 6, 2011.

⁴³ *Ibid.* 4, pg. 10-11.

countermeasures and related technologies. To do so FDA will: (1) increase regulatory review capacity and expertise in medical review divisions responsible for the evaluation of medical countermeasures and (2) establish multidisciplinary Public Health and Security Action Teams (Action Teams) that will help advance priority medical countermeasure development by working with internal and external entities—as appropriate—to identify and catalyze the resolution of challenges to navigating the medical countermeasure development pathway. The Action Teams will also foster medical countermeasure development more generally by helping to address a range of regulatory and policy issues facing medical countermeasure development and approval, including facilitating the use of consistent regulatory approaches, assisting in the identification and resolution of regulatory science gaps, and supporting the implementation of best regulatory review practices across FDA’s medical product centers.

- **Pillar II: Advance Regulatory Science for Medical Countermeasure Development and Evaluation** – Goal: to facilitate MCMi Pillar I and Pillar III activities by fostering regulatory science initiatives intended to help develop solutions to complex scientific regulatory problems and facilitate the incorporation of new, cutting edge science into the regulatory review process to simplify and speed development of medical countermeasures. This program will be implemented through both intramural and extramural collaborative research, as well as through partnerships with US government agencies, academia, non-government organizations, and industry. A critical component of Pillar II activities will be modernizing FDA’s infrastructure to support the medical countermeasure regulatory science program, including needed upgrades to laboratory equipment and information technology capabilities so that FDA researchers and reviewers have the tools they need to succeed.
- **Pillar III: Modernize the Legal, Regulatory, and Policy Framework for Effective Public Health Response** – Goal: to ensure that US laws, regulations, and policies enable and foster the application of advances in regulatory science to the regulatory review process and adequately support preparedness for and response to CBRN threats and EIDs with medical countermeasures. To do so, FDA will conduct a review of the strengths and weaknesses of the current legal, regulatory, and policy environment with respect to medical countermeasure development, distribution, administration, and use. When changes are needed to better protect public health, FDA will work with appropriate partners to develop and propose new approaches.

The three MCMi Pillars are interdependent and FDA will ensure cross-collaboration in their implementation.

MCMi Strategic Goals and Key Objectives

To achieve the MCMi mission, FDA will concentrate increased resources and management efforts on achieving the following strategic goals (figure 1) and underlying key objectives. In pursuing these strategic goals and objectives, FDA will adhere to its guiding principles: science-based decision making, innovation/collaboration, transparency, and accountability.



Figure 1.

Cross-Pillar Goals and Objectives

Goal 1: Strengthen the Workforce and Improve the Infrastructure Necessary to Support the MCMi

Standing up FDA's MCMi requires the development and maintenance of a highly qualified workforce with appropriate technical training, scientific skill, and subject-matter expertise. In addition, successful implementation of the MCMi will require improving infrastructure at FDA so that the MCMi workforce has the tools it needs to succeed. Establishing the infrastructure to support the MCMi will be pursued through the following three key objectives:

- **Objective 1.1— Build the Workforce Necessary to Implement the MCMi** – Increased staffing needs span the three MCMi Pillars and encompass a wide range of skills and expertise, from augmenting regulatory review capacity in the FDA review divisions responsible for the evaluation of medical countermeasures, to staffing Action Teams, to enhancing FDA regulatory science capacity, and expanding MCMi legal, regulatory, and policy capabilities. FDA will identify the staffing needs to fully support the implementation of the MCMi and establish and execute a prioritized plan to fill and support those needs.
- **Objective 1.2 – Develop and Sustain a Culture of Learning and Professional Development within FDA to Support the MCMi** – The MCMi spans a diverse set of issues, from national and homeland security to medicine and public health, and requires a multi-disciplinary staff with training and expertise in a diverse range of skills. FDA will develop programs to train MCMi personnel at all career stages to ensure that MCMi personnel have the requisite skills and abilities to implement and sustain the MCMi.
- **Objective 1.3 – Acquire the Infrastructure Necessary to Fully Support the MCMi** – The MCMi will require new and improved infrastructure within FDA to achieve its goals including, for example, improved or expanded information technologies and new laboratory equipment to support MCMi regulatory science. FDA will identify the infrastructure needs to fully support the MCMi and establish and execute a prioritized plan to fill those needs.

Goal 2: Build and Sustain Integrated and Coordinated MCMi Programs

FDA is committed to building and sustaining the integrated, coordinated agency programs necessary to achieve the MCMi mission. FDA is responsible not only for coordinating MCMi activities within and among its own offices and centers, but also for coordinating and aligning MCMi activities with federal partners and—where appropriate—external partners (e.g., industry, academia). MCMi program integration and coordination is essential to ensure that MCMi appropriately reflects Enterprise priorities and objectives and that MCMi programs are sufficiently resourced and aligned to facilitate the expeditious fulfillment of program goals and objectives. FDA is building and will sustain an integrated and coordinated MCMi through the following two key objectives:

- **Objective 2.1 – Coordinate MCMi Program Implementation and Activities** – To maximize the effectiveness of the MCMi, it is important to ensure that the efforts of the three MCMi Pillars are appropriately resourced and integrated and that the MCMi efforts across FDA centers and offices and across all levels of US government and—where appropriate—external partners (e.g., industry, academia) are appropriately targeted and integrated to facilitate fulfillment of MCMi program goals and objectives and minimize unnecessary redundancy. FDA will coordinate MCMi program implementation across the MCMi pillars and MCMi program activities across the Enterprise and among external partners to ensure that MCMi programs are effectively synchronized to maximize capital and capabilities.
- **Objective 2.2 – Evaluate MCMi Program Execution** – Building and sustaining a well-integrated, coordinated MCMi requires a planning and execution framework that is built on a foundation of continuous improvement supported by an evaluation of program execution. FDA will establish an evaluation framework to assess MCMi program execution based on defined metrics for success to ensure that MCMi priorities are reflected within program funding allocations and inform future strategy, planning, investments, and resourcing.

Goal 3: Actively Engage MCMi Stakeholders and Foster Transparency

Achieving the MCMi mission will require successful partnerships among all of the Enterprise stakeholders. FDA is committed to pursuing stakeholder engagement as a means of enabling effective collaboration with stakeholders to solicit input and feedback, improve MCMi program implementation, and maximize the transparency of MCMi programs and priorities. FDA will actively engage MCMi stakeholders and foster transparency through the following three key objectives:

- **Objective 3.1 – Engage MCMi Stakeholders in Developing MCMi Priorities** – To be maximally effective, the MCMi must deliver on the needs of its stakeholders. Accordingly, FDA is engaging its stakeholders in the US government and the private sector in developing MCMi program priorities and will create appropriate opportunities for stakeholder input into the MCMi.
- **Objective 3.2 – Strengthen Strategic Partnerships to Further MCMi Program Goals and Objectives** – The success of the MCMi depends on collaborations and partnerships with Enterprise and private sector partners in which FDA serves as a leader, facilitator, collaborator, and participant, as necessary and appropriate. FDA will continue to build and maintain a network of strategic partnerships that operate at multiple levels, across the public and private sectors, and are involved in and serve all aspects of the MCMi to maximize opportunities for collaboration and ensure that resources are appropriately prioritized.
- **Objective 3.3 – Clearly Articulate MCMi Program Priorities and Timelines** – Clear and timely communication of MCMi program priorities and associated timelines is critical to achieving the MCMi mission and maintaining effective engagement with stakeholders. FDA will continue to work to increase transparency and public visibility of its MCMi program, priorities, and timelines.

Goal 4: Integrate MCMi Program with Enterprise Public Health Preparedness Planning and Response Activities

The MCMi is part of a much larger US government initiative—coordinated through the Enterprise—to ensure that the nation has the medical countermeasure programs, products, and systems necessary to be appropriately prepared for, protected from, and resilient in the face of the highest priority CBRN and EID threats. The Enterprise mission space

spans the full scope of medical countermeasure program activities from threat assessment to medical countermeasure research and development to acquisition, deployment, and use. As many of the complex challenges that face the Enterprise are inherently cross-cutting and multi-faceted, integration of component Enterprise programs is critical for fostering effective preparedness, planning, and response capabilities. Accordingly, FDA is dedicated to ensuring that the MCMi is fully integrated into Enterprise activities, and FDA will pursue this goal through the following two key objectives:

- **Objective 4.1 – Represent MCMi in Enterprise Strategic Planning and Policy Development** – FDA supports the Enterprise strategic planning and policy development through participation of FDA subject matter experts in various Enterprise partner committees and working groups. FDA will continue to collaborate with Enterprise partners on strategic planning and policy development related to medical countermeasures to ensure that the MCMi is fully integrated into Enterprise activities and that MCMi developments and issues inform and shape the evolution of Enterprise planning and policies.
- **Objective 4.2 – Coordinate MCMi Activities and Programs with Enterprise Response Activities** – Response to a CBRN or EID event with medical countermeasures requires active engagement of FDA to enable effective and timely response activities. For example, during a domestic or military emergency, potentially useful medical countermeasures may be available, but not yet FDA-approved for the particular use contemplated. In this situation, FDA has a variety of regulatory mechanisms that can allow for the use of these products, including as part of a clinical trial or as part of an expanded access program.⁴⁴ In addition, medical countermeasures can be made available under the emergency use authorization (EUA). FDA may issue an EUA authorizing the use of an unapproved medical countermeasure, or the unapproved use of an approved medical countermeasure, during a declared emergency if there are no adequate, approved, and available alternatives and if other statutory criteria are met.⁴⁵ FDA exercised the EUA authority extensively during the 2009 H1N1 pandemic to facilitate effective response. FDA will continue to work closely with Enterprise partners, medical

⁴⁴ Expanded access refers to FDA procedures that enable the distribution of investigational drugs and devices to a patient or patients who have a serious or immediately life-threatening condition, and lack therapeutic alternatives, when the primary purpose is to diagnose, monitor, or treat the patients' condition Section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb). For more information see <http://edocket.access.gpo.gov/2009/pdf/E9-19005.pdf>

⁴⁵ Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb-3).

countermeasure developers, and first responders as appropriate to coordinate MCMi activities and programs with response activities to ensure that the nation is prepared to counter CBRN and EID threats.

Pillar I Goals and Objectives

Goal 5: Establish and Support Public Health and Security Action Teams

Action Teams will be established based on Enterprise partner priorities⁴⁶ and will support—as needed—the development of high-priority candidate medical countermeasure products, product classes, or critical medical countermeasure technologies. As FDA’s regulatory activities are governed by strict product confidentiality and non-disclosure rules, clear rules of engagement for Action Teams need to be defined so that they can function effectively and that relevant information can be shared between Action Team members and Enterprise partners. It is important that there is a common understanding of data, progress, and key challenges. Establishing and supporting Action Teams will be pursued through the following two key objectives:

- **Objective 5.1 – Establish Action Teams based on Near-, Mid-, and Long-Term Enterprise Priorities** – Given the large number of potential CBRN and EID threat agents, the inherent uncertainties associated with assessing the evolving threat space and the long timelines, risks, and high costs associated with developing medical countermeasures, it is not feasible to pursue medical countermeasure programs against every possible threat. Accordingly, HHS prioritizes both the threats for which medical countermeasure programs are pursued and the medical countermeasure programs that are pursued to counter those threats.⁴⁷ FDA will continually engage Enterprise partners to stay

⁴⁶ For more information on Enterprise partner medical countermeasure priorities see for example: *HHS Public Health Emergency Medical Countermeasure Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats* available at https://www.medicalcountermeasures.gov/BARDA/documents/phemce_implplan_041607final.pdf; *BARDA CBRN BAA- 11-100-SOL-00009* available at https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=89ba389b4424e98020cb3de547001825&_cview=0; and *Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza* available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf>.

⁴⁷ For example, as per HSPD-18, HHS is guided by 3 overarching principles to optimize investments in medical CBRN countermeasure programs : (1) Risk – focusing on countering current and anticipated CBRN threat agents that have the greatest potential for use by state and non-state actors to cause catastrophic public health consequences; (2) Medical Countermeasure

abreast of near-, mid-, and long-term medical countermeasure priorities and requirements and establish Action Teams—as needed—based on those priorities and in alignment with Enterprise partner investments in medical countermeasure programs.

- **Objective 5.2—Establish the Infrastructure and Policies to Support and Guide Action Team Activities**—Success of the Action Team program will require extensive collaboration and coordination among FDA centers and other relevant offices, as well as with Enterprise partners. FDA will establish internal processes, tools, and structures to manage individual Action Teams, track progress, and facilitate coordination of the Action Team program both internally and externally. In addition, FDA will establish policies that will guide Action Team activities and develop any agreements necessary to support their functions (e.g., confidentiality agreements, memoranda of understanding).

Pillar II Goals and Objectives

Goal 6: Establish and Sustain a Medical Countermeasures Regulatory Science Program

The MCMi regulatory science program will focus on high-priority projects that are of value for public health and national security. Topic areas of special interest for medical countermeasure regulatory science include: (1) animal model development and qualification; (2) identification and qualification of biomarkers for safety and efficacy; (3) immune responses including identification of correlates of protection; (4) methods to assess product quality and related product release assays; (5) risk communication to improve public health outcomes; (7) validation of next-generation *in vitro* diagnostics platforms; (8) assessing performance of emergency medical equipment; and (9) real-time tracking and evaluation of MCM safety and efficacy during public health emergencies.

Impact - investing in medical countermeasure programs that have the greatest potential to prevent, treat, and mitigate the consequences of CBRN threats; and (3) Feasibility - linking the development and acquisition of medical countermeasures to the existence of effective deployment strategies that are supportable by present and foreseeable operational and logistic capabilities of federal, state, regional, territorial, tribal, and local assets/authorities. See HSPD 18: Medical Countermeasures against Weapons of Mass Destruction. Washington, DC: White House. January 31, 2007. Available at: http://www.dhs.gov/xabout/laws/gc_1219175362551.shtm#1. Accessed April 4, 2011.

The MCMi regulatory science agenda will be pursued through internal research, as well as through collaborations and partnerships with academia, US government agencies, non-governmental organizations, and industry. Establishing and sustaining the MCMi regulatory science program will be pursued through the following four key objectives:

- **Objective 6.1 – Assess and Prioritize Medical Countermeasure Regulatory Science Needs** – FDA will work both internally and with external partners to assess and prioritize on an ongoing basis medical countermeasure regulatory science needs, which will inform investments in MCMi regulatory science. This assessment and prioritization will be based on Enterprise priorities, including those that foster MCMi Pillar I and Pillar III activities.
- **Objective 6.2 – Strengthen and Sustain the Intramural FDA Medical Countermeasures Regulatory Science Program** – FDA maintains a strong intramural regulatory science program in its three medical product centers. The MCMi will expand and strengthen this program for center-specific research and for cross-center collaborative research.
- **Objective 6.3 - Establish and Sustain an Extramural Medical Countermeasures Regulatory Science Program** – FDA will establish an extramural component that is complementary to its intramural MCMi regulatory science program to engage entities outside of FDA (e.g., other US government agencies, academia, non-governmental organizations, and industry) in medical countermeasure regulatory science.
- **Objective 6.4 - Establish Processes to Maintain Effective Oversight of the Medical Countermeasures Regulatory Science Program** – FDA will establish processes and protocols to manage the MCMi regulatory science program, track progress, and facilitate coordination of research efforts to ensure that the MCMi regulatory science program is appropriately targeted and integrated to facilitate fulfillment of MCMi regulatory science needs and minimize unnecessary redundancy.

Pillar III Goals and Objectives

Goal 7: Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health Response

It is essential that US laws, regulations, and policies continue to evolve to enable the application of advances in regulatory science to the regulatory review process for medical countermeasure development and to adequately support preparedness for and response to CBRN and EID threats with medical countermeasures. FDA is committed to expanding its work with Enterprise partners and external stakeholders to modernize its legal, regulatory, and policy environment and will pursue this goal through the following two key objectives:

- **Objective 7.1 – Identify Priorities for Modernizing the Legal, Regulatory, and Policy Framework for Effective Public Health Response** – FDA will assess on an ongoing basis the strengths and weaknesses of the legal, regulatory, and policy environment with respect to the development, distribution, administration and use of medical countermeasures and identify changes to the legal, regulatory, and policy framework that are necessary to foster medical countermeasure development and improve preparedness and response capabilities.
- **Objective 7.2 – Work with Enterprise Partners and External Stakeholders to Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health Response** – FDA will launch collaborative projects with Enterprise partners and external stakeholders as necessary and appropriate to address high-priority needs for modernizing the legal, regulatory, and policy framework with respect to medical countermeasure development, distribution, administration, and use.

Implementation

FDA will implement the *MCMi Strategic Plan 2012 – 2016* with the full involvement of its leadership and an unwavering commitment to turning strategy into concrete actions. FDA will integrate MCMi priorities into its annual budget formulation and implementation planning.

The *MCMi Strategic Plan* maps out a broad strategic direction for the MCMi. To maximize effective MCMi implementation and promote course corrections when needed, FDA will assess all MCMi activities in detail on an ongoing basis—including performance measures and milestones—for their contribution toward MCMi goals and objectives. FDA will update the *MCMi Strategic Plan* as necessary to reflect evolving activities, progress toward MCMi goals and objectives, and to ensure continued alignment with US government goals and priorities. In addition, MCMi program performance will be reviewed on a quarterly basis through the FDA-TRACK Initiative and through periodic FDA and Enterprise senior leadership reviews. FDA will issue annual status reports on MCMi accomplishments.

Conclusion

Mitigating the threats posed by CBRN agents and EIDs is a critical national security priority for the nation. Medical countermeasures are critical tools needed to promote and protect the health of the US population and security of the United States. As such, they are a significant piece of our national strategy to counter CBRN and EID threats.

The *MCMi Strategic Plan 2012-2016* establishes the goals and key objectives FDA will pursue as part of its ongoing efforts to ensure that the nation has the medical countermeasures necessary to protect the population from the highest priority CBRN and EID threats and the systems to deliver them. The plan also reflects FDA's commitment to help foster the evolution of the Enterprise to a capabilities-based posture that can produce medical countermeasures quickly in response to "...any attack or threat, known or unknown..."⁴⁸ as envisioned in the *Enterprise Review*. FDA's active engagement is fundamental to achieving this vision and to the ultimate success of the Enterprise.

⁴⁸ *Ibid.* 4, pg. 6.

Success of the medical countermeasures Enterprise is in the vital national security interests of the United States as it helps protect the United States from potentially catastrophic CBRN and EID threats and can also help strengthen national security by offering opportunities to promote US interests and security abroad. Achieving the Enterprise vision also creates opportunities to improve the United States' health security beyond countering CBRN and EID threats and offers sound opportunities to promote global health security.

For example, FDA's investments in regulatory science to advance medical countermeasure development will contribute directly and indirectly to the development of products to treat other diseases and conditions and help improve the safety and efficacy of and access to FDA-regulated products while reducing costs. The MCMi is clearly a timely and critical investment that will pay dividends far into the future of our nation.

Appendix A: Medical Countermeasures Initiative Organization

MCMi MISSION

The mission of HHS is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering strong, sustained advances in the sciences, underlying medicine, public health, and social services.⁴⁹ One of HHS's overarching strategic goals is to advance the health, safety, and well-being of the American people and one of the key strategies HHS is pursuing to achieve this goal is to "[m]odernize the medical countermeasure enterprise with more promising discoveries, advanced development, robust manufacturing, better stockpiling, and advanced distribution practices in the United States and abroad."⁵⁰ This strategy is in alignment with strategic objective #6 in the *National Health Security Strategy* to promote an effective medical countermeasures enterprise.⁵¹

HHS pursues a coordinated interagency approach to its medical countermeasures mission through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE or Enterprise). The mission of the Enterprise is to: (1) define and prioritize requirements for public health emergency medical countermeasures; (2) coordinate research, early- and late-stage product development and procurement activities addressing the requirements; and (3) set deployment and use strategies for medical countermeasures held by Enterprise partners.⁵²

The Enterprise is led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes three primary HHS internal agencies: (1) the Centers for Disease Control and Prevention (CDC); (2) the Food and Drug Administration (FDA); and (3) the National Institutes of Health (NIH). The Enterprise also includes key interagency partners: the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and the Department of Agriculture.

FDA's mission is to protect the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.⁵³ Specifically, FDA is responsible for advancing the public health by:

⁴⁹ *US Department of Health and Human Services Strategic Plan 2010-2015*. Washington, DC: US Department of Health and Human Services. Available at <http://www.hhs.gov/secretary/about/priorities/strategicplan2010-2015.pdf>. Accessed April 14, 2011.

⁵⁰ *Ibid* 49, pg. 67.

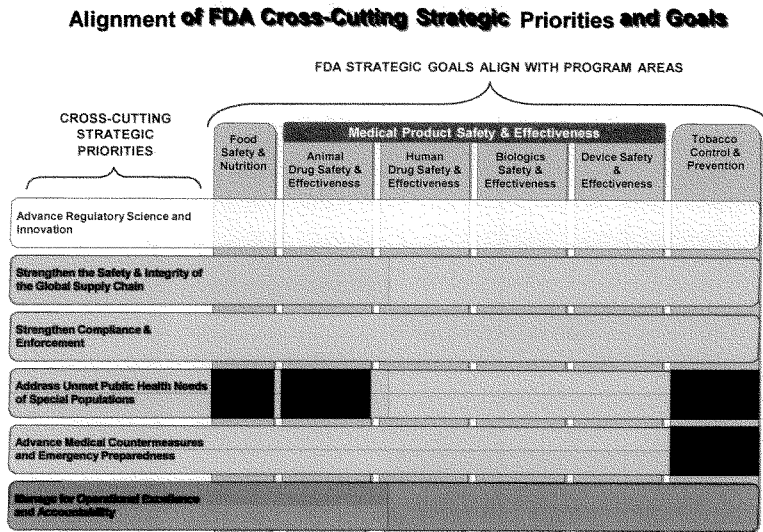
⁵¹ *Ibid* 23, pg. 13.

⁵² Parker, G. HHS Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats. *Federal Register*, 72 (53), 13109-13114. March 20, 2007, available at https://www.medicalcountermeasures.gov/BARDA/documents/federalreg_vol72no53_032007notices.pdf. Accessed April 14, 2011.

⁵³ *Ibid* 38, pg. 2.

- Helping to speed innovations that make medical products and foods safer and more effective
- Providing the public with the accurate, science-based information they need to use medical products and foods to improve their health
- Regulating the manufacture, marketing, and distribution of tobacco products to protect the public and reduce tobacco use by minors
- Addressing the Nation's counterterrorism capability by ensuring the security of the supply of foods and medical products and by fostering development of medical products to respond to deliberate and naturally emerging public health threats

Advancing medical countermeasures and emergency preparedness is a cross-cutting strategic priority for FDA that aligns with program-specific strategic goals and long-term objectives across FDA (figure 2).⁵⁴

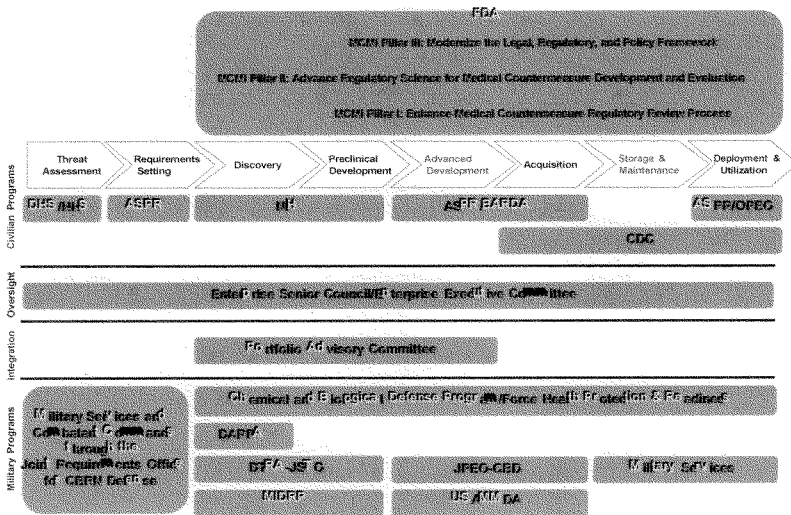


Source: U.S. Food and Drug Administration Strategic Priorities 2011-2015. April 20, 2011, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM252092.pdf>

Figure 2.

With respect to the Enterprise, FDA plays a primary role in the medical countermeasure mission from discovery through development to deployment and use (figure 3).

⁵⁴ *Ibid.* 38, pgs. 15-16.



FDA ensures that the medical countermeasures it regulates are safe and effective for their intended use(s) and that they meet specified quality standards. FDA also facilitates the development and availability of medical countermeasure by providing regulatory guidance and scientific and technical expert review of medical countermeasure product applications, with the goal of approving medical countermeasures. In addition, FDA fosters effective and timely responses to domestic or military emergencies with medical countermeasures that are available but not yet FDA-approved for the particular use contemplated through employment of a variety of regulatory mechanisms that allow for emergency use of such products. Furthermore, FDA supports the medical countermeasure mission by providing FDA subject matter expertise in various Enterprise partner committees and working groups that develop requirements, plans, priorities, and policies and conduct program oversight and integration.⁵⁵

The 2010 *Enterprise Review* called for greater investment in regulatory innovation and regulatory science and for FDA to take an even more active role in fostering the development and facilitating the deployment of medical countermeasures. In response, FDA launched its Medical Countermeasures Initiative (MCMi) to augment and better manage its ongoing medical countermeasure efforts. The mission of the MCMi is to promote the development of medical countermeasures by enhancing FDA's regulatory processes and fostering the establishment of clear regulatory pathways for medical countermeasures and to facilitate the timely use of available medical countermeasures by establishing effective regulatory policies and mechanisms.

MCMi ORGANIZATION

The MCMi builds on the substantial, ongoing medical countermeasures work at FDA and integrates new initiatives—as needed—based on the expected outcomes and elements of the 21st-Century Regulatory Science initiative as described in the *Enterprise Review*. FDA has organized the MCMi around an Action Plan built on a three pillar strategy that integrates medical countermeasure activities across FDA into a cohesive framework that enables improved strategic leadership and coordination of FDA's medical countermeasure activities (figure 4).

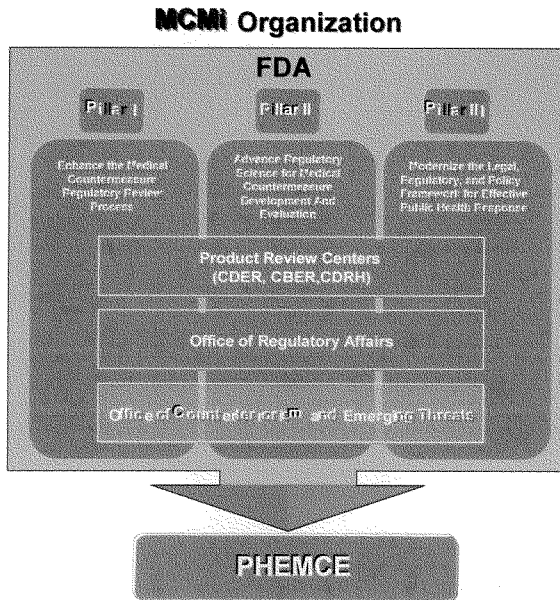


Figure 4

Pillar I: Enhance the Medical Countermeasure Regulatory Review Process

The goal of Pillar I is to advance the development of high-priority medical countermeasures and related technologies. FDA is pursuing this goal by increasing regulatory review capacity and expertise in the review divisions responsible for the evaluation of medical countermeasures and by establishing multidisciplinary Public Health and Security Action Teams. The Action Teams will work with sponsors, US government partners, and FDA review teams as appropriate to advance priority medical countermeasure development by tackling the range of regulatory, scientific and policy issues facing medical countermeasure development and approval.

Action Teams will be established as needed based on Enterprise priorities and may be charged with facilitating development of a *specific* medical countermeasure product, a *class or group* of medical countermeasure products, or to support the successful development of an important medical countermeasure technology. Action Teams will create collaborative environments within which to rapidly address both strategic and, as needed, special issues often associated with medical countermeasure development and approval. Action Teams will enhance the FDA review process by adding medical countermeasure-specific resources, such as scientists and other subject-matter experts, working collaboratively with the FDA review center Core Review Teams to help define and implement clear regulatory pathways, resolve regulatory science gaps that may currently impede medical countermeasure development, and align FDA's medical countermeasure regulatory strategy across products, programs, and Centers.

Pillar II: Advance Regulatory Science for Medical Countermeasure Development and Evaluation

The goal of Pillar II is to facilitate MCMi Pillar I and Pillar III activities by fostering medical countermeasure regulatory science intended to help develop solutions to complex scientific regulatory problems and facilitate the incorporation of new, cutting edge science into the regulatory review process to simplify and speed product development. Regulatory science is the applied research needed to develop and use new tools and standards to more efficiently develop and evaluate, through the regulatory review process, the safety, efficacy, and quality of medical products, including products suitable for at-risk populations (e.g., children, pregnant women, the elderly, and people with chronic health conditions).⁵⁶

The MCMi regulatory science program will focus on high-priority projects that are of value for public health and national security based on Enterprise partner priorities, including those that facilitate MCMi Pillar I and Pillar III activities. This program will have both internal and external research components. FDA maintains a strong intramural medical countermeasures regulatory science program in its three medical product centers and this program will be expanded and strengthened. FDA will also establish an extramural component to this program to engage

⁵⁶ *At-Risk Individuals*. Washington, DC: US Department of Health and Human Services. Available at <http://publichealthemergency.hhs.gov/Preparedness/planning/abc/Documents/AtRisk.pdf>. Accessed December 1, 2011.

entities outside of FDA (e.g., other US government agencies, academia, non-governmental organizations, and industry) in medical countermeasure regulatory science. Examples of scientific issues that this initiative will support include development and validation of novel manufacturing platforms; identification and qualification of animal models and surrogate measures of product efficacy; development of improved potency, sterility, and stability assays; development of standards for new point-of-care diagnostics; new approaches for statistical analyses of limited data sources; and new approaches for collecting and analyzing information about product use during emergencies.

Pillar III: Modernize the Legal, Regulatory, and Policy Framework for Effective Public Health Response

The goal of Pillar III is to ensure that US laws, regulations, and policies enable the application of advances in regulatory science to the regulatory review process and adequately support preparedness for and response to CBRN and EID threats. FDA will conduct a review of the strengths and weaknesses of the current legal, regulatory, and policy environment with respect to medical countermeasure development, distribution, administration, and use and, when changes are needed to better protect public health, FDA will work with appropriate partners to develop and propose new approaches.

Examples of the types of issues that this initiative will address—as identified in the *Enterprise Review*—include: (1) examining mechanisms for potential new or modified approaches for authorizing unapproved medical countermeasures that may be placed in the Strategic National Stockpile for use in emergencies; (2) examining approaches to minimize the need to issue emergency authorizations for unapproved uses of approved medical countermeasures; (3) identifying ways to collect product-related data during emergencies that may be useful in informing about the product’s safety and efficacy; and (4) assessing the current challenges posed by the Animal Efficacy Rule and identifying strategies to improve its implementation.

MCMi ROLES AND RESPONSIBILITIES

Office of Counterterrorism and Emerging Threats (OCET), Office of the Chief Scientist (OCS), Office of the Commissioner (OC)

OCET is responsible for providing strategic policy leadership and coordination for FDA’s counterterrorism and emerging threat portfolios and for working to identify and resolve complex scientific and regulatory challenges facing medical countermeasure development, approval, availability, and security.⁵⁷ The MCMi three pillar Action Plan is integrated into the existing OCET framework creating an OCET management structure that encompasses MCMi activities as well as OCET’s traditional strategic leadership and coordination functions within

⁵⁷ OCET’s mission is to facilitate the development and availability of safe and effective public health emergency medical countermeasures and establish policies to safeguard medical products from adulteration and prevent disruption of supplies as a result of terrorist activities.

FDA and in relation to the Enterprise, ensuring that the outputs of the MCMi inform updates to preparedness and response plans, address medical countermeasure needs not identified as Enterprise priorities (such as DoD specific medical countermeasure programs), and other liaison activities (such as coordinating Emergency Use Authorization activities).

Specific OCET roles and responsibilities within the MCMi include:

- Providing leadership, management, coordination, and accountability for the implementation of the MCMi
- Working in close partnership with FDA's three medical product centers—CDER, CBER, and CDRH—and the Office of Regulatory Affairs to manage and implement the MCMi
- Working with Enterprise partners to further medical countermeasure development and preparedness
- Facilitating relevant intra- and inter-agency communications

FDA Medical Product Centers

FDA's medical product centers are responsible for protecting the public health by ensuring the safety, effectiveness, and security of medical countermeasures including human and veterinary drugs, vaccines and other biological products, and medical devices under applicable federal laws.

- **Center for Drug Evaluation and Research (CDER)** - performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.
- **Center for Biologics Evaluation & Research (CBER)** - regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER protects and advances the public health by ensuring that biological products are safe and effective and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.
- **Center for Devices and Radiological Health (CDRH)** - is responsible for regulating firms who manufacture, repack, relabel, and/or import medical devices, such as *in vitro* diagnostics, sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as biodosimeters, lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

Specific FDA medical product center roles and responsibilities within the MCMi include:

- Working with medical countermeasure product sponsors on developing medical countermeasures
- Ensuring the reliability of Animal Rule efficacy studies and the integrity of the data generated to support the approval of drug and biologic medical countermeasures
- Reviewing medical countermeasure review submissions

- Working with OCET to implement and manage the three MCMi pillars
- Conducting intramural medical countermeasure regulatory science
- Working with Enterprise partners to further medical countermeasure development and preparedness

Office of Regulatory Affairs (ORA)

ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products. ORA is the lead office for all FDA Field activities as well as providing FDA leadership on imports, inspections, and enforcement policy. ORA supports FDA's medical product centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States. ORA also develops FDA-wide policy on compliance and enforcement and executes FDA's Import Strategy and Food Protection Plans.

Specific ORA roles and responsibilities within the MCMi include:

- Conducting inspections of medical countermeasure manufacturing sites
- Acting as subject matter experts for manufacturing quality issues on Action Teams, as needed

Appendix B: Alignments and Linkages

The following is a summary listing of key strategic drivers for the *MCMi Strategic Plan: 2012-2016*.

Strategy and Implementation Plans

- **National Security Strategy**, May 2010, available at http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf
- **National Strategy for Counterterrorism**, June 2011, available at http://www.whitehouse.gov/sites/default/files/counterterrorism_strategy.pdf
- **Quadrennial Homeland Security Review**, February 2010, available at http://www.dhs.gov/xlibrary/assets/qhsr_report.pdf
- **National Health Security Strategy**, December 2009, available at <http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf>
- **National Strategy for Countering Biological Threats**, November 2009, available at http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf
- **US Department of Health and Human Services Strategic Plan 2010-2015**, available at <http://www.hhs.gov/secretary/about/priorities/strategicplan2010-2015.pdf>
- **US Food and Drug Administration Strategic Priorities 2011-2015**, April 20, 2011, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM252092.pdf>
- **Advancing Regulatory Science at FDA: A Strategic Plan**, August 2011, available at <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM268225.pdf>
- **Advancing Regulatory Science for Public Health**, October 2010, available at <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM228444.pdf>
- **Center for Biologics Evaluation and Research Strategic Plan FY 2012 – 2016** (July 2011), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CBER/UCM266867.pdf>
- **ASPR Strategic Plan 2011-2015**, available at <http://www.phe.gov/about/aspr/strategic-plan/Pages/default.aspx>
- **The Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs**, August 2010, available at <https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf>
- **HHS Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats**, March 20, 2007, available at https://www.medicalcountermeasures.gov/BARDA/documents/federalreg_vol72no53_032007notices.pdf
- **HHS Public Health Emergency Medical Countermeasures Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats**, April 2007, available at https://www.medicalcountermeasures.gov/BARDA/documents/phemce_implplan_041607final.pdf
- **National Strategy for Pandemic Influenza**, November 2005, available at <http://www.pandemicflu.gov/professional/federal/pandemic-influenza.pdf>

- **National Strategy for Pandemic Influenza Implementation Plan**, May 2006, available at <http://www.pandemicflu.gov/professional/federal/pandemic-influenza-implementation.pdf>
- **HHS Pandemic Influenza Plan**, November 2005, available at <http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>
- **HHS Pandemic Influenza Implementation Plan**, November 2006, available at <http://www.hhs.gov/pandemicflu/implementationplan/pdf/Pandemic.pdf>
- **Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza**, August 2010, available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf>
- **NIAID Strategic Plan for Biodefense Research, 2007 Update**, September 2007, available at <http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/biosp2007.pdf>
- **NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats**, June 2005, available at <http://www.niaid.nih.gov/about/whoWeAre/Documents/radnucstrategicplan.pdf>
- **NIH Strategic Plan and Research Agenda for Medical Countermeasures against Chemical Threats, August 2007**, available at <http://www.niaid.nih.gov/topics/BiodefenseRelated/ChemicalCountermeasures/Documents/nihstrategicplanchem.pdf>

Presidential Policy Directives

- **PPD-8: National Preparedness**, March 30, 2011, available at http://www.dhs.gov/xabout/laws/gc_1215444247124.shtm

Homeland Security Presidential Directives

- **HSPD – 4: National Strategy to Combat Weapons of Mass Destruction**
- **HSPD – 10: Biodefense for the 21st Century**, April 28, 2004, available at http://www.dhs.gov/xabout/laws/gc_1217605824325.shtm
- **HSPD – 18: Medical Countermeasures against Weapons of Mass Destruction**, January 31, 2007, available at http://www.dhs.gov/xabout/laws/gc_1219175362551.shtm
- **HSPD – 21: Public Health and Medical Preparedness**, October 18, 2007, available at http://www.dhs.gov/xabout/laws/gc_1219263961449.shtm

Legislation

- **Public Health Security and Bioterrorism Preparedness and Response Act of 2002**, P.L. 107-188, June 12, 2002, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ188.107.pdf
- **Project BioShield Act of 2004**, P.L. 108-276, July 21, 2004, available at <http://www.gpo.gov/fdsys/pkg/PLAW-108publ276/pdf/PLAW-108publ276.pdf>
- **Public Readiness and Emergency Preparedness Act**, enacted as Division C of the Defense Appropriations Act for fiscal year 2006. PL No. 109-148, December 30, 2005, available at <http://www.gpo.gov/fdsys/pkg/PLAW-109publ148/pdf/PLAW-109publ148.pdf>

- *Pandemic and All-Hazards Preparedness Act*, P.L. 109-417, December 19, 2006, available at <http://www.gpo.gov/fdsys/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf>

Appendix C: Summary of MCMi Strategic Goals and Key Objectives

MCMi Strategic Goals 2012 - 2016	MCMi Key Objectives
Goal 1: Strengthen the Workforce and Improve the Infrastructure Necessary to Support the MCMi	Objective 1.1— Build the Workforce Necessary to Implement the MCMi
	Objective 1.2 – Develop and Sustain a Culture of Learning and Professional Development within FDA to Support the MCMi
	Objective 1.3 – Acquire the Infrastructure Necessary to Support the MCMi
Goal 2: Build and Sustain Integrated and Coordinated MCMi Programs	Objective 2.1 – Coordinate MCMi Program Implementation and Activities
	Objective 2.3 – Evaluate MCMi Program Execution
	Objective 3.1 – Engage MCMi Stakeholders in Developing MCMi Priorities
Goal 3: Actively Engage MCMi Stakeholders and Foster Transparency	Objective 3.2 – Establish and Maintain Strategic Partnerships to Further MCMi Program Goals and Objectives
	Objective 3.3 – Clearly Articulate MCMi Program Priorities and Timelines
	Objective 4.1 – Represent MCMi in Enterprise Strategic Planning and Policy Development
Goal 4: Integrate MCMi Program with Enterprise Public Health Preparedness Planning and Response Activities	Objective 4.2 – Coordinate MCMi Activities and Programs with Enterprise Response Activities
	Objective 5.1 – Establish Action Teams based on near-, mid-, and long-term Enterprise Priorities
Goal 5: Establish and Support Public Health and Security Action Teams	Objective 5.2 – Establish the Infrastructure and Policies to Support and Guide Action Team Activities
	Objective 6.1 – Assess and Prioritize Medical Countermeasure Regulatory Science Needs
Goal 6: Establish and Sustain a Medical Countermeasures Regulatory Science Program	Objective 6.2 – Strengthen and Sustain the Intramural FDA Medical Countermeasures Regulatory Science Program
	Objective 6.3 - Establish and Sustain an Extramural Medical Countermeasures Regulatory Science Program
	Objective 6.4 - Establish Processes to Maintain Effective Oversight of the Medical Countermeasures Regulatory Science Program
	Objective 7.1 – Identify Priorities for Modernizing the Legal, Regulatory, and Policy Framework for Effective Public Health Response
Goal 7: Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health Response	Objective 7.2 – Work with Enterprise Partners and External Stakeholders to Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health

Appendix D: Crosswalk of FDA Strategic Goals and Long-Term Objectives with MCMi Strategic Goals and Key Objectives

FDA Strategic Goals 2011 - 2015	FDA Long-Term Objectives	MCMi Strategic Goals 2012 - 2016	MCMi Key Objectives
3.2 Promote Public Health by Advancing the Safety and Effectiveness of Medical Products	3.2.1 Advance Human Drug Safety and Effectiveness 3.2.2 Advance Biologics Safety and Effectiveness 3.2.4 Advance Medical Device Safety and Effectiveness	Goal 4: Integrate MCMi Program with Enterprise Public Health Preparedness Planning and Response Activities	Objective 4.1 – Represent MCMi in Enterprise Strategic Planning and Policy Development Objective 4.2 – Coordinate MCMi Activities and Programs with Enterprise Response Activities
		Goal 5: Establish and Support Public Health and Security Action Teams (Action Teams)	Objective 5.1 – Establish Action Teams based on near-, mid-, and long-term Enterprise Priorities Objective 5.2 – Establish the Infrastructure and Policies to Support and Guide Action Team Activities
		Goal 6: Establish and Sustain a Medical Countermeasures Regulatory Science Program	Objective 6.1 – Assess and Prioritize Medical Countermeasure Regulatory Science Needs Objective 6.2 – Strengthen and Sustain the Intramural FDA Medical Countermeasures Regulatory Science Program Objective 6.3 – Establish and Sustain an Extramural Medical Countermeasures Regulatory Science Program Objective 6.4 – Establish Processes to Maintain Effective Oversight of the Medical Countermeasures Regulatory Science Program
			Objective 7.1 – Identify Priorities for Modernizing the Legal, Regulatory, and Policy Framework for Effective Public Health Response Objective 7.2 – Work with Enterprise Partners and External Stakeholders to Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health
3.4 Managing for Organizational Excellence and	3.4.1 Recruit, develop, retain, and strategically manage a world-class workforce	Goal 1: Establish the Workforce and Infrastructure Necessary to Support the	Objective 1.1— Build the Workforce Necessary to Implement the MCMi

FDA Strategic Goals 2011 - 2015	FDA Long-Term Objectives	MCMI Strategic Goals 2012 - 2016	MCMI Key Objectives
Accountability		MCMI	Objective 1.2 – Develop and Sustain a Culture of Learning and Professional Development within FDA to Support the MCMI
	3.4.2 Ensure program integrity and responsible stewardship through effective administration of fiduciary responsibilities	Goal 2: Build and Sustain Integrated and Coordinated MCMI Programs	Objective 2.1 – Coordinate MCMI Program Implementation and Activities Objective 2.3 – Evaluate MCMI Program Execution
		Goal 6: Establish and Sustain a Medical Countermeasures Regulatory Science Program	Objective 6.4 - Establish Processes to Maintain Effective Oversight of the Medical Countermeasures Regulatory Science Program
	3.4.3 Implement an information technology modernization program to support state-of-the-art networked information and shared data resources	Goal 1: Strengthen the Workforce and Improve the Infrastructure Necessary to Support the MCMI	Objective 1.3 – Acquire the Infrastructure Necessary to Support the MCMI
	3.4.4 Ensure facilities infrastructure provides dynamic capabilities	Goal 1: Strengthen the Workforce and Improve the Infrastructure Necessary to Support the MCMI	Objective 1.3 – Acquire the Infrastructure Necessary to Support the MCMI
	3.4.5 Improve the management of FDA by providing ongoing oversight, evaluation, and analysis of policies and programs and by ensuring effective strategic communications	Goal 3: Actively Engage MCMI Stakeholders and Foster Transparency	Objective 3.3 – Clearly Articulate MCMI Program Priorities and Timelines
	3.4.6 Foster a culture of continual business process improvement to improve the overall operation and effectiveness of FDA	Goal 2: Build and Sustain Integrated and Coordinated MCMI Programs	Objective 2.3 – Evaluate MCMI Program Execution
	3.4.7 Improve transparency, collaboration, and participation	Goal 3: Actively Engage MCMI Stakeholders and Foster Transparency	Objective 3.1 – Engage MCMI Stakeholders in Developing MCMI Priorities Objective 3.2 – Establish and Maintain Strategic Partnerships to Further MCMI Program Goals and Objectives Objective 3.3 – Clearly Articulate MCMI Program Priorities and Timelines

Appendix E: Acronyms

ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advance Research and Development Authority
CBRN	Chemical, Biological, Radiological, and Nuclear CBER
	Center for Biologics Evaluation and Research
CDC	US Centers for Disease Control and Prevention CDER
	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health DARPA
	Defense Advanced Research Projects Agency DTRA-JSTO
	Defense Threat Reduction Agency Joint Science and Technology Office
DHS	Department of Homeland Security
EID	Emerging Infectious Disease EUA
	Emergency Use Authorization
FDA	US Food and Drug Administration
HHS	US Department of Health and Human Services JPEO-CBD
	Joint Program Executive Office for Chemical and Biological Defense
MCMi	Medical Countermeasures Initiative MIDRP
	Military Infectious Diseases Research Program NIH
	US National Institutes of Health NHSS
	National Health Security Strategy
OCS	Office of the Chief Scientist OCET
	Office of Counterterrorism and Emerging Threats OPEO
	Office of Preparedness and Emergency Operations ORA
	Office of Regulatory Affairs
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
Action Teams	Public Health and Security Action Teams
PREP Act	Public Readiness and Emergency Preparedness Act
USAMMDA	US Army Medical Material Development Activity
WMD	Weapons of Mass Destruction



US Department of Health and Human
Services
Food and Drug Administration; Office of the
Commissioner
Office of the Chief Scientist; Office of Counterterrorism and Emerging
Threats
10903 New Hampshire
Ave
Silver Spring, MD
20993

45. Mr. Kingston: Provide a current update on the \$20,038,000 MCMi increase that the Congress provided to FDA in fiscal year 2012. Include a copy of the spend plan that accompanied this increase, and any modifications to that plan since it was submitted.

Response: FDA has continued to make progress under its MCMi using the \$20,038,000 increase Congress provided for Fiscal Year 2012 for MCMi activities. Our MCMi accomplishments in Fiscal Year 2012 to date include sustaining Action Teams for in-vitro diagnostic tests and acute radiation syndrome and establishing Action Teams for warfighter-trauma care, pediatric, pregnancy, and special populations, and next-generation assessment of medical countermeasure safety and performance during public health emergencies. Action Teams are multidisciplinary teams intended to identify and help resolve scientific, legal, regulatory, and policy gaps inhibiting the development of medical countermeasures. Our Acute Radiation Syndrome Action Team achieved a major milestone in February 2012 when FDA finalized the pre-Emergency Use Authorization package for an acute radiation syndrome medical countermeasure held in the Strategic National Stockpile. Finalizing this pre-Emergency Use Authorization package will facilitate the use of this medical countermeasure in case of a radiological or nuclear event.

FDA's MCMi also held a public workshop on the ethical and regulatory challenges in the development of pediatric medical countermeasures in February 2012. Future FY 2012 activities include a workshop on radiation biodosimetry in September 2012, an Advisory Committee meeting for antibiotic MedKits, and an Advisory Committee meeting on plague medical countermeasure in April 2012.

Additionally, FDA's MCMi has continued to strengthen its MCM regulatory science program. For example, FDA was recently authorized to become a member of the National Interagency Confederation for Biological Research. This action strengthens FDA's regulatory science partnership with the Department of Defense. The NICBR is a collaborative effort to coordinate and synchronize scientific interaction among Federal partners to enhance public health, medical research, and biotechnology development.

The following document is a copy of the spend plan for the \$20.038 million FY 2012 appropriation for the MCMi, which has not been modified since it was submitted to the subcommittee in January 2012.

FY 2012 Medical Countermeasures Increases Report on Funding Allocations, Outputs and Performance Budget Authority – Dollars in Thousands					
A. Medical Countermeasures (MCM) Priority	B. Center / Field Allocation	C. FTE	D. FDA Activity	E. FDA Performance	F. Public Health Benefit
MCM Objective I - Enhance Review Process	\$4,389	34	Establish Public Health and Security Action Teams to support enhanced review of the highest priority medical countermeasures, novel approaches to manufacturing, and related technologies to address the most pressing national security requirements.	Sustain Action Teams for in vitro diagnostics and acute radiation syndrome. Establish Action Teams for pediatric and maternal health, MCM surveillance, animal models, and mass casualty trauma care. Finalize analysis of the regulatory gaps associated with the development of critical MCM products to help ensure that the USG	Enhanced engagement with MCM developers and government partners will: o help FDA identify and resolve gaps that prevent successful MCM development and approval o facilitate the development of critical MCM products o help ensure that the USG
OC	\$2,185	8			
MCM Objective II - Advance MCM Regulatory Science	\$5,910	18	Establish an extramural MCM regulatory science program that included robust collaborations with MCM Enterprise partners such as the Department of Defense	Launch the extramural component of the MCM regulatory science program with a focus on tools to assess effectiveness, MCM product quality, and diagnostics Work with Enterprise partners to fill data needs associated with the development of pre-EUA pac	Building strategic partnerships with industry, academia and U.S. government (USG) partners will allow FDA to harness cutting-edge science and apply innovative approaches to the regulatory process to improve MCM development timelines and success rates.
OC	\$250	1			
OC	\$3,494	12			
MCM Objective III - Modernize Legal, Regulatory and Policy Framework	\$4,389	17	Work collaboratively with HHS to examine the legal framework and the regulatory and policy approaches for MCM development and availability to ensure these adequately support emergency preparedness and response	Issue a revised guidance on Animal Models—Essential Elements to Address Efficacy Under the Animal Rule Continue to identify legal barriers to MCM development and accessibility and propose solutions Establish MOUs with Enterprise partners to be	Modernizing the legal, regulatory, and policy framework will foster the application of advances in regulatory science to the regulatory review process, and thus help to ensure timely access to MCMs needed to prepare for and quickly respond to CBRN and
OC	\$280	1			
OC	\$246	1			
OC	\$500	2			
OC	\$3,354	13	Pay GSU Team and Other Staff and Reinforced costs for the facilities that support MCM program activities and the new employees hired under the MCM		Funding these rent activities will replace the need for FDA to redirect resources from other mission-critical public health activities to pay rent costs
Rent Activities	\$ 1,298				
Total	\$ 20,038	70			

New User Fees

46. Mr. Kingston: For each of the new user fees that FDA proposes for fiscal year 2013, provide the following:

Proposed legislative language;

the way in which proposed fee amounts were derived;

the customer (s);

estimated number of fee paying applicants;

estimated fiscal year 2012 spending on current FDA-related activity;

programs/activities that the fee will support, including FTE, by center/field; and, estimated collections.

Response: Regarding the Medical Products Reinspection User Fee, FDA does not have proposed authorizing language for medical product reinspection user fees at this time; however, I can describe the proposal under discussion. FDA will continue its work to develop a legislative proposal and will also engage with stakeholders to develop a fee proposal.

FDA will impose a full-cost recovery fee on medical product manufacturers to fully fund reinspections of facilities found, by inspection, to be out of compliance with regulations governing current Good Manufacturing Practices – GMPs – or other applicable statutory or regulatory requirements.

The customers are medical products manufacturers.

The estimated number of fee paying applicants is 800.

The domestic inventory of medical product establishments is 16,350.

The estimated fiscal year 2012 spending on current FDA-related activity is \$20 million.

The programs/activities that the fee will help support are: \$7 million for 46 field investigators and staff; \$6.2 million for Headquarters indirect and support costs – such as legal, science review, and IT – and 10 FTE; and \$1.5 million for GSA Rent and Rent Related costs.

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 reinspect firms that fail to comply with FDA regulations that are designed to protect the public from unsafe products.

The estimated collections are \$14.8 million.

Regarding the International Courier User Fee, FDA does not have proposed authorizing language for this user fee at this time. FDA will continue its work to develop a legislative proposal and will also engage with stakeholders to develop a fee proposal.

The fees will be assessed and resources will be allocated based on historical entry volumes by courier.

The customers are several large couriers offering international service with next-day delivery, who have requested that FDA increase staffing to help meet their business needs.

The estimated number of fee paying applicants is primarily the five largest express courier companies: – FedEx, UPS, DHL, Purolator, and TNT. These companies handle millions of shipments of FDA-regulated commodities, predominantly medical products, entering the United States through their facilities, and the number continues to grow.

The estimated fiscal year 2012 spending on current FDA-related activity is \$5.5 million for staffing after hours and on weekends.

The programs/activities that the fee will support are \$4.8 million and 20 field FTEs to conduct entry reviews, sample collections, and physical exams to determine product admissibility into the U.S.; initiate actions to prevent release of unsafe products into U.S. commerce; and establish import controls to help 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.

The estimated collections are \$5.6 million.

Regarding the Cosmetic Safety User Fee, FDA does not have proposed authorizing language to establish a system of user fees to support the FDA Cosmetics Safety Program. FDA will continue its work to develop a legislative proposal and will also engage with stakeholders to develop a fee proposal.

The user fee request represents the level of resources required to administer these additional authorities for cosmetic safety.

The customers are the cosmetic product consumers and industry.

The estimated number of fee paying applicants is unknown. While more than 1,600 cosmetic establishments have registered voluntarily with FDA, covering over 39,000 products, 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.

The estimated fiscal year 2012 spending on current FDA-related activity is approximately \$11.9 million and 51 FTE.

FDA will conduct Center for Food Safety and Applied Nutrition – CFSAN – and ORA activities with the new user fee resources. The fees provide \$12.0 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 \$4.3 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 \$980,000 and 3 FTE for program support activities and \$1.4 million for rent activities.

A fee structure would be developed through negotiations with industry.

Regarding the Food Contact Notification – FCN – User Fee, FDA does not have proposed authorizing language for this user fees at this time. However, the proposal would authorize the Food and Drug Administration to establish a system of user fees to support the food contact substance safety review program. FDA will continue its work to develop a legislative proposal and will also engage with stakeholders to develop a fee proposal.

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.

The customers are consumers and food contact product industry, including food manufacturers, distributors, and marketers

In estimating the number of fee paying applicants, annually, there is an average of 94 new FCN filings, with 79 becoming effective. As of December 2011, there were 888 effective FCNs.

The estimated fiscal year 2012 spending on current FDA-related activity is 6.7 million and 16 FTE.

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 \$267,000 and 1 FTE for program support and \$176,000 for rent activities.

A user fee system for the FCN program is expected to generate approximately \$4.9 million in the first year.

Regarding the Generic Drug User Fee – GDUFA, the proposed legislative language was sent to Congress on January 13, 2012, and is available on FDA’s website.

For GDUFA, as in PDUFA, individual fee amounts will vary each year, but the overall program revenue is specified by statute. In GDUFA, that is an inflation-adjusted \$299 million per year, which was the amount needed to undertake the performance commitments and goals that FDA committed to in the goals letter that is also posted on FDA’s website, and that was also provided to Congress on January 13, 2013, with the proposed legislative language.

FDA and the industry trade associations based the projections on an estimated 2,000 finished dosage form and active pharmaceutical ingredient facilities supporting Abbreviated New Drug Applications – ANDAs. The parties projected approximately 750 ANDAs per year, along with 750 prior approval supplements and 350 Type II Active Pharmaceutical Drug Master Files.

With the user fee resources, FDA will enhance and expand business processes key to improving the generics program and invest in much-needed IT and other technology infrastructure, as well as hire additional staff for generic review and inspections and compliance activities. There is no single budget line that corresponds to all costs attributable to the generic drugs program and FDA has not finalized its implementation plan.

Regarding the Biosimilars User Fee, the proposed legislative language was sent to Congress January 13, 2012.

To derive proposed fee amounts, application, product, and establishment fees for biosimilar biological products are set equal to the application, product, and establishment fee amounts established under PDUFA for that fiscal year. However, portions of the application fee are paid during the developmental phase of the proposed biosimilar product. These development-phase fees are called biosimilar biological product development fees. When a biosimilar biological product application is submitted for a product, the cumulative amount of any biosimilar biological product development fees paid for that product are subtracted from the amount of the application fee that would otherwise be due.

The biosimilars industry and regulatory program are both relatively new, leading to uncertainty and variability in estimates of future program and industry size.

The estimated fiscal year 2012 spending on current FDA-related activity for the biosimilars program is \$8.158M.

Biosimilars user fees would support FDA activities related to the review of submissions in connection with biosimilar biological product development, biosimilars biological product applications, and supplements. This work would include biosimilar product development meetings and activities related to investigational new drug applications – INDs, and issuing action letters that communicate decisions on biosimilar product applications. Once biosimilar biological products are on the market, fees would also support post-market safety activities as they do in the PDUFA program. Additionally, fees would support development of the scientific, regulatory, and policy infrastructure necessary for review of biosimilar biological product applications, such as regulation and policy development related to the review of biosimilar biological product applications, and development of standards for products subject to review and evaluation.

Regarding the Food Establishment Registration Fee, FDA does not have proposed authorizing language for this user fee at this time. However, the proposal will authorize the Food and Drug Administration to establish a system of food establishment registration user fees to support food safety activities. FDA will continue its work to develop a legislative proposal and will also engage with stakeholders to develop a fee proposal.

The Food Establishment Registration User Fee structure would be developed through negotiations with industry. A registration fee system for food establishments would be developed with a target revenue of approximately \$220 million annually.

The customers are consumers and the food industry.

Estimated number of fee paying applicants is based on Domestic Establishments – estimated at 175,000, plus Foreign Establishments – estimated at 265,000, for a total estimate of 440,000.

The estimated fiscal year 2012 spending on current FDA-related activity is \$853.2 million.

The programs/activities that the fee will support are: establishing new, effective, and comprehensive food safety standards; establishing a new program for import safety; increasing the number and efficiency of inspections; launching an integrated national food safety system with states and localities; expanding research activities, including improved data collection and risk analysis; and maintaining a current facilities

registration database and supporting other information technologies to improve FDA's risk-based decision capabilities.

The fees will support CFSAN at \$89.5 million and 100 FTE; CVM at \$5.7 million and 11 FTE; ORA at \$104.1 million and 130 FTE; Headquarters Program Support at \$12.5 million and 32 FTE; and rent activities at \$8.4 million, for a total of \$220.2 million and 273 FTE.

The Food Establishment Registration User Fee is expected to generate \$220 million annually in collections.

Generic Drugs

47. Mr. Kingston: The GAO released a report regarding the cost savings of prescription drugs. The report said that the use of generic drugs "had mixed results regarding the effect of using these generics, in that some found they raised healthcare costs, while others found they led to cost savings." Did the FDA anticipate this study before submitting the proposal for generic drug user fees? If not, does the study have any impact on FDA's ability to win approval for these user fees?

Response: FDA did not anticipate this study before submitting the proposal for generic drug user fees, nor does it have an impact on FDA's need or commitment to these user fees. As stated in the proposed Generic Drug User Fee Agreement, the purpose of the proposed Generic Drug User fee is "to help FDA ensure that participants in the U.S. generic drug system comply with U.S. quality standards, and to increase the likelihood that American consumers get timely access to low cost, high quality generic drugs," Regarding access to generic drugs, the purpose of the User Fee Agreement is to "expedite the availability of low cost, high quality generic drugs by bringing greater predictability to the review times for abbreviated new drug applications, amendments and supplements, increasing predictability and timeliness in the review process."

The GAO report examined three groups of studies regarding the cost savings of prescription drugs. The conclusion regarding mixed results was with respect to the third group of studies examined in the GAO report. The first group of studies estimated the savings in reduced drug costs that have accrued from the uses of generics. One of these studies found that substituting generic drugs for their brand name counterparts saved more than \$1 trillion in the U.S. health care system from 1999 through 2010. The second group of studies estimated the potential to save more on drugs through greater use of generics. Their review of the literature confirms that generics have had a positive impact on drug expenditures, and that their greater use would have an even larger positive impact on such expenditures. The third group consisted of studies that estimated the impact of overall healthcare costs. Upon reviewing the GAO report we feel that more research is needed regarding this third group of studies. GAO cites only four studies on

this topic. Two of these studies looked at generic substitution of a small subset of drugs with narrow therapeutic index. One study of such drugs found cost savings and the other one found added healthcare costs. The remaining two studies looked at therapeutic substitution in select-serotonin reuptake inhibitors -SSRIs-. Again, one study found cost savings while the other one found potential cost increases.

48. Mr. Kingston: How much does FDA plan to spend in fiscal year 2012 on generic drug approvals?

Response: According to the FY2013 President's budget, the estimated Fiscal Year 2012 spending on current FDA-related activity for the generic drugs program is \$105.7 million. In addition to this amount, FDA will expend other resources on generic drug approvals, such as expenditures for inspections and consults from other parts of the agency during the generic drug review process.

Biosimilars

49. Mr. Kingston: Similarly, questions have been raised about healthcare cost-savings with the biosimilars proposal in FDA's budget. Does the FDA anticipate that having a biosimilars program in place will save on healthcare costs?

Response: FDA anticipates that having a dedicated biosimilars program in place will ultimately reduce the cost of therapeutic biological products and increase patient access to these products because it will facilitate product development and expedite review. For example, the program would provide FDA with the resources needed to clarify the policies and pathways for biosimilar biological product development, including through development of guidance and regulation and through detailed review and feedback to sponsors during the development phase of their products. This initiative will help sponsors identify the most efficient next steps in analysis or data collection to demonstrate biosimilarity. The program would also facilitate the review of marketing applications within predictable timeframes.

50. Mr. Kingston: How much is FDA spending in fiscal year 2012 on biosimilars?

Response: The estimated fiscal year 2012 spending on current FDA-related activity for the biosimilars program is \$8.2 million.

Orange Book

51. Mr. Kingston: Public Law 110-379 included a provision that enabled the FDA to award 3 years of extra Hatch-Waxman exclusivity for antibiotics which have received FDA approval for labeling changes resulting from new clinical data. FDA is currently reviewing a request for such exclusivity on an antibiotic with new clinical labeling approved this past December. Does the FDA have a timeline for completing this review? When will FDA make a decision?

Response: FDA is currently evaluating a request for a three-year exclusivity period for changes to an antibiotic product's labeling that FDA approved in December 2011. The relevant statutory and regulatory provisions require FDA to consider complex scientific, legal, and regulatory questions in evaluating any claim for three-year exclusivity. FDA anticipates making a determination on this exclusivity request in the near future.

Medical Device User Fee Reauthorization

52. Mr. Kingston: Dr. Hamburg you have stated that FDA and the medical device industry have reached an agreement in principle on reauthorization of medical devices. At what point, do you remove the qualifier from this statement and send the legislation to the Congress?

Response: I am happy to report that we have completed negotiations with the medical device industry and have reached agreement on the complete set of draft recommendations. The full set of draft recommendations will be available for public comment for 30 days, as required by 21 U.S.C. 738A of the Federal Food, Drug, and Cosmetic Act. After the public comment period ends, which we anticipate to be in mid-April, we will complete our analysis and consideration of the comments and make any revisions to the recommendations if warranted. We expect to transmit the final recommendations to Congress by late April.

53. Mr. Kingston: Do you foresee any major hangups at OMB? If so, what are they?

Response: I do not expect any major problems with the Administration review and clearance, and I am pleased with the expedited review that the Office of Management and Budget is providing, in close coordination with the Department of Health and Human Services and other agencies.

54. Mr. Kingston: Can you outline for the Subcommittee the agreement, and highlight some of the elements that are going to be key factors in driving the success of this new agreement?

Response: The agreement we reached with the medical device industry reflects a number of important improvements to the user fee program that strike a careful balance

between the amount of fees that industry is willing to pay and the level of improvement in performance to which FDA can commit for the agreed-upon level of resources. Highlights of the agreement include:

- more transparent and predictable interactions between FDA and medical device manufacturers, both before they submit an application and during the review process;
- development of guidance on objective acceptance criteria and improved screening procedures that will ensure that FDA accepts for review only those submissions that are complete;
- a streamlined structure for FDA review goals, with a single target timeline for each submission type; and if we miss a target timeline for the review of a submission by more than several days, a commitment to communicate with the applicant about a plan for completing the review;
- shared outcome goals in which both FDA and the medical device industry will strive to reduce the total elapsed calendar time to decisions for premarket notifications – otherwise known as 510(k) submissions – and Premarket Approval applications, or PMAs;
- more detailed reporting of program performance; and
- an independent assessment of the pre-market review program, and a corrective action plan, to ensure that FDA stays on track to meet the performance commitments in the agreement.

55. Mr. Kingston: How will FDA review times improve under the new agreement?

Response: In this new agreement, FDA will increase the percentage of 510(k) reviews that are completed in 90 review days, from the current 90 percent to 95 percent by fiscal year 2015. FDA will increase the percentage of PMA reviews that are completed within 180 review days from the current 60 percent to 90 percent by fiscal year 2016 for those PMAs that do not require review by an external advisory panel. For PMAs that do undergo review by an advisory panel, we will complete 90 percent of the reviews within 320 review days by fiscal year 2017 – a significant improvement over our current performance, which is less than 50 percent within 320 days for these applications.

Perhaps most importantly, FDA and the medical device industry have jointly committed to shared outcome goals to reduce the average total elapsed calendar days from the acceptance of a submission to the final decision for original PMA and 510(k) submissions, regardless of whether the review was placed on “hold” while the applicant addresses questions about their submission. Based on the definitions in the draft Commitment Letter, the shared outcome goal is to achieve an average total time of 135

days for 510(k) submissions received in fiscal year 2013, which is reduced to an average of 124 days for submissions received in fiscal year 2017. Similarly, FDA and the industry agreed to achieve a three-year average total time of 395 days for PMA submissions received in fiscal years 2011 through 2013, which will be reduced to a three-year average of 385 days for the PMA submissions received in fiscal years 2015 through 2017.

These improvements in review times will improve public health by providing patients and health care providers with more timely access to safe and effective medical devices.

56. Mr. Kingston: What type of process improvements will be made that will improve the consistency and timeliness of the approval process?

Response: This new agreement will improve the transparency, consistency, timeliness, and predictability of the medical device review process.

First, we are improving the process by which we provide guidance and device-specific advice to manufacturers before they submit applications to FDA. This should better clarify our review requirements up front, before the manufacture invests significant time and resources in studies and tests that produce the data we review.

Second, we are enhancing our initial acceptance criteria and screening procedures to include an objective and efficient basis for determining submission quality and completeness, which will save resources and time from being wasted on reviewing submissions that do not meet our standards.

Third, we are putting in place standard interim milestones for completing the initial review well ahead of our target timeline for reaching a decision, and clarifying our procedures for having a substantive interaction with the applicant at that interim milestone, so that we can work out any additional information requirements in a timely and efficient manner.

Fourth, we have committed to additional interactions with applicants if FDA's review of a 510(k) or PMA submission misses the target review timeline by more than 10 or 20 days, respectively. FDA will provide written feedback to the applicant regarding all outstanding issues that must be addressed to allow FDA to reach a decision, and we will discuss these requirements with the applicant.

FDA also committed to improving the technical guidance development process to provide enhanced opportunities for input from stakeholders, and to clarify which existing guidance documents are currently under review and therefore may be updated to reflect new scientific knowledge or regulatory experience.

Finally, we committed to engaging a consultant to conduct an independent assessment of the device review program to assure that we are managing the program effectively and efficiently.

QUESTION SUBMITTED BY CHAIRMAN JACK KINGSTON

FDA Pay Awards and Bonuses

Please provide for the record a summary of total bonus and award resources (total number of awards/bonuses and dollar amount) for every position type (i.e., SES, SL/ST, GS, etc.) for each center and office as described in the appropriations language accompanying the FDA account for fiscal years 2010 and 2011. Provide a separate breakout for excepted positions. Do not exclude any type of bonus or award payment (e.g., include all types of monetary payments, including incentives, individual and group awards, bonuses, performance awards, Presidential Rank Awards, etc.). In addition to the summary level data, provide the Subcommittee with an electronic file (excel format) containing the data requested above on an individual basis without personally identifiable information. Lastly, for each center and office as described in the appropriations language accompanying the FDA account, provide the Subcommittee with the total number of promotions, within-grade increases or promotion equivalents) for fiscal years 2009, 2010, and 2011.

Response: I am happy to provide the data you requested for FDA Pay Awards and Bonuses.

[The information follows:]

1)Summary of Pay Awards and Bonuses by FDA Component for FYs 2010 and 2011 with a separate breakout for Excepted Service employees. The Excepted Service employee awards and bonuses are also included in the overall summary for all employees.

U.S. Department of Health and Human Services
FDA Pay Awards and Bonuses (Excepted Positions)
Incentives Paid between PP 21,2009 through PP 20, 2010
PP Ending Dates: 10/10/2009 - 09/25/2010

<u>NAME</u>	<u>ADMIN CD PP</u>	<u>CASH AWARD</u> <u>AMT</u>	<u>RECRUITMENT</u> <u>BONUS</u>	<u>RELOCATION</u> <u>BONUS</u>	<u>RETENTION</u> <u>BONUS</u>
CENTER FOR DEVICES & RADIOLOGICAL HEALTH					
PAY PLAN: AD					
<i>CDRH/AD Incentive Paid</i>		\$188,515.00	\$40,000.00	\$0.00	\$0.00
<i>Amount</i>					
<i>CDRH/AD Cash Award</i>		167			
<i>Count</i>					

<i>CDRH/AD Employee Count</i>		1	0	0
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: EG

<i>CDRH/EG Incentive Paid</i>	\$2,841.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				

<i>CDRH/EG Cash Award</i>	2			
<i>Count</i>				

<i>CDRH/EG Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: GP

<i>CDRH/GP Incentive Paid</i>	\$21,373.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				

<i>CDRH/GP Cash Award</i>	18			
<i>Count</i>				

<i>CDRH/GP Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: GS

<i>CDRH/GS Incentive Paid</i>	\$42,987.00	\$0.00	\$0.00	\$1,048.48
<i>Amount</i>				

<i>CDRH/GS Cash Award</i>	51			
<i>Count</i>				

<i>CDRH/GS Employee Count</i>		0	0	1
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: RS

<i>CDRH/RS Incentive Paid</i>	\$10,429.80	\$0.00	\$0.00	\$0.00
<i>Amount</i>				

<i>CDRH/RS Cash Award</i>	5			
<i>Count</i>				

<i>CDRH/RS Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

<i>CDRH Incentive Paid</i>	\$266,145.80	\$40,000.00	\$0.00	\$1,048.48
<i>Amount</i>				

<i>CDRH Cash Award Count</i>	243			
-------------------------------------	-----	--	--	--

<i>CDRH Employee Count</i>		1	0	1
<i>with 3Rs Incentive (distinct)</i>				

CENTER FOR DRUG EVALUATION & RESEARCH
PAY PLAN: AD

<i>CDER/AD Incentive Paid</i>	\$462,340.00	\$42,292.00	\$0.00	\$58,202.96
<i>Amount</i>				
<i>CDER/AD Cash Award</i>	356			
<i>Count</i>				
<i>CDER/AD Employee Count</i>		4	0	7
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: EG

<i>CDER/EG Incentive Paid</i>	\$900.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>CDER/EG Cash Award</i>	1			
<i>Count</i>				
<i>CDER/EG Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: GP

<i>CDER/GP Incentive Paid</i>	\$178,471.00	\$49,064.00	\$0.00	\$0.00
<i>Amount</i>				
<i>CDER/GP Cash Award</i>	105			
<i>Count</i>				
<i>CDER/GP Employee Count</i>		3	0	0
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: GS

<i>CDER/GS Incentive Paid</i>	\$23,190.00	\$0.00	\$0.00	\$60,280.24
<i>Amount</i>				
<i>CDER/GS Cash Award</i>	27			
<i>Count</i>				
<i>CDER/GS Employee Count</i>		0	0	6
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: RS

<i>CDER/RS Incentive Paid</i>	\$3,103.20	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>CDER/RS Cash Award</i>	1			
<i>Count</i>				
<i>CDER/RS Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

CDER Incentive Paid	\$668,004.20	\$91,356.00	\$0.00	\$118,483.20
----------------------------	---------------------	--------------------	---------------	---------------------

Amount

CDER Cash Award Count	490			
CDER Employee Count with 3Rs Incentive (distinct)		7	0	13

CENTER FOR FOOD SAFETY & APPLIED NUTRITION**PAY PLAN: AD**

<i>CFSAN/AD Incentive Paid</i>	\$193,457.00	\$0.00	\$0.00	\$7,121.51
<i>Amount</i>				
<i>CFSAN/AD Cash Award</i>	93			
<i>Count</i>				
<i>CFSAN/AD Employee</i>		0	0	1
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: GS

<i>CFSAN/GS Incentive Paid</i>	\$9,920.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>CFSAN/GS Cash Award</i>	10			
<i>Count</i>				
<i>CFSAN/GS Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: RS

<i>CFSAN/RS Incentive Paid</i>	\$2,507.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>CFSAN/RS Cash Award</i>	2			
<i>Count</i>				
<i>CFSAN/RS Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				

CFSAN Incentive Paid	\$205,884.00	\$0.00	\$0.00	\$7,121.51
Amount				
CFSAN Cash Award	105			
Count				
CFSAN Employee Count with 3Rs Incentive (distinct)		0	0	1

CENTER FOR TOBACCO PRODUCTS

PAY PLAN: AD

CTP/AD Incentive Paid	\$4,164.00	\$0.00	\$0.00	\$0.00
Amount				
CTP/AD Cash Award Count	3			
CTP/AD Employee Count		0	0	0
with 3R Incentive (distinct)				

PAY PLAN: GS

CTP/GS Incentive Paid	\$1,972.00	\$0.00	\$0.00	\$0.00
Amount				
CTP/GS Cash Award Count	2			
CTP/GS Employee Count		0	0	0
with 3R Incentive (distinct)				

CTP Incentive Paid	\$6,136.00	\$0.00	\$0.00	\$0.00
Amount				
CTP Cash Award Count	5			
CTP Employee Count		0	0	0
with 3Rs Incentive (distinct)				

CTR FOR BIOLOGICS EVALUATION & RESEARCH

PAY PLAN: AD

CBER/AD Incentive Paid	\$280,617.00	\$0.00	\$0.00	\$3,973.74
Amount				
CBER/AD Cash Award	176			
Count				
CBER/AD Employee Count		0	0	1
with 3R Incentive (distinct)				

PAY PLAN: GP

CBER/GP Incentive Paid	\$13,013.00	\$0.00	\$0.00	\$0.00
Amount				
CBER/GP Cash Award	10			
Count				
CBER/GP Employee Count		0	0	0
with 3R Incentive (distinct)				

PAY PLAN: GS

CBER/GS Incentive Paid	\$19,903.00	\$0.00	\$0.00	\$0.00
Amount				
CBER/GS Cash Award	21			

Count

<i>CBER/GS Employee Count</i>	0	0	0
<i>with 3R Incentive (distinct)</i>			

CBER Incentive Paid Amount	\$313,533.00	\$0.00	\$0.00	\$3,973.74
CBER Cash Award Count	207			
CBER Employee Count with 3Rs Incentive (distinct)	0	0	1	

CTR FOR VETERINARY MEDICINE**PAY PLAN: AD**

<i>CVM/AD Incentive Paid</i>	\$80,148.00	\$0.00	\$0.00	\$0.00
------------------------------	--------------------	---------------	---------------	---------------

Amount

<i>CVM/AD Cash Award</i>	50
--------------------------	-----------

Count

<i>CVM/AD Employee Count with 3R Incentive (distinct)</i>	0	0	0
---	---	---	---

PAY PLAN: GS

<i>CVM/GS Incentive Paid</i>	\$13,223.00	\$0.00	\$0.00	\$750.88
------------------------------	--------------------	---------------	---------------	-----------------

Amount

<i>CVM/GS Cash Award</i>	13
--------------------------	-----------

Count

<i>CVM/GS Employee Count with 3R Incentive (distinct)</i>	0	0	1
---	---	---	---

CVM Incentive Paid Amount	\$93,371.00	\$0.00	\$0.00	\$750.88
CVM Cash Award Count	63			
CVM Employee Count with 3Rs Incentive (distinct)	0	0	1	

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH**PAY PLAN: AD**

<i>NCTR/AD Incentive Paid</i>	\$65,996.00	\$0.00	\$0.00	\$0.00
-------------------------------	--------------------	---------------	---------------	---------------

Amount

<i>NCTR/AD Cash Award</i>	51
---------------------------	-----------

Count

<i>NCTR/AD Employee Count with 3R Incentive (distinct)</i>	0	0	0
--	---	---	---

PAY PLAN: GS

<i>NCTR/GS Incentive Paid</i>	\$3,315.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>NCTR/GS Cash Award</i>	3			
<i>Count</i>				
<i>NCTR/GS Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: RS

<i>NCTR/RS Incentive Paid</i>	\$18,179.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>NCTR/RS Cash Award</i>	9			
<i>Count</i>				
<i>NCTR/RS Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

NCTR Incentive Paid	\$87,490.00	\$0.00	\$0.00	\$0.00
Amount				
NCTR Cash Award Count	63			
NCTR Employee Count		0	0	0
with 3Rs Incentive (distinct)				

OFC OF REGULATORY AFFAIRS

PAY PLAN: AD

<i>ORA/AD Incentive Paid</i>	\$76,323.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>ORA/AD Cash Award</i>	21			
<i>Count</i>				
<i>ORA/AD Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: GS

<i>ORA/GS Incentive Paid</i>	\$116,399.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>ORA/GS Cash Award</i>	263			
<i>Count</i>				
<i>ORA/GS Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

ORA Incentive Paid	\$192,722.00	\$0.00	\$0.00	\$0.00
Amount				

ORA Cash Award Count	284			
ORA Employee Count		0	0	0
with 3Rs Incentive				
(distinct)				

OFC OF THE COMMISSIONER

PAY PLAN: AD

<i>OC/AD Incentive Paid</i>	\$107,150.00	\$0.00	\$0.00	\$45.36
-----------------------------	---------------------	---------------	---------------	----------------

Amount

<i>OC/AD Cash Award Count</i>	21			
<i>OC/AD Employee Count</i>		0	0	1
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: GP

<i>OC/GP Incentive Paid</i>	\$3,800.00	\$0.00	\$0.00	\$0.00
-----------------------------	-------------------	---------------	---------------	---------------

Amount

<i>OC/GP Cash Award Count</i>	2			
<i>OC/GP Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

PAY PLAN: GS

<i>OC/GS Incentive Paid</i>	\$40,861.00	\$0.00	\$0.00	\$0.00
-----------------------------	--------------------	---------------	---------------	---------------

Amount

<i>OC/GS Cash Award Count</i>	50			
<i>OC/GS Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				

OC Incentive Paid	\$151,811.00	\$0.00	\$0.00	\$45.36
Amount				

OC Cash Award Count	73			
OC Employee Count with		0	0	1
3Rs Incentive (distinct)				

Incentive Paid Amount	\$1,985,097.00	\$131,356.00	\$0.00	\$131,423.17
Grand Total				
Total Cash Award Count	1,533			
Total Employee Count with		8	0	18
3Rs Incentive (distinct)				

U.S. Department of Health and Human Services

FDA Pay Awards and Bonuses

Incentives Paid between PP 21,2009 through PP 20, 2010
PP Ending Dates: 10/10/2009 - 09/25/2010

<u>NAME</u>	<u>ADMIN PP</u> <u>CD</u>	<u>CASH AWARD</u> <u>AMT</u>	<u>RECRUITMENT</u> <u>BONUS</u>	<u>RELOCATION</u> <u>BONUS</u>	<u>RETENTION</u> <u>BONUS</u>
CENTER FOR DEVICES & RADIOLOGICAL HEALTH					
PAY PLAN: AD					
<i>CDRH/AD Incentive</i>		\$188,515.00	\$40,000.00	\$0.00	\$0.00
<i>Paid Amount</i>					
<i>CDRH/AD Cash Award</i>		167			
<i>Count</i>					
<i>CDRH/AD Employee</i>			1	0	0
<i>Count with 3R Incentive</i> <i>(distinct)</i>					
PAY PLAN: EG					
<i>CDRH/EG Incentive</i>		\$2,841.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>					
<i>CDRH/EG Cash Award</i>		2			
<i>Count</i>					
<i>CDRH/EG Employee</i>			0	0	0
<i>Count with 3R Incentive</i> <i>(distinct)</i>					
PAY PLAN: ES					
<i>CDRH/ES Incentive</i>		\$63,174.00	\$0.00	\$0.00	\$24,971.24
<i>Paid Amount</i>					
<i>CDRH/ES Cash Award</i>		6			
<i>Count</i>					
<i>CDRH/ES Employee</i>			0	0	2
<i>Count with 3R Incentive</i> <i>(distinct)</i>					
PAY PLAN: GM					
<i>CDRH/GM Incentive</i>		\$11,832.00	\$0.00	\$0.00	\$15,436.48
<i>Paid Amount</i>					
<i>CDRH/GM Cash Award</i>		7			
<i>Count</i>					
<i>CDRH/GM Employee</i>			0	0	1
<i>Count with 3R Incentive</i> <i>(distinct)</i>					

PAY PLAN: GP

<i>CDRH/GP Incentive</i>	\$169,512.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDRH/GP Cash Award</i>	80			
<i>Count</i>				
<i>CDRH/GP Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: GS

<i>CDRH/GS Incentive</i>	\$1,326,372.00	\$0.00	\$0.00	\$260,526.85
<i>Paid Amount</i>				
<i>CDRH/GS Cash Award</i>	1,143			
<i>Count</i>				
<i>CDRH/GS Employee</i>		0	0	33
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: RS

<i>CDRH/RS Incentive</i>	\$20,087.80	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDRH/RS Cash Award</i>	9			
<i>Count</i>				
<i>CDRH/RS Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

CDRH Incentive Paid Amount	\$1,782,333.80	\$40,000.00	\$0.00	\$300,934.57
CDRH Cash Award Count	1,414			
CDRH Employee Count with 3Rs Incentive (distinct)		1	0	36

CENTER FOR DRUG EVALUATION & RESEARCH

PAY PLAN: AD

<i>CDER/AD Incentive</i>	\$462,340.00	\$42,292.00	\$0.00	\$58,202.96
<i>Paid Amount</i>				
<i>CDER/AD Cash Award</i>	356			
<i>Count</i>				
<i>CDER/AD Employee</i>		4	0	7

*Count with 3R Incentive
(distinct)*

PAY PLAN: EG

<i>CDER/EG Incentive</i>	\$900.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDER/EG Cash Award</i>	1			
<i>Count</i>				
<i>CDER/EG Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: ES

<i>CDER/ES Incentive</i>	\$122,187.84	\$44,925.00	\$0.00	\$136,540.15
<i>Paid Amount</i>				
<i>CDER/ES Cash Award</i>	7			
<i>Count</i>				
<i>CDER/ES Employee</i>		1	0	5
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: GM

<i>CDER/GM Incentive</i>	\$13,546.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDER/GM Cash Award</i>	6			
<i>Count</i>				
<i>CDER/GM Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: GP

<i>CDER/GP Incentive</i>	\$1,132,034.00	\$49,064.00	\$0.00	\$13,818.80
<i>Paid Amount</i>				
<i>CDER/GP Cash Award</i>	477			
<i>Count</i>				
<i>CDER/GP Employee</i>		3	0	3
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: GR

<i>CDER/GR Incentive</i>	\$6,329.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				

<i>CDER/GR Cash Award</i>	2			
<i>Count</i>				
<i>CDER/GR Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GS				
<i>CDER/GS Incentive</i>	\$2,879,072.09	\$13,354.00	\$0.00	\$4,146,784.42
<i>Paid Amount</i>				
<i>CDER/GS Cash Award</i>	2,397			
<i>Count</i>				
<i>CDER/GS Employee</i>		1	0	378
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: RS				
<i>CDER/RS Incentive</i>	\$26,687.20	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDER/RS Cash Award</i>	11			
<i>Count</i>				
<i>CDER/RS Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: WG				
<i>CDER/WG Incentive</i>	\$2,566.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDER/WG Cash Award</i>	4			
<i>Count</i>				
<i>CDER/WG Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
CDER Incentive Paid Amount	\$4,645,662.13	\$149,635.00	\$0.00	\$4,355,346.33
CDER Cash Award Count	3,261			
CDER Employee Count with 3Rs Incentive (distinct)		9	0	391

CENTER FOR FOOD SAFETY & APPLIED NUTRITION

PAY PLAN: AD

<i>CFSAN/AD Incentive</i>	\$193,457.00	\$0.00	\$0.00	\$7,121.51
<i>Paid Amount</i>				
<i>CFSAN/AD Cash Award</i>	93			
<i>Count</i>				
<i>CFSAN/AD Employee</i>		0	0	1
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
 PAY PLAN: ES				
<i>CFSAN/ES Incentive</i>	\$49,991.00	\$0.00	\$0.00	\$56,785.64
<i>Paid Amount</i>				
<i>CFSAN/ES Cash Award</i>	5			
<i>Count</i>				
<i>CFSAN/ES Employee</i>		0	0	2
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
 PAY PLAN: GM				
<i>CFSAN/GM Incentive</i>	\$9,191.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CFSAN/GM Cash</i>	5			
<i>Award Count</i>				
<i>CFSAN/GM Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
 PAY PLAN: GP				
<i>CFSAN/GP Incentive</i>	\$18,751.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CFSAN/GP Cash</i>	7			
<i>Award Count</i>				
<i>CFSAN/GP Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
 PAY PLAN: GS				
<i>CFSAN/GS Incentive</i>	\$1,005,266.00	\$0.00	\$0.00	\$229,243.51
<i>Paid Amount</i>				
<i>CFSAN/GS Cash</i>	789			
<i>Award Count</i>				
<i>CFSAN/GS Employee</i>		0	0	26
<i>Count with 3R Incentive</i>				

*(distinct)***PAY PLAN: RS**

<i>CFSAN/RS Incentive</i>	\$11,502.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CFSAN/RS Cash Award</i>	6			
<i>Count</i>				
<i>CFSAN/RS Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

CFSAN Incentive Paid	\$1,288,158.00	\$0.00	\$0.00	\$293,150.66
Amount				
CFSAN Cash Award	905			
Count				
CFSAN Employee		0	0	28
Count with 3Rs				
Incentive (distinct)				

CENTER FOR TOBACCO PRODUCTS**PAY PLAN: AD**

<i>CTP/AD Incentive Paid</i>	\$4,164.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>CTP/AD Cash Award</i>	3			
<i>Count</i>				
<i>CTP/AD Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: ES

<i>CTP/ES Incentive Paid</i>	\$2,394.00	\$0.00	\$0.00	\$11,802.24
<i>Amount</i>				
<i>CTP/ES Cash Award</i>	1			
<i>Count</i>				
<i>CTP/ES Employee</i>		0	0	1
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: GP

<i>CTP/GP Incentive Paid</i>	\$4,067.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>CTP/GP Cash Award</i>	1			
<i>Count</i>				

CTP/GP Employee	0	0	0
Count with 3R Incentive (distinct)			

PAY PLAN: GS

CTP/GS Incentive Paid Amount	\$112,629.00	\$0.00	\$0.00	\$0.00
CTP/GS Cash Award Count	80			
CTP/GS Employee Count with 3R Incentive (distinct)		0	0	0

CTP Incentive Paid Amount	\$123,254.00	\$0.00	\$0.00	\$11,802.24
CTP Cash Award Count	85			
CTP Employee Count with 3Rs Incentive (distinct)		0	0	1

CTR FOR BIOLOGICS EVALUATION & RESEARCH

PAY PLAN: AD

CBER/AD Incentive Paid Amount	\$280,617.00	\$0.00	\$0.00	\$3,973.74
CBER/AD Cash Award Count	176			
CBER/AD Employee Count with 3R Incentive (distinct)		0	0	1

PAY PLAN: ES

CBER/ES Incentive Paid Amount	\$40,688.00	\$0.00	\$0.00	\$26,754.84
CBER/ES Cash Award Count	4			
CBER/ES Employee Count with 3R Incentive (distinct)		0	0	1

PAY PLAN: GM

CBER/GM Incentive Paid Amount	\$400.00	\$0.00	\$0.00	\$0.00
----------------------------------	----------	--------	--------	--------

<i>CBER/GM Cash Award</i>	1			
<i>Count</i>				
<i>CBER/GM Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GP				
<i>CBER/GP Incentive</i>	\$208,146.00	\$0.00	\$0.00	\$37,031.32
<i>Paid Amount</i>				
<i>CBER/GP Cash Award</i>	125			
<i>Count</i>				
<i>CBER/GP Employee</i>		0	0	2
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GS				
<i>CBER/GS Incentive</i>	\$970,085.14	\$0.00	\$0.00	\$324,715.74
<i>Paid Amount</i>				
<i>CBER/GS Cash Award</i>	885			
<i>Count</i>				
<i>CBER/GS Employee</i>		0	0	32
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: RS				
<i>CBER/RS Incentive</i>	\$11,599.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CBER/RS Cash Award</i>	7			
<i>Count</i>				
<i>CBER/RS Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: WG				
<i>CBER/WG Incentive</i>	\$400.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CBER/WG Cash Award</i>	1			
<i>Count</i>				
<i>CBER/WG Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

CBER Incentive Paid	\$1,511,935.14	\$0.00	\$0.00	\$392,475.64
Amount				
CBER Cash Award	1,199			
Count				
CBER Employee		0	0	35
Count with 3Rs				
Incentive (distinct)				

CTR FOR VETERINARY MEDICINE

PAY PLAN: AD

CVM/AD Incentive Paid	\$80,148.00	\$0.00	\$0.00	\$0.00
Amount				
CVM/AD Cash Award	50			
Count				
CVM/AD Employee		0	0	0
Count with 3R Incentive				
(distinct)				

PAY PLAN: ES

CVM/ES Incentive Paid	\$73,166.00	\$0.00	\$0.00	\$6,199.20
Amount				
CVM/ES Cash Award	5			
Count				
CVM/ES Employee		0	0	1
Count with 3R Incentive				
(distinct)				

PAY PLAN: GM

CVM/GM Incentive Paid	\$0.00	\$0.00	\$0.00	\$3,699.85
Amount				
CVM/GM Cash Award	0			
Count				
CVM/GM Employee		0	0	1
Count with 3R Incentive				
(distinct)				

PAY PLAN: GS

CVM/GS Incentive Paid	\$612,322.00	\$11,301.00	\$0.00	\$36,188.28
Amount				
CVM/GS Cash Award	490			
Count				
CVM/GS Employee		1	0	16

*Count with 3R Incentive
(distinct)*

PAY PLAN: RS

<i>CVM/RS Incentive Paid</i>	\$2,312.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>CVM/RS Cash Award</i>	2			
<i>Count</i>				
<i>CVM/RS Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: WG

<i>CVM/WG Incentive Paid</i>	\$4,898.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>CVM/WG Cash Award</i>	8			
<i>Count</i>				
<i>CVM/WG Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				

CVM Incentive Paid	\$772,846.00	\$11,301.00	\$0.00	\$46,087.33
Amount				
CVM Cash Award	555			
Count				
CVM Employee Count with 3Rs Incentive (distinct)		1	0	18

FOOD AND DRUG ADMINISTRATION

PAY PLAN: GS

<i>missing/GS Incentive</i>	\$400.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>missing/GS Cash</i>	1			
<i>Award Count</i>				
<i>missing/GS Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				
missing Incentive Paid	\$400.00	\$0.00	\$0.00	\$0.00
Amount				
missing Cash Award	1			
Count				
missing Employee		0	0	0

**Count with 3Rs
Incentive (distinct)**

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

PAY PLAN: AD

<i>NCTR/AD Incentive</i>	\$65,996.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>NCTR/AD Cash Award</i>	51			
<i>Count</i>				
<i>NCTR/AD Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: ES

<i>NCTR/ES Incentive</i>	\$10,682.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>NCTR/ES Cash Award</i>	1			
<i>Count</i>				
<i>NCTR/ES Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: GS

<i>NCTR/GS Incentive</i>	\$192,181.00	\$0.00	\$0.00	\$2,241.12
<i>Paid Amount</i>				
<i>NCTR/GS Cash Award</i>	178			
<i>Count</i>				
<i>NCTR/GS Employee</i>		0	0	3
<i>Count with 3R Incentive (distinct)</i>				

PAY PLAN: RS

<i>NCTR/RS Incentive</i>	\$21,533.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>NCTR/RS Cash Award</i>	11			
<i>Count</i>				
<i>NCTR/RS Employee</i>		0	0	0
<i>Count with 3R Incentive (distinct)</i>				

NCTR Incentive Paid Amount	\$290,392.00	\$0.00	\$0.00	\$2,241.12
---------------------------------------	---------------------	---------------	---------------	-------------------

NCTR Cash Award

241

Count**NCTR Employee Count
with 3Rs Incentive
(distinct)**

0

0

3

OFC OF REGULATORY AFFAIRS**PAY PLAN: AD***ORA/AD Incentive Paid*

\$76,323.00

\$0.00

\$0.00

\$0.00

*Amount**ORA/AD Cash Award*

21

*Count**ORA/AD Employee*

0

0

0

*Count with 3R Incentive
(distinct)***PAY PLAN: ES***ORA/ES Incentive Paid*

\$94,640.00

\$0.00

\$0.00

\$62,566.76

*Amount**ORA/ES Cash Award*

7

*Count**ORA/ES Employee*

0

0

3

*Count with 3R Incentive
(distinct)***PAY PLAN: GM***ORA/GM Incentive Paid*

\$4,099.00

\$0.00

\$0.00

\$0.00

*Amount**ORA/GM Cash Award*

3

*Count**ORA/GM Employee*

0

0

0

*Count with 3R Incentive
(distinct)***PAY PLAN: GS***ORA/GS Incentive Paid*

\$3,783,976.00

\$0.00

\$41,616.00

\$132,277.03

*Amount**ORA/GS Cash Award*

4,094

*Count**ORA/GS Employee*

0

3

17

*Count with 3R Incentive
(distinct)*

PAY PLAN: WG

<i>ORA/WG Incentive Paid</i>	\$17,631.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>ORA/WG Cash Award</i>	34			
<i>Count</i>				
<i>ORA/WG Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
ORA Incentive Paid	\$3,976,669.00	\$0.00	\$41,616.00	\$194,843.79
Amount				
ORA Cash Award	4,159			
Count				
ORA Employee Count		0	3	20
with 3Rs Incentive				
(distinct)				

OFC OF THE COMMISSIONER

PAY PLAN: AD

<i>OC/AD Incentive Paid</i>	\$107,150.00	\$0.00	\$0.00	\$45.36
<i>Amount</i>				
<i>OC/AD Cash Award</i>	21			
<i>Count</i>				
<i>OC/AD Employee</i>		0	0	1
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: ES

<i>OC/ES Incentive Paid</i>	\$253,151.36	\$0.00	\$0.00	\$174,448.89
<i>Amount</i>				
<i>OC/ES Cash Award</i>	21			
<i>Count</i>				
<i>OC/ES Employee Count</i>		0	0	6
<i>with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: GM

<i>OC/GM Incentive Paid</i>	\$14,427.00	\$0.00	\$0.00	\$9,261.94
<i>Amount</i>				
<i>OC/GM Cash Award</i>	8			
<i>Count</i>				
<i>OC/GM Employee</i>		0	0	1

Count with 3R Incentive
(distinct)

PAY PLAN: GP

OC/GP Incentive Paid Amount	\$50,399.00	\$0.00	\$0.00	\$0.00
OC/GP Cash Award Count	15			
OC/GP Employee Count with 3R Incentive (distinct)		0	0	0

PAY PLAN: GR

OC/GR Incentive Paid Amount	\$614.00	\$0.00	\$0.00	\$0.00
OC/GR Cash Award Count	1			
OC/GR Employee Count with 3R Incentive (distinct)		0	0	0

PAY PLAN: GS

OC/GS Incentive Paid Amount	\$1,793,162.41	\$0.00	\$0.00	\$410,279.57
OC/GS Cash Award Count	1,330			
OC/GS Employee Count with 3R Incentive (distinct)		0	0	33

PAY PLAN: SL

OC/SL Incentive Paid Amount	\$2,969.00	\$0.00	\$0.00	\$0.00
OC/SL Cash Award Count	2			
OC/SL Employee Count with 3R Incentive (distinct)		0	0	0

PAY PLAN: WG

OC/WG Incentive Paid Amount	\$3,994.00	\$0.00	\$0.00	\$0.00
--------------------------------	------------	--------	--------	--------

<i>OC/WS Cash Award</i>	6			
<i>Count</i>				
<i>OC/WS Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: WS				
<i>OC/WS Incentive Paid</i>	\$993.00	\$0.00	\$0.00	\$0.00
<i>Amount</i>				
<i>OC/WS Cash Award</i>	1			
<i>Count</i>				
<i>OC/WS Employee Count</i>		0	0	0
<i>with 3R Incentive (distinct)</i>				
OC Incentive Paid	\$2,226,859.77	\$0.00	\$0.00	\$594,035.76
Amount				
OC Cash Award Count	1,405			
OC Employee Count		0	0	41
with 3Rs Incentive				
(distinct)				

Incentive Paid Amount	\$16,618,509.84	\$200,936.00	\$41,616.00	\$6,190,917.4
Gran Total				4
Total Cash Award Count	13,225			
Total Employee Count		11	3	569
with 3Rs Incentive				
(distinct)				



U.S. Department of Health and Human Services
FDA Pay Awards and Bonuses (Excepted Positions)
Incentives Paid between PP 21,2010 through PP 20, 2011
PP Ending Dates: 10/09/2010 - 09/24/2011

<u>NAME</u>	<u>ADMIN</u>	<u>PP</u>	<u>CASH AWARD</u>	<u>RECRUITMENT</u>	<u>RELOCATION</u>	<u>RETENTION</u>
<u>CD</u>	<u>CD</u>		<u>AMT</u>	<u>BONUS</u>	<u>BONUS</u>	<u>BONUS</u>
CENTER FOR DEVICES & RADIOLOGICAL HEALTH						
PAY PLAN: AD						
<i>CDRH/AD Incentive</i>			\$267,052.00	\$0.00	\$0.00	\$3,173.76
<i>Paid Amount</i>						
<i>CDRH/AD Cash Award</i>			151			
<i>Count</i>						
<i>CDRH/AD Employee</i>				0	0	1

*Count with 3R Incentive
(distinct)*

PAY PLAN: EI

<i>CDRH/EI Incentive Paid Amount</i>	\$20.00	\$0.00	\$0.00	\$0.00
<i>CDRH/EI Cash Award Count</i>	1			
<i>CDRH/EI Employee Count with 3R Incentive (distinct)</i>		0	0	0

PAY PLAN: GP

<i>CDRH/GP Incentive Paid Amount</i>	\$36,587.00	\$0.00	\$0.00	\$0.00
<i>CDRH/GP Cash Award Count</i>	20			
<i>CDRH/GP Employee Count with 3R Incentive (distinct)</i>		0	0	0

PAY PLAN: GS

<i>CDRH/GS Incentive Paid Amount</i>	\$31,396.00	\$0.00	\$0.00	\$2,621.20
<i>CDRH/GS Cash Award Count</i>	35			
<i>CDRH/GS Employee Count with 3R Incentive (distinct)</i>		0	0	1

PAY PLAN: RS

<i>CDRH/RS Incentive Paid Amount</i>	\$664.80	\$0.00	\$0.00	\$0.00
<i>CDRH/RS Cash Award Count</i>	1			
<i>CDRH/RS Employee Count with 3R Incentive (distinct)</i>		0	0	0
CDRH Incentive Paid Amount	\$335,719.80	\$0.00	\$0.00	\$5,794.96

CDRH Cash	208			
Award Count				
CDRH Employee		0	0	2
Count with 3Rs				
Incentive (distinct)				

CENTER FOR DRUG EVALUATION & RESEARCH

PAY PLAN: AD

CDER/AD	\$523,732.00	\$0.00	\$0.00	\$39,331.48
Incentive Paid Amount				
CDER/AD Cash	357			
Award Count				
CDER/AD		0	0	5
Employee Count with				
3R Incentive				
(distinct)				

PAY PLAN: GP

CDER/GP	\$169,879.00	\$0.00	\$0.00	\$0.00
Incentive Paid Amount				
CDER/GP Cash	94			
Award Count				
CDER/GP		0	0	0
Employee Count with				
3R Incentive				
(distinct)				

PAY PLAN: GS

CDER/GS	\$86,291.93	\$0.00	\$0.00	\$127,654.12
Incentive Paid Amount				
CDER/GS Cash	33			
Award Count				
CDER/GS		0	0	9
Employee Count with				
3R Incentive				
(distinct)				

PAY PLAN: RS

CDER/RS	\$664.80	\$0.00	\$0.00	\$0.00
Incentive Paid Amount				
CDER/RS Cash	1			
Award Count				

<i>CDER/RS</i>		0	0	0
<i>Employee Count with 3R Incentive (distinct)</i>				
CDER Incentive Paid Amount	\$780,567.73	\$0.00	\$0.00	\$166,985.60
CDER Cash Award Count	485			
CDER Employee Count with 3Rs Incentive (distinct)		0	0	14

CENTER FOR FOOD SAFETY & APPLIED NUTRITION

PAY PLAN: AD

<i>CFSAN/AD</i>	\$166,342.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>CFSAN/AD Cash</i>	91			
<i>Award Count</i>				
<i>CFSAN/AD</i>		0	0	0
<i>Employee Count with 3R Incentive (distinct)</i>				

PAY PLAN: GS

<i>CFSAN/GS</i>	\$8,653.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>CFSAN/GS Cash</i>	10			
<i>Award Count</i>				
<i>CFSAN/GS</i>		0	0	0
<i>Employee Count with 3R Incentive (distinct)</i>				

PAY PLAN: RS

<i>CFSAN/RS</i>	\$3,693.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>CFSAN/RS Cash</i>	1			
<i>Award Count</i>				
<i>CFSAN/RS</i>		0	0	0
<i>Employee Count with 3R Incentive</i>				

(distinct)

CFSAN Incentive	\$178,688.00	\$0.00	\$0.00	\$0.00
Paid Amount				
CFSAN Cash	102			
Award Count				
CFSAN Employee		0	0	0
Count with 3Rs				
Incentive (distinct)				

CENTER FOR TOBACCO PRODUCTS

PAY PLAN: AD

CTP/AD Incentive	\$45,206.00	\$0.00	\$0.00	\$0.00
Paid Amount				
CTP/AD Cash	8			
Award Count				
CTP/AD Employee		0	0	0
Count with 3R				
Incentive (distinct)				

PAY PLAN: GS

CTP/GS Incentive	\$4,164.00	\$0.00	\$0.00	\$0.00
Paid Amount				
CTP/GS Cash	4			
Award Count				
CTP/GS Employee		0	0	0
Count with 3R				
Incentive (distinct)				

CTP Incentive	\$49,370.00	\$0.00	\$0.00	\$0.00
Paid Amount				
CTP Cash Award	12			
Count				
CTP Employee		0	0	0
Count with 3Rs				
Incentive (distinct)				

CTR FOR BIOLOGICS EVALUATION & RESEARCH

PAY PLAN: AD

CBER/AD	\$328,173.00	\$0.00	\$0.00	\$0.00
Incentive Paid Amount				
CBER/AD Cash	179			
Award Count				
CBER/AD		0	0	0

*Employee Count with
3R Incentive
(distinct)*

PAY PLAN: GP

<i>CBER/GP</i>	\$14,247.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>CBER/GP Cash</i>	13			
<i>Award Count</i>				
<i>CBER/GP</i>		0	0	0

*Employee Count with
3R Incentive
(distinct)*

PAY PLAN: GS

<i>CBER/GS</i>	\$18,644.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>CBER/GS Cash</i>	15			
<i>Award Count</i>				
<i>CBER/GS</i>		0	0	0

*Employee Count with
3R Incentive
(distinct)*

CBER Incentive Paid Amount	\$361,064.00	\$0.00	\$0.00	\$0.00
CBER Cash	207			
Award Count				
CBER Employee Count with 3Rs Incentive (distinct)		0	0	0

CTR FOR VETERINARY MEDICINE

PAY PLAN: AD

<i>CVM/AD Incentive</i>	\$100,263.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CVM/AD Cash</i>	40			
<i>Award Count</i>				
<i>CVM/AD</i>		0	0	0

*Employee Count with
3R Incentive
(distinct)*

PAY PLAN: GS

<i>CVM/GS Incentive</i>	\$12,420.00	\$0.00	\$0.00	\$16,288.06
<i>Paid Amount</i>				
<i>CVM/GS Cash</i>	8			
<i>Award Count</i>				
<i>CVM/GS</i>		0	0	2
<i>Employee Count with</i>				
<i>3R Incentive</i>				
<i>(distinct)</i>				
<i>CVM Incentive</i>	\$112,683.00	\$0.00	\$0.00	\$16,288.06
<i>Paid Amount</i>				
<i>CVM Cash Award</i>	48			
<i>Count</i>				
<i>CVM Employee</i>		0	0	2
<i>Count with 3Rs</i>				
<i>Incentive (distinct)</i>				

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

PAY PLAN: AD

<i>NCTR/AD</i>	\$12,701.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>NCTR/AD Cash</i>	2			
<i>Award Count</i>				
<i>NCTR/AD</i>		0	0	0
<i>Employee Count with</i>				
<i>3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: GS

<i>NCTR/GS</i>	\$0.00	\$0.00	\$0.00	\$1,643.12
<i>Incentive Paid Amount</i>				
<i>NCTR/GS Cash</i>	0			
<i>Award Count</i>				
<i>NCTR/GS</i>		0	0	1
<i>Employee Count with</i>				
<i>3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: RS

<i>NCTR/RS</i>	\$664.80	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				

<i>NCTR/RS Cash</i>	1			
<i>Award Count</i>				
<i>NCTR/RS</i>		0	0	0
<i>Employee Count with</i>				
<i>3R Incentive</i>				
<i>(distinct)</i>				
NCTR Incentive	\$13,365.80	\$0.00	\$0.00	\$1,643.12
Paid Amount				
NCTR Cash Award	3			
Count				
NCTR Employee		0	0	1
Count with 3Rs				
Incentive (distinct)				

OFC OF REGULATORY AFFAIRS

PAY PLAN: AD

<i>ORA/AD Incentive</i>	\$106,984.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>ORA/AD Cash</i>	21			
<i>Award Count</i>				
<i>ORA/AD</i>		0	0	0
<i>Employee Count with</i>				
<i>3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: GS

<i>ORA/GS Incentive</i>	\$49,513.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>ORA/GS Cash</i>	122			
<i>Award Count</i>				
<i>ORA/GS</i>		0	0	0
<i>Employee Count with</i>				
<i>3R Incentive</i>				
<i>(distinct)</i>				
ORA Incentive	\$156,497.00	\$0.00	\$0.00	\$0.00
Paid Amount				
ORA Cash Award	143			
Count				
ORA Employee		0	0	0
Count with 3Rs				
Incentive (distinct)				

OFC OF THE COMMISSIONER

PAY PLAN: AD

<i>OC/AD Incentive</i>	\$151,208.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>OC/AD Cash</i>	70			
<i>Award Count</i>				
<i>OC/AD Employee</i>		0	0	0
<i>Count with 3R</i>				
<i>Incentive (distinct)</i>				

PAY PLAN: GP

<i>OC/GP Incentive</i>	\$2,288.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>OC/GP Cash</i>	1			
<i>Award Count</i>				
<i>OC/GP Employee</i>		0	0	0
<i>Count with 3R</i>				
<i>Incentive (distinct)</i>				

PAY PLAN: GS

<i>OC/GS Incentive</i>	\$57,277.00	\$0.00	\$0.00	\$5,797.10
<i>Paid Amount</i>				
<i>OC/GS Cash</i>	55			
<i>Award Count</i>				
<i>OC/GS Employee</i>		0	0	1
<i>Count with 3R</i>				
<i>Incentive (distinct)</i>				

PAY PLAN: RS

<i>OC/RS Incentive</i>	\$17,749.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>OC/RS Cash Award</i>	7			
<i>Count</i>				
<i>OC/RS Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

OC Incentive Paid	\$228,522.00	\$0.00	\$0.00	\$5,797.10
Amount				
OC Cash Award	133			
Count				
OC Employee		0	0	1
Count with 3Rs				

Incentive (distinct)

Incentive Paid	\$2,216,477.33	\$0.00	\$0.00	\$196,508.84
Amount Grand Total				
Total Cash Award	1,341			
Count				
Total Employee		0	0	19
Count with 3Rs				
Incentive (distinct)				



U.S. Department of Health and Human Services
FDA Pay Awards and Bonuses
Incentives Paid between PP 21,2010 through PP 20, 2011
PP Ending Dates: 10/09/2010 - 09/24/2011

<u>NAME</u>	<u>ADMI</u> <u>N CD</u>	<u>PP</u>	<u>CASH AWARD</u> <u>AMT</u>	<u>RECRUITMENT</u> <u>BONUS</u>	<u>RELOCATION</u> <u>BONUS</u>	<u>RETENTION</u> <u>BONUS</u>
CENTER FOR DEVICES & RADIOLOGICAL HEALTH						
PAY PLAN: AD						
<i>CDRH/AD Incentive</i>			\$267,052.00	\$0.00	\$0.00	\$3,173.76
<i>Paid Amount</i>						
<i>CDRH/AD Cash</i>			151			
<i>Award Count</i>						
<i>CDRH/AD</i>				0	0	1
<i>Employee Count with</i>						
<i>3R Incentive (distinct)</i>						
PAY PLAN: EI						
<i>CDRH/EI Incentive</i>			\$20.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>						
<i>CDRH/EI Cash</i>			1			
<i>Award Count</i>						
<i>CDRH/EI Employee</i>				0	0	0
<i>Count with 3R Incentive</i>						
<i>(distinct)</i>						
PAY PLAN: ES						
<i>CDRH/ES Incentive</i>			\$79,966.00	\$0.00	\$0.00	\$33,786.00
<i>Paid Amount</i>						

<i>CDRH/ES Cash</i>	7			
<i>Award Count</i>				
<i>CDRH/ES Employee</i>		0	0	3
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GM				
<i>CDRH/GM Incentive</i>	\$5,803.00	\$0.00	\$0.00	\$4,291.78
<i>Paid Amount</i>				
<i>CDRH/GM Cash</i>	4			
<i>Award Count</i>				
<i>CDRH/GM</i>		0	0	1
<i>Employee Count with</i>				
<i>3R Incentive (distinct)</i>				
PAY PLAN: GP				
<i>CDRH/GP Incentive</i>	\$202,939.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDRH/GP Cash</i>	94			
<i>Award Count</i>				
<i>CDRH/GP</i>		0	0	0
<i>Employee Count with</i>				
<i>3R Incentive (distinct)</i>				
PAY PLAN: GS				
<i>CDRH/GS Incentive</i>	\$1,626,037.22	\$0.00	\$0.00	\$544,420.99
<i>Paid Amount</i>				
<i>CDRH/GS Cash</i>	1,222			
<i>Award Count</i>				
<i>CDRH/GS</i>		0	0	53
<i>Employee Count with</i>				
<i>3R Incentive (distinct)</i>				
PAY PLAN: RS				
<i>CDRH/RS Incentive</i>	\$16,341.80	\$17,478.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDRH/RS Cash</i>	6			
<i>Award Count</i>				
<i>CDRH/RS</i>		1	0	0
<i>Employee Count with</i>				
<i>3R Incentive (distinct)</i>				

CDRH Incentive	\$2,198,159.02	\$17,478.00	\$0.00	\$585,672.53
<i>Paid Amount</i>				
CDRH Cash Award	1,485			
<i>Count</i>				
CDRH Employee		1	0	57
<i>Count with 3Rs</i>				
<i>Incentive (distinct)</i>				

CENTER FOR DRUG EVALUATION & RESEARCH

PAY PLAN: AD

CDER/AD Incentive	\$523,732.00	\$0.00	\$0.00	\$39,331.48
<i>Paid Amount</i>				
CDER/AD Cash	357			
<i>Award Count</i>				
CDER/AD Employee		0	0	5
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: ES

CDER/ES Incentive	\$88,080.08	\$0.00	\$0.00	\$125,451.52
<i>Paid Amount</i>				
CDER/ES Cash	6			
<i>Award Count</i>				
CDER/ES Employee		0	0	5
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: GM

CDER/GM Incentive	\$10,362.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
CDER/GM Cash	4			
<i>Award Count</i>				
CDER/GM		0	0	0
<i>Employee Count with</i>				
<i>3R Incentive (distinct)</i>				

PAY PLAN: GP

CDER/GP Incentive	\$1,336,650.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
CDER/GP Cash	513			
<i>Award Count</i>				
CDER/GP		0	0	0

*Employee Count with
3R Incentive (distinct)*

PAY PLAN: GR

<i>CDER/GR Incentive</i>	\$8,241.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDER/GR Cash</i>	1			
<i>Award Count</i>				
<i>CDER/GR</i>		0	0	0
<i>Employee Count with 3R Incentive (distinct)</i>				

PAY PLAN: GS

<i>CDER/GS Incentive</i>	\$3,565,655.93	\$0.00	\$0.00	\$4,644,514.23
<i>Paid Amount</i>				
<i>CDER/GS Cash</i>	2,549			
<i>Award Count</i>				
<i>CDER/GS</i>		0	0	433
<i>Employee Count with 3R Incentive (distinct)</i>				

PAY PLAN: RS

<i>CDER/RS Incentive</i>	\$21,766.20	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDER/RS Cash</i>	14			
<i>Award Count</i>				
<i>CDER/RS Employee Count with 3R Incentive (distinct)</i>		0	0	0

PAY PLAN: WG

<i>CDER/WG Incentive</i>	\$914.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CDER/WG Cash</i>	2			
<i>Award Count</i>				
<i>CDER/WG</i>		0	0	0
<i>Employee Count with 3R Incentive (distinct)</i>				

CDER Incentive Paid Amount	\$5,555,401.21	\$0.00	\$0.00	\$4,809,297.23
CDER Cash Award Count	3,446			

**CDER Employee
Count with 3Rs
Incentive (distinct)**

0 0 441

CENTER FOR FOOD SAFETY & APPLIED NUTRITION

PAY PLAN: AD

<i>CFSAN/AD</i>	\$166,342.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>CFSAN/AD Cash</i>	91			
<i>Award Count</i>				
<i>CFSAN/AD</i>		0	0	0
<i>Employee Count with 3R Incentive (distinct)</i>				

PAY PLAN: ES

<i>CFSAN/ES</i>	\$45,204.80	\$0.00	\$0.00	\$44,123.00
<i>Incentive Paid Amount</i>				
<i>CFSAN/ES Cash</i>	4			
<i>Award Count</i>				
<i>CFSAN/ES</i>		0	0	1
<i>Employee Count with 3R Incentive (distinct)</i>				

PAY PLAN: GM

<i>CFSAN/GM</i>	\$5,208.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>CFSAN/GM Cash</i>	3			
<i>Award Count</i>				
<i>CFSAN/GM</i>		0	0	0
<i>Employee Count with 3R Incentive (distinct)</i>				

PAY PLAN: GP

<i>CFSAN/GP</i>	\$12,505.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>CFSAN/GP Cash</i>	11			
<i>Award Count</i>				
<i>CFSAN/GP</i>		0	0	0
<i>Employee Count with 3R Incentive</i>				

*(distinct)***PAY PLAN: GS**

<i>CFSAN/GS</i>	\$1,152,177.00	\$0.00	\$0.00	\$412,452.11
<i>Incentive Paid Amount</i>				
<i>CFSAN/GS Cash</i>	847			
<i>Award Count</i>				
<i>CFSAN/GS</i>		0	0	41
<i>Employee Count with</i>				
<i>3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: RS

<i>CFSAN/RS</i>	\$10,909.00	\$0.00	\$0.00	\$0.00
<i>Incentive Paid Amount</i>				
<i>CFSAN/RS Cash</i>	4			
<i>Award Count</i>				
<i>CFSAN/RS</i>		0	0	0
<i>Employee Count with</i>				
<i>3R Incentive</i>				
<i>(distinct)</i>				

<i>CFSAN Incentive</i>	\$1,392,345.80	\$0.00	\$0.00	\$456,575.11
<i>Paid Amount</i>				
<i>CFSAN Cash</i>	960			
<i>Award Count</i>				
<i>CFSAN Employee</i>		0	0	42
<i>Count with 3Rs</i>				
<i>Incentive (distinct)</i>				

CENTER FOR TOBACCO PRODUCTS**PAY PLAN: AD**

<i>CTP/AD Incentive</i>	\$45,206.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CTP/AD Cash</i>	8			
<i>Award Count</i>				
<i>CTP/AD Employee</i>		0	0	0
<i>Count with 3R</i>				
<i>Incentive (distinct)</i>				

PAY PLAN: ES

<i>CTP/ES Incentive</i>	\$14,539.00	\$16,590.00	\$0.00	\$35,638.92
<i>Paid Amount</i>				

CTP/ES Cash	1			
Award Count				
CTP/ES Employee		1	0	2
Count with 3R				
Incentive (distinct)				
 PAY PLAN: GP				
CTP/GP Incentive	\$4,818.00	\$0.00	\$0.00	\$0.00
Paid Amount				
CTP/GP Cash	1			
Award Count				
CTP/GP Employee		0	0	0
Count with 3R				
Incentive (distinct)				
 PAY PLAN: GS				
CTP/GS Incentive	\$234,123.00	\$0.00	\$0.00	\$19,242.09
Paid Amount				
CTP/GS Cash	139			
Award Count				
CTP/GS Employee		0	0	5
Count with 3R Incentive				
(distinct)				
 CTP Incentive Paid	\$298,686.00	\$16,590.00	\$0.00	\$54,881.01
Amount				
CTP Cash Award	149			
Count				
CTP Employee		1	0	7
Count with 3Rs				
Incentive (distinct)				

CTR FOR BIOLOGICS EVALUATION & RESEARCH

PAY PLAN: AD				
CBER/AD Incentive	\$328,173.00	\$0.00	\$0.00	\$0.00
Paid Amount				
CBER/AD Cash	179			
Award Count				
CBER/AD Employee		0	0	0
Count with 3R Incentive				
(distinct)				

PAY PLAN: ES

<i>CBER/ES Incentive</i>	\$49,114.00	\$0.00	\$0.00	\$26,449.92
<i>Paid Amount</i>				
<i>CBER/ES Cash</i>	4			
<i>Award Count</i>				
<i>CBER/ES Employee</i>		0	0	1
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GM				
<i>CBER/GM Incentive</i>	\$825.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CBER/GM Cash</i>	1			
<i>Award Count</i>				
<i>CBER/GM</i>		0	0	0
<i>Employee Count with</i>				
<i>3R Incentive (distinct)</i>				
PAY PLAN: GP				
<i>CBER/GP Incentive</i>	\$213,472.00	\$0.00	\$0.00	\$37,523.05
<i>Paid Amount</i>				
<i>CBER/GP Cash</i>	112			
<i>Award Count</i>				
<i>CBER/GP Employee</i>		0	0	2
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GS				
<i>CBER/GS Incentive</i>	\$1,091,717.00	\$0.00	\$0.00	\$432,094.40
<i>Paid Amount</i>				
<i>CBER/GS Cash</i>	874			
<i>Award Count</i>				
<i>CBER/GS Employee</i>		0	0	43
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: RS				
<i>CBER/RS Incentive</i>	\$7,433.80	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CBER/RS Cash</i>	3			
<i>Award Count</i>				
<i>CBER/RS Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				

*(distinct)***PAY PLAN: WG**

<i>CBER/WG Incentive</i>	\$250.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CBER/WG Cash</i>	1			
<i>Award Count</i>				
<i>CBER/WG Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

CBER Incentive	\$1,690,984.80	\$0.00	\$0.00	\$496,067.37
Paid Amount				
CBER Cash Award	1,174			
Count				
CBER Employee		0	0	46
Count with 3Rs				
Incentive (distinct)				

CTR FOR VETERINARY MEDICINE**PAY PLAN: AD**

<i>CVM/AD Incentive</i>	\$100,263.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>CVM/AD Cash</i>	40			
<i>Award Count</i>				
<i>CVM/AD Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: ES

<i>CVM/ES Incentive</i>	\$89,601.00	\$0.00	\$0.00	\$15,153.60
<i>Paid Amount</i>				
<i>CVM/ES Cash</i>	5			
<i>Award Count</i>				
<i>CVM/ES Employee</i>		0	0	1
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				

PAY PLAN: GS

<i>CVM/GS Incentive</i>	\$691,713.00	\$0.00	\$0.00	\$328,375.69
<i>Paid Amount</i>				
<i>CVM/GS Cash</i>	440			
<i>Award Count</i>				

CVM/GS Employee		0	0	42
Count with 3R Incentive				
(distinct)				

PAY PLAN: RS

CVM/RS Incentive	\$9,582.00	\$0.00	\$0.00	\$0.00
Paid Amount				
CVM/RS Cash	4			
Award Count				
CVM/RS Employee		0	0	0
Count with 3R Incentive				
(distinct)				

PAY PLAN: WG

CVM/WG Incentive	\$3,312.00	\$0.00	\$0.00	\$0.00
Paid Amount				
CVM/WG Cash	6			
Award Count				
CVM/WG Employee		0	0	0
Count with 3R Incentive				
(distinct)				

PAY PLAN: WL

CVM/WL Incentive	\$1,373.00	\$0.00	\$0.00	\$0.00
Paid Amount				
CVM/WL Cash	2			
Award Count				
CVM/WL Employee		0	0	0
Count with 3R Incentive				
(distinct)				

CVM Incentive Paid Amount	\$895,844.00	\$0.00	\$0.00	\$343,529.29
CVM Cash Award Count	497			
CVM Employee Count with 3Rs Incentive (distinct)		0	0	43

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

PAY PLAN: AD

NCTR/AD Incentive	\$12,701.00	\$0.00	\$0.00	\$0.00
Paid Amount				

<i>NCTR/AD Cash</i>	2			
<i>Award Count</i>				
<i>NCTR/AD Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: ES				
<i>NCTR/ES Incentive</i>	\$11,815.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>NCTR/ES Cash</i>	1			
<i>Award Count</i>				
<i>NCTR/ES Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GS				
<i>NCTR/GS Incentive</i>	\$3,950.00	\$0.00	\$0.00	\$15,506.32
<i>Paid Amount</i>				
<i>NCTR/GS Cash</i>	3			
<i>Award Count</i>				
<i>NCTR/GS Employee</i>		0	0	5
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: RS				
<i>NCTR/RS Incentive</i>	\$664.80	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>NCTR/RS Cash</i>	1			
<i>Award Count</i>				
<i>NCTR/RS Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
NCTR Incentive Paid Amount	\$29,130.80	\$0.00	\$0.00	\$15,506.32
NCTR Cash Award Count	7			
NCTR Employee Count with 3Rs Incentive (distinct)		0	0	5

OFC OF REGULATORY AFFAIRS

PAY PLAN: AD

<i>ORA/AD Incentive</i>	\$106,984.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>ORA/AD Cash</i>	21			
<i>Award Count</i>				
<i>ORA/AD Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: ES				
<i>ORA/ES Incentive</i>	\$86,173.00	\$0.00	\$0.00	\$26,439.96
<i>Paid Amount</i>				
<i>ORA/ES Cash Award</i>	6			
<i>Count</i>				
<i>ORA/ES Employee</i>		0	0	2
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GM				
<i>ORA/GM Incentive</i>	\$2,561.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>ORA/GM Cash</i>	1			
<i>Award Count</i>				
<i>ORA/GM Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GS				
<i>ORA/GS Incentive</i>	\$5,363,603.00	\$16,606.00	\$67,751.00	\$127,303.29
<i>Paid Amount</i>				
<i>ORA/GS Cash</i>	5,046			
<i>Award Count</i>				
<i>ORA/GS Employee</i>		1	4	14
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: WG				
<i>ORA/WG Incentive</i>	\$17,580.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>ORA/WG Cash</i>	28			
<i>Award Count</i>				
<i>ORA/WG Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				

(distinct)

ORA Incentive Paid Amount	\$5,576,901.00	\$16,606.00	\$67,751.00	\$153,743.25
ORA Cash Award Count	5,102			
ORA Employee Count with 3Rs Incentive (distinct)		1	4	16

OFC OF THE COMMISSIONER**PAY PLAN: AD**

<i>OC/AD Incentive</i>	\$151,208.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>OC/AD Cash Award Count</i>	70			
<i>OC/AD Employee Count with 3R Incentive (distinct)</i>		0	0	0

PAY PLAN: ES

<i>OC/ES Incentive</i>	\$256,309.40	\$0.00	\$0.00	\$85,080.59
<i>Paid Amount</i>				
<i>OC/ES Cash Award Count</i>	20			
<i>OC/ES Employee Count with 3R Incentive (distinct)</i>		0	0	4

PAY PLAN: GM

<i>OC/GM Incentive</i>	\$12,013.00	\$0.00	\$0.00	\$9,179.68
<i>Paid Amount</i>				
<i>OC/GM Cash Award Count</i>	5			
<i>OC/GM Employee Count with 3R Incentive (distinct)</i>		0	0	1

PAY PLAN: GP

<i>OC/GP Incentive</i>	\$78,689.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>OC/GP Cash Award Count</i>	20			

<i>OC/GP Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: GS				
<i>OC/GS Incentive</i>	\$2,766,663.68	\$0.00	\$0.00	\$458,740.57
<i>Paid Amount</i>				
<i>OC/GS Cash Award</i>	1,791			
<i>Count</i>				
<i>OC/GS Employee</i>		0	0	47
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: RS				
<i>OC/RS Incentive</i>	\$21,365.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>OC/RS Cash Award</i>	9			
<i>Count</i>				
<i>OC/RS Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: SL				
<i>OC/SL Incentive</i>	\$4,867.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>OC/SL Cash Award</i>	2			
<i>Count</i>				
<i>OC/SL Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
PAY PLAN: WG				
<i>OC/WG Incentive</i>	\$4,043.00	\$0.00	\$0.00	\$0.00
<i>Paid Amount</i>				
<i>OC/WG Cash Award</i>	3			
<i>Count</i>				
<i>OC/WG Employee</i>		0	0	0
<i>Count with 3R Incentive</i>				
<i>(distinct)</i>				
OC Incentive Paid Amount	\$3,295,158.08	\$0.00	\$0.00	\$553,000.84

OC Cash Award	1,920			
Count				
OC Employee Count		0	0	52
with 3Rs Incentive				
(distinct)				

Incentive Paid	\$20,932,610.71	\$50,674.00	\$67,751.00	\$7,468,272.95
Amount Gran Total				
Total Cash Award	14,740			
Count				
Total Employee Count		3	4	695
with 3Rs Incentive				
(distinct)				

2) Electronic files in Excel format that contain cash award data on an individual basis that excludes personally identifiable information. The Excepted Positions data is also included separately for each Fiscal Year.

]CLERK'S NOTE: The data listing is too voluminous to print,
and is on record in Committee files.[]

3) Summary of Promotions, within grade increases, and promotion equivalents by FDA Component for FYs 2009, 2010, and 2011.

Please note that we were not able to provide data on promotion equivalents for Title 42 (f), (g), and Senior Biomedical Research Service (SBRS) employees. We were advised that the data systems are not set up in such a way that would allow us to pull the information electronically. Pay adjustments could be reflective of cost of living adjustments, performance based increases, equivalent within grade increases or equivalent promotions, but distinctions cannot be made from the electronic files.

]CLERK'S NOTE: The data listing is too voluminous to print,
and is on record in Committee files.[]

QUESTIONS SUBMITTED BY REPRESENTATIVE JO ANN EMERSON

Appropriations for Biosimilar Trigger

57. Ms. Emerson: FDA believes the approval program for biosimilar drugs requires \$20 million in non-user fee funding. Can you explain the purpose of these funds? Why, for example, is this funding not included under PDUFA but as a separate line item in the budget request?

Response: FDA will allocate at least \$20 million, adjusted for inflation, of non-user fee funding for biosimilars review activities. This will ensure that user fees supplement

budget authority funding for the BsUFA program and will avoid redirecting resources from PDUFA to BsUFA activities.

58. Ms. Emerson: Do you expect FDA will exhaust the entire \$20 million in FY2013?

Response: Yes, FDA plans to spend an estimated \$20.1 million in budget authority in FY 2013.

Administration's Proposal for Cosmetics User Fee

59. Ms. Emerson: Commissioner Hamburg, as you are aware Congress has provided for significant increases to FDA for cosmetic program activities over the past five years. In FY 2006 Congress provided \$3.5 million. In FY 2012 that number more than tripled to at least \$11.7 million for cosmetics activities, including \$7.2 million for the Office of Colors and Cosmetics. Despite Congress' commitment to funding the cosmetics program, the President's budget includes a new cosmetic facility registration fee that raises \$19 million for FDA annually. How does FDA justify this new user fee on businesses in light of the significant budget increases the agency has received over the past 5 years?

Response: FDA is requesting authorization for cosmetic facility registration user fees for FY 2013 to support expanded authorities for cosmetic safety, including facility registration and ingredient listing.

60. Ms. Emerson: What is FDA's basis for calculating the \$19 million in fees and how would the FDA structure the proposed annual registration fee?

Response: The user fee request represents the level of resources required to administer these additional authorities for cosmetic safety. FDA plans to develop a fee structure during negotiations with industry and other stakeholders.

61. Ms. Emerson: Have you been engaged with the cosmetics industry in detailed discussions or negotiations?

Response: FDA has met with industry representatives to discuss their ideas for possible new authorities, such as facility registration and ingredient listing.

Full Time Equivalent regarding Cosmetics User Fee Proposal

62. Ms. Emerson: In 2005 the Office of Cosmetics and Colors had been reduced to \$3.5 million and 10 FTE's to oversee 11 billion products sold annually. In 2007, the independent FDA Science Advisory Board recommended the program be increased to

\$10 million. Congress responded and FDA's cosmetics activities were funded in FY2012 at \$11.7 million with 25+ FTE positions. Does FDA have a proposal for how many FTEs it would expect to hire with this massive increase in programmatic funding through the cosmetics user fees and what priorities these positions would serve?

Response: FDA is requesting authorization for \$18.7 million and 63 FTE in user fees for FY 2013 to support expanded authorities for cosmetic safety, including mandatory facility registration and ingredient listing. Of the 63 FTE requested, 42 FTE would be hired at the Center level in order to: establish and maintain a Cosmetic Registration Program and issue standards to implement the 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. 18 FTE would be hired at the Field level 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 request also includes 3 FTE for program support activities.

QUESTIONS SUBMITTED BY REPRESENTATIVE ROBERT ADERHOLT

Pilot Project to Expedite Imports

63. Mr. Aderholt: Last year the Committee strongly encouraged FDA to establish a pilot project to expedite imports for highly compliant importers in order to better target FDA's limited resources on higher risk importers. Can you please update the committee on that pilot project, including whether FDA plans to implement it in FY2013? Does FDA need resources specifically for it?

Response: FDA developed the Secure Supply Chain Pilot Program, also known as SSC, which is a voluntary pilot program to allow FDA to determine the practicality of developing a secure supply chain program. A SSC program would assist FDA in its efforts to prevent the import of adulterated, misbranded, or unapproved drugs by allowing FDA to focus its resources on imported drugs that pose higher risks while increasing the likelihood of expedited entry for specific finished drug products and active pharmaceutical ingredients imported to the United States that meet criteria for selection under the program.

FDA is preparing to issue a second Federal Register Notice for the SSC Pilot Program, which will specify the information that should be included in an application to participate in the pilot. FDA intends to issue a third Federal Register Notice detailing the submission process and the date on which 100 applications will be accepted. Until the applications are received and reviewed, we are unable to determine if additional resources would be needed to implement the pilot.

Secure Supply Chain Initiative

64. Mr. Aderholt: I understand the Administration is undertaking a Secure Supply Chain Initiative. Could you speak more to that, and specifically what FDA's role in that has been? Have you been asked by OMB to submit any proposals for review? If FDA has been asked to submit a proposal to OMB but has not yet, then why not?

Response: In 2005, FDA began working with Customs and Border Protection (CBP) to develop the Secure Supply Chain (SSC) proposal. The SSC Pilot Program would propose an increase in the likelihood of expedited entry for specific finished drug products and active pharmaceutical ingredients (APIs) imported into the U.S. that meet the criteria for selection under the program.

The goal of the pilot is to allow FDA to determine the practicality of developing a secure supply chain program that would assist FDA in its efforts to prevent the importation of drugs that do not comply with applicable FDA requirements, allowing FDA to focus its resources on foreign-produced drugs that fall outside the program and that may not comply with FDA standards.

This program will also increase the likelihood of expedited entry into the United States of products meeting the pilot's criteria. The SSC program includes verification that participants meet certain requirement of CBP's Customs-Trade Partnership Against Terrorism (C-TPAT) program.

Menu Labeling Requirements

65. Mr. Aderholt: Last year, I wrote the Agency with concerns over how menu labeling requirements would affect non-dine in restaurants like pizza delivery operations whose bulk of business is done with online or over the phone ordering. Could the Commissioner please update us on how the proposed rule will affect pizza delivery and other such delivery restaurants?

Response: On April 6, 2011, FDA issued a proposed rule entitled, "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments." The comment period for the proposed rule was 60 days, but was subsequently extended an additional 30 days and closed on July 5.

FDA received approximately 900 comments. FDA did receive comments about pizza delivery operations, and we are in the process of developing the final rule. We do want to clarify, however, that the proposed rule, if finalized, would not mandate in-store menu boards in establishments that do not already have such menu boards. Rather, the proposed rule would require calorie labeling for standard menu items on in-store menu boards if a covered establishment provides such a menu board.

Voluntary Qualified Importer Program

66. Mr. Aderholt: The Voluntary Qualified Importer Program (VQIP), authorized under the Food Safety Modernization Act (FSMA), offers expedited importation procedures to vetted companies, but only to their food products. Would FDA prefer to apply the VQIP approach to all sectors? Could FDA implement a program that goes beyond expedited clearance, offering immediate clearance to VQIP participants, allowing FDA to focus its resources on shipments from unknown and potentially dangerous importers?

Response: There may be merits in applying some or all of the VQIP approach to other FDA-regulated products. However, before making this decision, FDA would need to carefully consider how this approach aligns with other product-specific regulatory models. In addition, applying this model before evaluating its success in the food sector may be premature. For this reason, the FDA does not support expanding the VQIP approach to non-food regulated products at this time.

Leveraging Third Party Resources

67. Mr. Aderholt: The Committee wants to help FDA shift from an import safety approach based on reacting to problems to one that prevents such problems from occurring at appropriate points along the global supply chain. For the agency to realize this important goal, it seems FDA needs to leverage third party resources, both public and private, and the control systems of highly compliant importers. What is FDA doing to better account for the work of competent foreign agencies and highly compliant importers?

Response: With the enactment of the FDA Food Safety Modernization Act, also known as FSMA, FDA is implementing new authority that will provide greater assurance that food imported into the United States meets FDA standards even before it reaches our borders. For example, the Voluntary Qualified Importer Program, which FDA is currently developing, will allow participating importers to establish with FDA that they are following good importation practices in exchange for expedited review resulting in expedited release of shipments at the time of entry. FDA is also establishing a system for accrediting third-party auditors of foreign food facilities – auditors who can certify that a foreign firm or a foreign facility is complying with U.S. standards. Foreign cooperatives and government agencies are eligible for accreditation as third-party auditors. FSMA also recognizes the importance of strengthening FDA's collaboration with trusted foreign regulators.

In the medical products area, FDA has various programs to assess information obtained from foreign regulators to better target facilities for FDA inspection. For example, the Center for Devices and Radiological Health has established the single audit program, which is intended to increase regulatory cooperation with our foreign counterparts and to minimize the regulatory burden on FDA. Additionally in the drug area, FDA has established a program with the European Medicines Agency (EMA) for confidence

building and reliance upon other foreign regulatory reports. FDA expects that this program will enable FDA to better target its inspection resources.

Once all of these programs, rules and regulations are established, FDA will be able to better leverage third party resources, both public and private.

QUESTIONS SUBMITTED BY REPRESENTATIVE CYNTHIA LUMMIS

New Dietary Ingredients

68. Ms. Lummis: In July, 2011, FDA issued Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues. How many new dietary ingredient applications does FDA expect if this guidance became binding? Is there a budget for reviewing these applications? Has FDA conducted an analysis of the cost of this guidance on dietary supplement manufacturers and how that would increase the amount consumers pay?

Response: Please note that the draft guidance is not binding and will not become binding if issued in final form; guidance only reflects FDA's current thinking and does not create any requirements. To date, FDA has received 550 unique New Dietary Ingredient (NDI) notifications since the passage of DSHEA. Based on conservative industry estimates, we would expect to receive a minimum of 15,450 additional notifications if industry fully complied with the statute. Industry has indicated that they believe that 16,000 to 25,000 required notifications have not been submitted to FDA.

There are currently 22 FTEs in the Division of Dietary Supplement Programs, 9 of whom currently participate in the review of NDI notifications.

FDA has not done a cost estimate for the draft guidance, but has estimated the time burden on the dietary supplement industry to meet the NDI notification requirements of the Federal Food, Drug, and Cosmetic Act and FDA's regulation on NDI notifications. FDA's most recent estimate was published in the *Federal Register* on June 3, 2011, in a notice seeking comment under the Paperwork Reduction Act. FDA estimated a minimal paperwork burden, approximately 20 hours per notification. This estimate was based on and is consistent with the statute. The regulations require a notification to contain information that the manufacturer or distributor should already have developed as the basis for its conclusion that a dietary supplement containing an NDI will reasonably be expected to be safe. Because of this, the burden is limited to extracting and summarizing the relevant information from the company's files and presenting it in a format that will meet the requirements of the Federal Food, Drug, and Cosmetic Act and relevant FDA regulations.

QUESTIONS SUBMITTED BY REPRESENTATIVE TOM GRAVES

Budget

69. Mr. Graves: Around this time last year I sent your agency I letter requesting alternative budget scenarios to see how your agency would handle funding reductions of 25, 20 and 10 percent.

I received your response 3 months later, but unfortunately this response did not include those budget scenarios I requested that you provide for the committee.

I understand the important work that your agency does, however I would like to see in which specific areas you could make reductions. Will you please have your budget commissioner provide these scenarios to the committee and my office?

Response: The response that FDA provided to your March 31, 2011 letter was prepared to be consistent with the Administration's budget policy and the Administration's work with Congress during consideration of the FY 2012 budget. During the first session of the 112th Congress, FDA supported the ongoing bicameral, bipartisan discussions between the Administration and Congress to address the nation's long-term fiscal picture. These budget discussions produced appropriations for federal agencies that met the requirements of the Deficit Reduction Act of 2011. Under any funding level, FDA works to prioritize resources to meet its mission. Significant reductions in funding would reduce staff and have real consequences on FDA's ability to protect the public's health and assure the American consumer that food and medical products are safe.

COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEES
AGRICULTURE, RURAL DEVELOPMENT, FOOD AND
DRUG ADMINISTRATION AND RELATED AGENCIES

COMMERCE, JUSTICE,
SCIENCE AND RELATED AGENCIES

FINANCIAL SERVICES AND
GENERAL GOVERNMENT



TOM GRAVES
9TH DISTRICT, GEORGIA

Congress of the United States
House of Representatives

March 31, 2011

WASHINGTON OFFICE:
1113 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-1009
(202) 225-9211

DISTRICT OFFICE:
311 GREEN STREET NW, SUITE 302
GAINESVILLE, GA 30601
(770) 535-7582

702 S. TUCKERMAN AVENUE
DALLAS, GA 30720
(706) 226-5328

<http://tomgraves.house.gov>

The Honorable Margaret Hamburg
Commissioner, Food and Drug Administration
United States Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

I am writing today to request that your agency submit budgets to the Sub-Committee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies within the Committee on Appropriations that represent in detail how your agency would operate with a 25 percent reduction in funds, a 20 percent reduction in funds and a 10 percent reduction in funds.

As you know, as of this writing, we are months away from reaching our debt ceiling of \$14.29 trillion. The Congressional Budget Office (CBO) projects that the gross federal debt will increase every year of the 2011-2020 period, reaching \$23.1 trillion in 2020 and costing Americans over \$1 trillion in interest payments alone by 2020.

According to CBO, at the end of the fiscal year of 2008, the debt held by the public was \$5.8 trillion. Since then the public debt has shot to \$9 trillion by the end of fiscal year 2010. While the government experienced lower tax revenues due to the economic recession, the response by the Administration and Congress to jolt the economy with higher federal spending coupled with the past imbalance between spending and revenues has led to an unsustainable debt.

Our fiscal situation is unacceptable. The responsibility for our debt is shared jointly by Democrat and Republican Administrations and Congresses of the past and finding solutions must be a bipartisan endeavor. That is why I am writing to you today to ask that your agency work with Republicans to begin reigning in spending and start our nation on a fiscally responsible course.

Thank you in advance for your willingness to work with the Sub-Committee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies on this important issue.

Sincerely,

Tom Graves
Member of Congress



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

June 27, 2011

Honorable Tom Graves
1113 Longworth House Office Building
Washington, D.C. 20515

Dear Representative Graves:

Thank you for your letter about the federal budget and the deficit.

FDA is responsible for protecting Americans many times each day and through every stage of their lives. FDA's role in protecting public health is unique, and there is no one to backstop us.

The public health landscape that FDA works in is constantly evolving, which means that FDA must address new challenges to achieve its mission. At FDA, we evaluate our programs and priorities to identify ways to efficiently use our resources and to operate within our means. When we identify program activities that are not working well, we work to reform them to achieve better results.

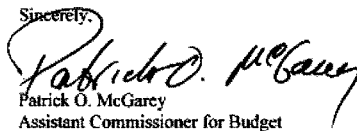
We review our budget with these principles in mind. The FDA FY 2012 budget supports many urgent public health priorities. It contains the resources to achieve fundamental public health responsibilities entrusted to FDA. The budget recommends new resources for FDA to transform America's food safety and nutrition, speed the development of medical countermeasures to meet critical national security priorities, protect American patients, and advance the science that is the foundation for FDA public health decisions.

FDA is monitoring the progress of the ongoing bicameral, bipartisan discussions between the Administration and Congressional leadership on the nation's long-term fiscal picture. These discussions will likely affect the overall funding for federal programs, the scope of many programs and the size of individual budgets. We look forward to working with you and others in Congress as this process moves forward.

The Administration is committed to making the difficult decisions necessary to reduce the deficit. However, we must do so in a way that safeguards the health of Americans now and in the future. That is what FDA and its employees strive to do every day.

Thank you for contacting FDA concerning this matter. If you have further questions, please let us know.

Sincerely,



Patrick O. McGarvey
Assistant Commissioner for Budget

Tobacco

70. Mr. Graves: It appears that in past few years, funding for user fee programs has risen significantly. In FY 12, application review fees are \$1,841,500 per drug—an increase of nearly \$300,000 over FY 11. Despite this increase in funding, it seems that the time FDA takes to respond to applications submitted by industry continues to lag and remain a sticking point.

In my mind, the problem is not adequate funding. The problem cannot be fixed by throwing more money at it, as the Obama Administration has been so quick to do. The problem is that the FDA *seems* unwilling to respond to manufacturers, and this problem persists across all user fee programs.

If you take tobacco manufacturers, for example, in this fiscal year 2012, they will be paying over \$470 million in user fees, as required by Section 919 of the Family Smoking Prevention and Tobacco Control Act.

Despite this wealth of funding, the FDA does not communicate well with tobacco manufacturers, who make their product in this country and even export domestically made tobacco products.

This problem is especially troubling because the FDA is accountable to no one when it comes to the Tobacco User Fee Program. The Center for Tobacco Products (CTP) is not required to submit a performance report on the tobacco user fee program to Congress. Other user fee programs are required to submit a performance report. Additionally, there are no negotiations over the rates like there are for the Prescription Drug User Fee Program.

Could you please explain the agency's apparent unwillingness to allow for public participation and an open of exchange of ideas? Could you please highlight and explain some of the major roadblocks or sticking points that create this vacuum of communication? Is this your impression as well, or do you feel the agency does a sufficient job of communicating with industry?

Response: CTP works actively to share information and develop and strengthen relationships with its tobacco industry stakeholders to support FDA tobacco product regulation and its public health goals.

FDA has received 53 requests for meetings from tobacco manufacturers or related trade associations and CTP has granted 46 of the requests. One meeting request was cancelled by the manufacturer. Additionally, CTP has initiated meetings with the tobacco industry. For example, CTP met seven times with either individual manufacturers or multiple manufacturers on the general science of smoked and smokeless tobacco products. CTP also met three times with individual manufacturers on science related to dissolvable tobacco products and met three times with individual manufacturers on science related to e-cigarettes. In December 2011, CTP also conducted six manufacturing site visits at the

invitation of industry to learn more about the manufacturing, marketing and distribution of tobacco products. Several more educational site visits are planned this year. And finally, CTP has sponsored two specific stakeholder discussion meetings for industry. The first was held with large and small tobacco manufacturers and growers in December 2011 and was attended by more than 30 industry leaders. The second was conducted in August 2011 with tobacco distributors, wholesalers, importers, and retailers. Also, at the request of the Tobacco Manufacturers Association, CTP leadership made presentations at the last two annual meetings and will be doing so again in 2012.

In addition, CTP undertakes a number of outreach activities with tobacco industry stakeholders including weekly emails on a variety of subjects including manufacturers, retailers, labeling, regulations and advertising, as well as updates as appropriate. Industry stakeholders are also regularly notified of relevant announcements, including opportunities for public comment on new guidances and rules. Industry stakeholders are offered calls or webinars for all major announcements with a question-and-answer component.

71. Mr. Graves: The Tobacco Control Act called for hundreds of millions in user fees to fund the Center for Tobacco Products at FDA. What kind of transparency is there for the money spent at FDA on tobacco-related activities? Is there enough transparency?

Response: CTP's obligating authorities are clearly identified in the Tobacco Control Act. The Center operates within the statute and clearly communicates its activities to stakeholders. CTP has developed a robust communications effort that works with tobacco product manufacturers and distributors to articulate proposed and new guidances and policies related to the sales and manufacturing of tobacco products. All draft and final guidances, compliance, and regulatory information, as well as warning letters are published on the FDA-CTP website.

CTP also maintains an interactive relationship with tobacco product related industry and stakeholders through webinars, meetings, published action plans, public dockets and various media devices to clearly articulate its activities and allow for industry comments. Also, any stakeholder may request automatic weekly updates from CTP on new information, announcements, guidance documents, regulations, proposals and meetings. More than 11,400 individuals currently receive these weekly updates from CTP. This transparency ensures that industry and stakeholders are aware of CTP's activities and plans.

In furtherance of its transparency objectives, FDA provided quarterly reports to the House and Senate Appropriations Committees in FY 2009 and FY 2010. FDA intends to provide Congress with an annual financial report going forward.

72. Mr. Graves: For example, as part of PDUFA, the FDA puts out financial and performance reports that show how the FDA spends user fee money. Does the FDA put

out a report on how it spends the tobacco user fee money? Is this a statutory requirement?

Response: The Family Smoking Prevention and Tobacco Control Act required FDA to produce a quarterly report to the House and Senate Appropriations Committees through FY 2010. FDA submitted each quarterly report to the Committees. There is no statutory requirement to issue a report on FDA use of tobacco user fees similar to requirements for reporting on PDUFA or any of FDA's other user fees. Going forward, FDA intends to provide the Committee with an annual tobacco user fees report containing financial information related to its use of tobacco user fees, including collection rates, arrears, and obligations by fiscal year.

73. Mr. Graves: Should the agency put out such a report?

Response: Yes, FDA agrees that it should issue an annual tobacco user fees report and intends to do so.

Lack of Enforcement Questions

74. Mr. Graves: Section 919 of the Family Smoking Prevention and Tobacco Control Act requires manufacturers and importers of tobacco products to pay user fees. Are you aware of any companies that have registered as establishments with the FDA that have not paid user fees?

Response: The Tobacco Control Act did not give FDA authority to collect user fees for all types of tobacco products immediately upon enactment, so there are some registered establishments that have not paid user fees because the types of products they produce are not currently subject to assessment by FDA. However, there are currently 29 registered establishments that are currently in arrears to FDA for either all or part of the user fees that they owe to FDA. Overall, the collection rate of tobacco user fees has been 99.4 percent of fees billed.

75. Mr. Graves: Are you aware of retail establishments selling consumers pipe tobacco that has been dried out for use by the consumer to convert this pipe tobacco into a cigarette through the use of a roll-your-own machine?

Response: FDA is aware of retail establishments selling consumers pipe tobacco for use in roll-your-own cigarette machines and is gathering more information about this practice to determine the appropriate regulatory response.

76. Mr. Graves: Would you agree that tobacco sold by a retailer for the intended purpose of manufacturing a cigarette makes the tobacco cigarette tobacco the resulting product a cigarette?

Response: FDA currently is examining the facts and evaluating available options for regulatory action pursuant to the Tobacco Control Act.

77. Mr. Graves: And if that is the case, doesn't that require the retail establishment to register the store as a manufacturer establishment under the Act?

Response: FDA is gathering information and considering its regulatory options based on this information.

78. Mr. Graves: With respect to the Tobacco Control Act, FDA is now starting to impose fines for retailers that fail inspections, but they are imposing multiple fines and alleging multiple violations for a single inspection. That seems to be contrary to the provisions of the law establishing the Center for Tobacco Products, which specifically states that retailers must be informed of all previous violations before being charged with another violation. Can you explain how FDA imposing multiple fines for a single inspection is consistent with the law?

Response: This question raises two distinct issues. First, whether FDA, as a matter of policy and practice, is providing notice of previous violations to retailers before seeking to impose civil money penalties for subsequent violations. The answer is yes. FDA has contracted with states and U.S. territories to conduct tobacco compliance check inspections of retailers that sell or advertise regulated tobacco products to determine whether those retailers are complying with the Family Smoking Prevention and Tobacco Control Act, also known as the Tobacco Control Act and its implementing regulations. Inspectors working under these contracts are commissioned by FDA to conduct such activities on FDA's behalf. After each inspection, the commissioned inspector submits their observations and inspection results to FDA. FDA then takes the appropriate regulatory actions based on its review of the inspection data and evidence. Although FDA is not required to issue a warning letter before taking further regulatory action, the first time FDA identifies violation at a retail outlet, FDA generally issues a Warning Letter that describes each violation.

FDA then issues an assignment to a commissioned inspector to conduct follow-up inspections of this retail establishment. Subsequent violations may result in FDA issuing a complaint seeking civil money penalties. Thus, violations documented during initial inspections by FDA-commissioned inspectors are communicated to retailers through an FDA Warning Letter, rather than a fine. It is only violations documented during subsequent inspections that have resulted in civil money penalty complaints.

The Tobacco Control Act requires that FDA provide "timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at

a particular retail outlet prior to conducting a follow-up compliance check.” FDA accomplishes this by sending written notice to a retailer of their violations through a Warning Letter or through a civil money penalty complaint as described earlier.

Additionally, the Tobacco Control Act provides that the amount of a civil penalty to be applied for violations will depend on the number of violations and the time period during which the violations occurred, as noted in the schedule of fines in section of the Tobacco Control Act.

As noted in both sections of the Tobacco Control Act mentioned earlier, the language refers to violations not to inspections. FDA has interpreted this to mean that each violation is a separate finable offense, even if several violations happen within one inspection. It is important to note that all initial violations documented by FDA-commissioned inspectors are communicated to retailers by an FDA Warning Letter and not a fine. Only subsequent violations may result in civil money penalties.

79. Mr. Graves: Are internet sellers of cigarettes being inspected to see whether people delivering their products actually verify the age of the person to whom cigarettes are delivered? If not, how do you plan to enforce the law?

Response: The Prevent All Cigarette Trafficking Act of 2009 or PACT Act which was enacted after the Tobacco Control Act, imposes a number of restrictions related to the sale of cigarettes and smokeless tobacco through the U.S. mail, including through internet-based and other remote sellers. The purpose of the PACT Act, among others, is to create disincentives for the illegal smuggling of tobacco products, stem trafficking, and prevent youth access through illegal Internet and contraband sales.

The United States Attorney General is responsible for administering and enforcing the PACT Act.

Nicotine Replacement Therapy Questions

80. Mr. Graves: Please provide a specific update on the Agency’s compliance with Section 917 of the Tobacco Control Act regarding recommendations on expanding the use of nicotine replacement therapy products in order to increase the rate of smoking cessation the U.S. Please include whether the Agency is considering changes to current labels, indications and/or claims for these products and the process for review and approval of NRT dose forms and new active pharmacological ingredients.

Response: FDA is actively reviewing the potential for additional and modified indications for nicotine replacement therapies, also referred to as NRTs, including extended use, indications for craving relief, and indications for relapse prevention, as referenced in Section 918 of the Tobacco Control Act or TCA. In addition, FDA’s Center for Drug Evaluation and Research is carefully considering these and other issues as part of the Agency’s review of three pending citizen petitions relating to NRTs. The

process for approval of new drugs, including new dosage forms and new indications, continues to be governed by Section 505 of the FD&C Act.

81. Mr. Graves: Your agency seems to be unresponsive to American manufacturers, who pay a substantial user fee. The FDA should comply with President's Obama's call for public participation and an open exchange of ideas, despite your own personal opinion of the stakeholder industries involved. Regardless of your perceived notions of a certain industry, you regulate them, they pay a substantial amount in user fees, you therefore must communicate with them. Will you work with the subcommittee to improve communication between you and the industries you regulate, and provide positive solutions in a timely fashion?

Response: FDA is always willing to share information, as appropriate, with manufacturers and other industry stakeholders and is committed to transparency and to public participation. FDA welcomes suggestions about ways to improve communication with its stakeholders.

Center for Tobacco Products

82. Mr. Graves: In FY 2011 CTP collected \$421.4 million in user fees. However, only \$135.7 million was actually spent in that year. What did CTP do with the unobligated balance of these funds?

Response: It is important to note that FDA anticipated and planned to carry over tobacco industry user fees during CTP's start-up phase, which is one of the reasons Congress had the foresight to make the tobacco user fees available as "no year" funds. CTP has retained these unobligated balances to fulfill the requirements established by Congress under the Family Smoking Prevention and Tobacco Control Act. CTP plans full use of unexpended balances, and will depend on those carryover funds to build the scientific base for tobacco product regulation, to enforce the law, and to launch FDA's science-based public health education program about the contents and dangers of tobacco products.

Since CTP was established in August of 2009, the agency has used tobacco user fees to establish the regulatory framework and staffing foundation necessary for tobacco product regulation. During this start-up period, all statutory obligations were met and recruitment and hiring has proceeded as projected.

It is also important to remember that since tobacco industry user fees are collected at the end of each quarter, the fourth quarter collections will not be available for obligation until the first quarter of the following fiscal year. Therefore, there will always be a carry-over balance equal to at least the fourth quarter projected collections. Because the user fees are the only funds available for tobacco regulation, this carry-over balance ensures operating funds for the subsequent fiscal year.

During the remainder of FY 2012, CTP has concrete plans to use the carry-over funds and the user fees collected in the current fiscal year to continue hiring staff and investing in the scientific, educational, and enforcement programs required to implement the Tobacco Control Act.

83. Mr. Graves: How is CTP insuring that its activities are not duplicative of the Department of Health and Human Services efforts from monies provided by Prevention and Wellness Fund contained in the American Recovery and Reinvestment Act of 2009 and section 4002 of ObamaCare? (Patient Protection and Affordable Care Act (the Prevention and Public Health Fund))?

Response: The Tobacco Control Act authorizes the FDA to collect quarterly fees from the tobacco industry. These fees are to be available only for the purposes of paying the costs of the activities of the Food and Drug Administration related to the regulation of tobacco product. Furthermore, the Act specifies that these tobacco user fees are the only funds authorized to be made available for tobacco regulation activities.

FDA has put a comprehensive financial stewardship and accounting plan in place to ensure that tobacco user fees only support its statutory and regulatory authorities. While many agencies and offices in HHS, including FDA, are working together to address the significant public health concerns created by the use of tobacco products, the Agency does not provide cessation services or engage in community-based tobacco prevention activities that are funded by the Prevention and Wellness Fund section of the American Recovery and Reinvestment Act of 2009 or the Prevention and Public Health Fund authorized by the Patient Protection and Affordable Care Act. FDA works closely with other HHS components to ensure the various tobacco programs are coordinated and are not duplicative.

84. Mr. Graves: Reports indicate that CTP is planning to expand its regulatory authority over certain sectors of the tobacco industry. Does CTP believe this is a prudent allocation of scarce resources while a backlog with SE Reports persists and the use of mislabeled “pipe tobacco” and “you’re your own” cigarette machines proliferates?

Response: The Tobacco Control Act provided FDA with immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Act also authorizes FDA to deem, by regulation, other tobacco products to be subject to Chapter IX of the Food, Drug, and Cosmetic Act, or FD&C Act, to protect the public health. Consistent with the authority that Congress granted, FDA publicly announced its intention to deem all products that meet the statutory definition of tobacco product to be subject to the FD&C Act. This deeming would ensure that all tobacco products are subject to FDA's tobacco control authority, which will help to address existing regulatory gaps or loopholes. FDA is confident that it has adequate resources to effectively apply the FD&C Act and related rules to these other tobacco products without interfering with its ability to complete its other regulatory activities related to tobacco product applications or other regulatory submissions.

85. Mr. Graves: Many of my adult constituents enjoy cigars. Those adults who choose to enjoy cigars, do so knowing the health concerns associated with it. However, they have the freedom in this country to enjoy what they would like to.

I understand and appreciate the FDA's efforts to reduce youth consumption of cigarettes and tobacco products. However some of your recent proposals to regulate tobacco advertising and production, to curb cigarette smoking among youths, will also affect premium cigars and those small businesses and retailer who sell them to responsible adults.

Do you plan to burden these small businesses with regulations that will totally change a responsible adult's shopping experience when he or she goes to purchase large, expensive cigars? Do you believe children are entering cigar shops to buy expensive cigars?

Response: The Tobacco Control Act provides FDA with immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Agency's tobacco product authorities found in Chapter 9 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 February 2012 edition of the Unified Agenda, FDA included an entry for a proposed rule that would deem products meeting the statutory definition of "tobacco product" to be subject to Chapter 9 of the FD&C Act and would clarify additional restrictions under the FD&C Act. FDA also explained that the scope of the proposed rule deeming cigars that was previously included in the Unified Agenda was being broadened to encompass products that meet the statutory definition of tobacco products.

It is important to note that FDA's assertion of jurisdiction over other tobacco products does not automatically apply to all current Tobacco Control Act rules and regulations that now apply to cigarettes and smokeless tobacco to the newly deemed products. The provisions that would automatically apply to newly deemed tobacco products would include registration, product listing, ingredient listing, good manufacturing practices when applicable regulations are issued, user fees for certain products, premarket requirements, and the adulteration and misbranding provisions of the Tobacco Control Act.

During the past year, FDA has had meetings with representatives of the 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 on this issue 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.

QUESTIONS SUBMITTED BY REPRESENTATIVE SAM FARR

FDA Food Safety Modernization Act (FSMA) implementation

86. Mr. Farr: Commissioner Hamburg – the regulatory proposal for FDA Food Safety Modernization Act (FSMA) implementation promises to be quite lengthy and no doubt controversial. Are your people cognizant of Congressional concern regarding over regulation of the private sector and thus is it your intent to submit a regulation that is one size fits all thereby dragging all commodities, regardless of risk, into this massive system?

Response: The FDA is aware of concerns about issuing one size fits all regulations. As the FDA Food Safety Modernization Act, also known as FSMA, directs, FDA intend to promulgate risk-based regulations for preventive controls and produce safety in which the risk mitigation measures are tailored to the specific hazards identified for the product and operation. There will be an opportunity for public comment once the proposed rules have published. FDA will consider all comments before finalizing the new rules.

Monitoring FSMA Implementation

87. Mr. Farr: Commissioner Hamburg – you have a finite budget for monitoring FSMA implementation regulations at the producer level. Is it your intent to treat all producers of all commodities equally? If so does this assume you will not dilute monitoring efforts in those areas or on those commodities in which repeated food safety issues have risen? Do you believe your resources should/could be more focused on high risk commodities and if not why not?

Response: Yes, we do believe that we should target our resources on the highest risk commodities and operations. FDA's food safety inspection resources are currently allocated according to risk. We intend to be able to focus our resources more efficiently in the future as we establish the risk-based preventive controls framework envisioned in the FDA Food Safety Modernization Act. This will not dilute our monitoring efforts, but will help us identify where they should be focused. Just as we expect producers to focus more monitoring efforts on higher risk situations, FDA will also focus its efforts on higher risk situations.

Import Equivalency

88. Mr. Farr: Commissioner Hamburg – I understand FSMA requires you to hold off shore producers and arriving product to the same standards as our domestic producers. Does your plan for evaluating the safety of product from another nation include a dialogue with USDA or USTR regarding possible trade reverberations? A knee jerk response by one country or a protest from one segment of agriculture could trigger trade

issues for our domestic producers. It would seem the expertise in these two agencies could be helpful in minimizing concern. Do you agree or disagree and why?

Response: We agree. We have a close working relationship with the Office of the U.S. Trade Representative, known as USTR, and several U.S. Department of Agriculture, or USDA, agencies including the Foreign Agricultural Service. We have regular contact with these agencies. Section 404 of the FDA Food Safety Modernization Act, or FSMA, directs FDA to be ever mindful of our trade obligations by stating that nothing in FSMA shall be construed in a manner inconsistent with the World Trade Organization or other treaty or other international agreement to which the United States is a party. To that end, we have had interagency briefings at various stages of FSMA proposed rule development and the input from USTR and USDA has been most helpful. FDA believes that the structured interagency review and clearance process for draft proposals provides an excellent opportunity for sister federal agencies to note any concerns, including potential trade concerns that might occur. FDA relies not only on the thoroughness and rigor of the review process, but also on routine meetings with agencies to identify issues and minimize potential impacts.

Quantifying Risk

89. Mr. Farr: Commissioner Hamburg – what is your thought regarding the identification of risk within specific commodity areas and while not exempting any producer but at least minimizing the burden on those producers in those commodities that have not had a food safety concern nor are likely too? I am thinking of artichokes, potatoes and citrus for example.

Response: The FDA Food Safety Modernization Act requires the Secretary to adopt a final produce safety regulation to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks. The goal is to establish science-based standards that minimize the risk of serious adverse health consequences or death. FDA is committed to promulgating a produce safety regulation that addresses the known safety risks associated with produce, as described in the scientific literature and in international standards, while considering the differences in risk posed by certain commodities. Risk mitigation measures should be tailored to the specific hazards identified for the product and the operation. There will be an opportunity for public comment once the proposed rule has published. FDA will consider all comments before finalizing the new rule.

Fresh Produce Testing

90. Mr. Farr: Commissioner Hamburg - When FDA conducts testing on fresh produce, please provide summaries of the time it takes from the time the shipment is sampled until

reports the results to the shipper? In addition to the average time, please also provide range of time it has taken. Has FDA analyzed the costs of delays in reporting test results in terms of the loss of value of produce held while awaiting test results?

Response: In FY 2011, FDA collected 3,495 samples from 3,490 lines of imported fresh produce, which accounts for 0.18 percent of the total number of imported fresh produce lines. From date of FDA sample collection to final admissibility decision entered into the system for electronic notification to the import broker via U.S. Customs and Border Protection's Automated Broker Interface, the average time was 6.6 days. This average includes all sample collection and analyses timeframes regardless of analyses performed and whether a violation was or was not identified. The minimum time from sample collection to final admissibility decision for a line was one day; the maximum was 92 days. In the case of the 92 days, this line was refused admission due to pesticide contamination.

Common laboratory analyses for fresh produce are for the presence of pesticide and microbiological contamination, which require varying times to complete. Non-violative lab results for a line generally receive a final admissibility decision faster than violative lab results.

FDA has not performed a financial analysis evaluating changes in value of produce held while awaiting lab results. FDA is aware of and sensitive to the costs that may be incurred by the industry due to FDA's surveillance actions. FDA takes steps to minimize any unnecessary delays; however, surveillance sampling is an important part of FDA's consumer protection activities related to imported products. FDA surveillance of imported produce in FY 2011 resulted in the refusal of over 200 lines of products, keeping them from U.S. consumers.

Fast Track for Imports

91. Mr. Farr: Commissioner Hamburg - The new food safety law gives FDA the authority to create a "fast track" where in exchange for additional safeguards importers may cross the border faster. How will FDA coordinate with other agencies such as Customs so that this voluntary program offers a quick entry into the country which is so important for perishable commodities such as produce?

Response: FDA continues to work on the operational design of the Voluntary Qualified Importer Program, also known as VQIP, authorized under the FDA Food Safety Modernization Act, or FSMA. VQIP will be a formal voluntary program under which importers may submit evidence of regulatory compliance and safety controls, according to established criteria, in return for expedited review of entries. VQIP will, among other things, require importers to obtain food from certified foreign entities FDA intends to harmonize VQIP with existing initiatives like Custom and Border Protection's Customs Trade Partnership Against Terrorism and Importers Self Assessment programs.

Front of Pack Nutrition Rating Systems

92. Mr. Farr: Commissioner Hamburg - The Institute of Medicine (IOM) has issued a report entitled *Front of Package Nutrition Rating Systems and Symbols* (Phase II - 2011) that recommends that "FDA and USDA should develop, test, and implement a single standard FOP system to appear on all products." The FDA has conducted its own research and stated that the agency is developing a proposed regulation that would more explicitly define the nutritional criteria that would have to be met by manufacturers making broad FOP or shelf label claims concerning the nutrition quality of a food . . ." (Letter from Dr. Margaret Hamburg, Commissioner of Foods and Drugs, to the Honorable Rosa L. DeLauro, October 19, 2009).

In the interim, a number of nutrition rating systems have been developed by the private sector and are now in use.

Please provide the subcommittee with the agency's views regarding front of pack and shelf label nutrition rating systems based on proprietary algorithms not available to the public. Does the FDA consider such nutrition rating systems to be consistent with the IOM's recommendations to the agency?

Response: FDA continues to seek a standardized FOP system that will provide consumers with nutrition information that is noticed, understood and used by consumers to make healthy food choices to prevent obesity and chronic disease. Numerous FOP and shelf labeling systems exist. FDA is reviewing the IOM report and will be monitoring the effectiveness of various FOP labeling systems (including the system developed by the Grocery Manufacturers Association and the Food Marketing Institute) to determine what is most useful to consumers in making healthier choices.

93. Mr. Farr: Please provide the subcommittee with a timetable for the publication of the agency's proposed regulation on nutritional criteria for front of pack and shelf labeling systems.

Response: FDA intends to develop a proposed rule to define the nutritional criteria for broad front-of-pack or shelf label claims about the nutritional quality of foods, although we have not set a timetable for its completion. FDA is assessing the IOM recommendations and will be monitoring various existing systems to inform FDA's plans for a FOP labeling system.

U.S. Drug/Medical Device Approval and Recall Rates Versus That In the European Union

94. Mr. Farr: Commissioner Hamburg - The issue was raised that the EU seems to approve drugs and medical devices more quickly than the U.S. does. Does the FDA have data on the relative time it takes to approve drugs and medical devices in the EU versus in the U.S?

Response: Statistics demonstrate that PDUFA has led to the reversal of the drug lag that prompted Congress to adopt this law. Since the enactment of PDUFA, FDA has steadily increased the speed of Americans' access to important new drugs compared to the EU and to the world as a whole. Of the 35 innovative drugs approved in fiscal year 2011, 24 drugs—nearly 70 percent—were approved by FDA before any other regulatory agency in the world, including the European Medicines Agency. Of 57 novel drugs approved by both FDA and the EU between 2006 and 2010, 43 drugs, or 75 percent, were approved first in the United States.

In recent years, the average FDA drug review time also has been significantly faster than those in the EU. For priority drugs approved between 2006 and 2010, FDA's median time to approval was six months or 183 days. This is more than twice as fast as the EU time to approval for those drugs, which took a median time of 13.2 months, or 403 days. For standard drug reviews, FDA's median time to approval was 13 months, or 396 days. This time to approval was 53 days faster than the EU time to approval of 14.7 months, or 449 days for those drugs.

FDA is not aware of any comprehensive database that contains information related to device approval status in the EU. It is difficult to track medical device approvals or other data on devices in the EU because there are few or no publicly accessible, centralized systems for collecting and monitoring information about medical device approvals or safety problems in the EU. Manufacturers use Notified Bodies, which are private, non-governmental entities that review and approve devices by giving them a CE Mark, also known as a Conformité Européenne or European Conformity. The bases for the decisions of Notified Bodies are kept confidential and are not released to the public or to EU regulatory bodies.

95. Mr. Farr: Also, is there data on recall actions? How does the U.S. compare to the E.U. in terms of recalling drugs or medical devices? Does it happen more or less often in the U.S. than it does overseas?

Response: Yes, FDA does collect and maintain data on recall actions of FDA-regulated products. FDA annually publishes summary recall statistics on the FDA website.

Because recalling of drugs and medical devices are handled differently in the E.U., I will speak to each separately. For drugs, health authorities in the EU have the authority to require companies to recall drug products, while the FDA currently does not have this authority. Rather, recalls of drug products in the United States are undertaken voluntarily by the responsible company. Therefore, it is difficult to compare and draw conclusions about recall rates in the United States and EU countries.

In contrast, FDA has the authority to require companies to recall medical devices. Yet both in the US and EU recalls are primarily conducted voluntarily. FDA has observed

inconsistencies in recall reporting in EU countries. As with drugs, it is difficult to compare and draw conclusions about recall rates in the United States and EU countries.

QUESTIONS SUBMITTED BY REPRESENTATIVE ROSA DELAURO

510(k) Device Approval

In July of last year, the Institute of Medicine released its findings on the 510(k) clearance process. The IOM noted that the current process is deeply flawed and in need of fundamental reform – I could not agree more and was disappointed by the Agency’s rapid dismissal of the IOM report. A series of reports and studies by the Government Accountability Office reinforce the IOM’s concern.

Collectively, these studies indicate that the process simply is not effective in protecting the public health and ensuring the safety of devices. Especially when you look at the incredible diversity of devices approved through this process. Take just one example: more than three-quarters of a million Americans have a hip or knee replaced each year.

96. Ms. DeLauro: Can you tell me about FDA’s review of the IOM findings since they were announced in July 2011? How have they been a part of the Agency’s discussions on the 510(k) process?

Response: The Institute of Medicine, or IOM July 2011 report made several recommendations as part of their independent review of the 510(k) program. FDA solicited feedback on the IOM report through an open public docket and held a public meeting to obtain stakeholder feedback. FDA carefully considered the report findings and stakeholder feedback and the Agency is implementing many of the recommendations. For example, FDA is addressing the remaining Class III 510(k) preamendment devices by setting a goal of publishing proposed rules for all remaining devices by the end of 2012. FDA is also developing a comprehensive plan for medical device postmarket surveillance, which will be communicated with the public by April 30, 2012. FDA is conducting an evaluation of CDRH staffing, infrastructure, policies, and practices pertaining to medical device software. And, FDA is also establishing a Quality Assurance program.

In addition, while we did express our belief that the 510(k) program should not be completely eliminated, we have acknowledged that the program could benefit from improvements. We have already begun implementing more than 25 specific actions that will strengthen the program and that address many of the shortcomings identified by the IOM.

97. Ms. DeLauro: Has the Agency taken them into consideration when looking at the need to reauthorize and update the Medical Device User Fee and Modernization Act,

MDUFA? What is the Agency doing to ensure that this program is strengthened to better protect the health of Americans?

Response: It is important to note that many of the findings in the IOM report parallel the changes the FDA has already agreed to make. The MDUFA reauthorization will ensure that we obtain needed resources to continue to review applications according to newly developed goals, while completing an aggressive action plan that is designed to improve predictability, consistency, and transparency under the existing statutory framework. This stronger and more consistent program will support a robust medical device industry in the United States by bringing safe and effective devices to market for the patients who need them.

Trade and Food Safety

Roughly 80% of the seafood, 50% of the fresh fruits, and 20% of the fresh vegetables consumed in the United States have been produced outside of the United States. As your testimony notes, these food products come from over 200 countries and more than a quarter of a million foreign establishments.

Products enter the U.S. through over 350 different ports, but at the peak of its funding, FDA had inspectors on-site at only 90 of these ports. Today, the agency likely only covers half that number.

The FDA inspects less than one percent of food at the U.S. border. And while imports of FDA-regulated foods have more than tripled in the last decade, the rate of inspections has remained woefully low as the sheer quantity of imports has steadily increased. In fact, only 0.2 percent of the shipments received in 2006 were analyzed in a laboratory as part of their inspection process. Clearly we must do more.

99. Ms. DeLauro: Three new Free Trade Agreements that were recently signed into law may result in further increases, as will the Trans Pacific Partnership FTA that we are currently negotiating. Can you tell me what the Agency's role is in those negotiations? How will we ensure that as we continue to import more food products, the Agency has the capacity to adequately ensure their safety?

Response: FDA has participated as a member of the U.S. interagency negotiation team for Free Trade Agreements. FDA's role is to provide information and advice to the lead negotiator on regulatory, food safety and public health issues related to trade. FDA representatives on negotiating teams ensure that our regulatory authority is not compromised during the negotiations and that food safety and public health considerations are properly addressed.

To protect the food supply as imports increase, FDA's enforcement of food safety regulations must remain vigilant with regard to compliance and will be strengthened by the import mandates of the FDA Food Safety Modernization Act.

100. Ms. DeLauro: The FDA Food Safety Modernization Act included some steps forward in the area of ensuring the safety of imported food. But it seems that, like many rules, regulations, and guidance – we are still waiting to see them. This includes the foreign supplier verification rules. It looks like those are nearly two months behind schedule already. Can you tell me why it is taking so long? Is this something that the Agency would be able to better address with additional staff dedicated to the issue?

I find it simply unacceptable that the health of consumers is at risk from imported foods and food ingredients because of a lack of resources in one part of the Administration while another part negotiates additional FTAs that will exacerbate the problem.

Response: The foreign supplier verification program proposed rule is a high priority for FDA. We believe this program is a critical part of the enhanced import oversight envisioned in the FDA Food Safety Modernization Act, or FSMA. It complements the preventive controls proposed rule for human food processing facilities, the proposed rule for animal food processing facilities, and the produce safety standards proposed rule. These are complex and inter-related rules that together form the foundation of the new preventive framework called for by FSMA, which is designed to improve the safety of domestic and imported food and feed. We have dedicated staff who worked tirelessly to develop these proposed rulemakings. To expedite future work, we are using 2012 resources to hire additional staff to work on FSMA regulation and guidance documents.

Post-Market Surveillance and REMS

Both the Congress and the American public expect the FDA to be able to quickly identify signals of concerns with any new drug, device, or biologic to ensure that those products are both safe and effective for the entire population.

The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require a Risk Evaluation and Mitigation Strategy, or REMS, from manufacturers to ensure that the benefits of a product outweigh its risks. And in other approval decisions for drugs, devices, and biologics, FDA has the power to require post market surveillance to identify signals of concern, either market-wide or within a sub-population.

101. Ms. DeLauro: How does FDA enforce this post market surveillance?

Response: FDAAA gave FDA the authority to require drug companies to conduct postmarketing studies or clinical trials, known as postmarketing requirements or PMRs, to assess signals of serious risk or a known serious risk related to the use of the drug, or to identify an unexpected serious risk when available data indicates the potential for a serious risk, if the agency becomes aware of new safety information. FDA can also use postmarketing requirements to identify an unexpected serious risk when available data indicates the potential for a serious risk, if FDA becomes aware of new safety information. Once FDA notifies a drug sponsor of the need for a postmarketing study or

clinical trial, the company is required to provide a timetable for completing the study or trial, study milestones, and periodic status reports on progress toward completing the PMRs. If a company fails to comply with the timetable, FDA is authorized to take enforcement action against the company, unless the company can demonstrate good cause for the failures.

In February 2012, FDA put industry on notice that FDA intends to take enforcement action against companies that fail to conduct required postmarket studies and clinical trials. On February 17, 2012, FDA issued the first-ever Warning Letter to a sponsor, citing violations of the FD&C ACT Section 505(o)(3) for Merck's failure to adhere to milestone dates in the timetable for completing a PMR.

The Office of Compliance within FDA's Center for Drug Evaluation and Research, known as CDER, instituted a REMS-specific surveillance inspection program during FY 2010. The program monitors compliance with the REMS requirements and assesses possible violations by applicants, manufacturers, packers, distributors, and contractors.

The Office of Compliance conducts approximately 15 REMS inspections annually. Compliance oversight includes collaboration with other offices, including but not limited to, the Office of Regulatory Affairs, the following three offices within CDER: the Office of Surveillance and Epidemiology, the Office of Regulatory Policy, and the Office of New Drugs. To date, no enforcement actions related to the inspections of a REMS program have been taken; however, the inspection results have been useful in identifying problems that have resulted in FDA seeking REMS modifications. No inspection has yet identified deficiencies rising to the level of a significant violation of a REMS requirement.

102. Ms. DeLauro: What is the usual time lag between the decision to implement REMS and the instructions and implementation of the REMS?

Response: For drugs that require a REMS when they are approved, that is, in cases where FDA determines that the drug cannot be approved without a REMS, the time between approval of the REMS to the time it is implemented can be immediately if the company is ready to launch the REMS program. This is usually the case for REMS with fairly simple communication plans.

However, if the REMS is complex and includes elements to assure safe use, also known as ETASU, it may take the company several weeks to months after approval of the REMS to fully implement the program. For example, Abstral was approved on January 7, 2011, with a REMS that included an ETASU. The sponsor needed to take a number of steps to implement the program. These steps included establishing the Abstral website and REMS call center, sending letters to healthcare providers, establishing prescriber and pharmacy enrollment systems and making Abstral available to distributors, wholesalers, and pharmacies.

The sponsor began marketing Abstral on 01 April 2011, about three months following approval of the drug, after completing these steps.

For drugs that require a REMS post approval, when FDA becomes aware of new safety information and determines a REMS is necessary, the time between approval of the REMS and the time it is implemented can be immediate to within 30 days if the REMS is a simple communication plan. If the REMS includes an ETASU, it may take the company six months to one year to fully implement the REMS. Implementing the REMS in the postmarketing setting can be more complex because the drug is generally already available in pharmacies and is being used by patients. In addition to the processes outlined above, the sponsors must make plans to transition prescribers, pharmacies, and current patients to the program.

103. Ms. DeLauro: Is there any area where the FDA needs additional authority to ensure that it obtains the data it needs in relation to REMS or post market surveillance and that it has the ability to act on that data?

Response: FDA has the authority to require postmarketing clinical trials and studies to investigate a serious safety risk. In implementing this provision, FDA has found that because the statute does not explicitly include a requirement that a sponsor submit an adequate protocol for FDA review within any specified period, after a sponsor is notified of the need to conduct a study or trial in the postmarket setting, that is, after approval, there is an opportunity for substantial delay, including indefinite delay in obtaining a protocol from a sponsor that FDA considers to be adequate for the conduct of a well-designed study or trial. In relation to REMS, although the sponsor is required to submit a REMS within a particular period of time, if the REMS is inadequate, there is no explicit mechanism to order the sponsor to submit a revised proposed REMS that FDA considers to be adequate.

104. Ms. DeLauro: How does the public access the post market surveillance results and REMS data?

Response: FDA provides several ways that the public can access the results of the postmarketing surveillance of drugs.

CDER provides a website for patients and providers that includes links to certain drug safety information and communications. These links are quarterly postings of safety issues identified from the AERS Database, drug safety communications, and summary information about ongoing and completed postmarket safety evaluations of adverse drug experience reports made to FDA.

In January 2010, CDER began issuing a single type of communication to provide the public with easy access to important postmarket drug safety information. The Drug Safety Communications are written in an interactive messaging format that allows the public to access information most relevant to them. The following link provides more information on FDA's drug safety communications to the public.

(<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM295217.pdf>).

The public can access REMS data through the FDA website and general summaries of REMS assessment findings are shared at annual professional conferences. In addition, FDA is required annually to bring at least one drug with a REMS with elements to assure safe use to the Drug Safety and Risk Management Advisory Committee –DSaRM- to assess whether the elements: assure the safe use of the drug, are not unduly burdensome on patient access to the drug and to the extent practicable, minimize the burden on the healthcare delivery system. In December 2011, FDA convened the DSaRM advisory committee to discuss the isotretinoin REMS. Information presented at that meeting is posted on the FDA website.

105. Ms. DeLauro: From 2007-2012, what percentage of post market surveillance studies resulted in changes to patient packet inserts or other patient/provider information? Of these changes, what percent have related to women and minorities?

Response: FDA's databases are not configured to systematically report the information requested in your question, nor does FDA routinely compile it. Therefore, we are unable to provide you with the requested information. Nevertheless, we can assure you that all information that is obtained from postmarketing studies and trials, whether requested under our regulations or required under our statutory authorities, is carefully evaluated to determine whether or not the labeling should be revised. Revisions to labeling include clarifying information about the product as well as adding new safety or efficacy information. The revisions are made to better inform all patients and providers about the benefits and risks of a drug product and the optimal uses(s) of the drug.

FDA Information Technology

The FDA is tasked with guarding the safety and efficacy of drugs, biologics, medical devices, and food yet the Agency continues to have insufficient resources relating to the information technology that is needed. An insufficient IT system inhibits the FDA from fulfilling its mission and puts American patients and consumers at risk.

This has been highlighted numerous times, including the December 2011 OIG report – a report that found while the FDA was increasingly relying on States for food facility inspections, the Agency was not able to accurately track, classify, or follow up on those State inspections or the associate violations.

Congress, and the American public, expect the FDA to have the technological capabilities to quickly and effectively do appropriate data analyses and reporting, safety analyses, access and analyze clinical data, capture emerging trends, and act on safety concerns. We also clearly expect the various offices and divisions to have easy access to electronic information so our health is not unnecessarily at risk.

And while I commend the agency for finding savings related to duplicative IT equipment, I cannot help but wonder how such savings were found in the face of these reports of the Agency's inability to use, store, catalog, and communicate many of these data sets.

106. Ms. DeLauro: Are the IT systems in the various FDA centers and offices capable of quickly exchanging high level of information efficiently and effectively across the Agency between headquarters and field offices on a regular basis?

Response: Yes, the FDA IT systems are capable of quickly exchanging high level information across FDA. As a result of various initiatives completed and underway, FDA continues to improve the Agency's ability to exchange information efficiently and effectively. The data center modernization completed 2011 provided an advanced computing infrastructure that is secure, scalable, and reliable, and that enables interoperability across FDA.

FDA is now in the position to move forward with modernization of software systems. Additionally, in October 2011, FDA implemented enhancements to the Center Views or CV module, improving the productivity of FDA Domestic and Import Reviewers, Investigators and Consumer Safety Officers by providing improved and efficient access to FDA data. CV provides the capability to search various Center data sources, eliminating the need to directly access Center legacy systems when retrieving product and firm information and provides a comprehensive product data set to aid FDA personnel in regulatory decision making.

There are challenges introduced by our inability to consistently and uniquely identify specific firms and facilities that process FDA-regulated products. FDA processes more than 20 million import transactions per year that relate to FDA-regulated products. The data coming from Customs to identify parties are neither unique nor consistent, creating duplicate records in our databases that do not link to the information we maintain on business entities. It is labor-intensive to match entities to our information so we can make informed decisions for import purposes. Therefore, FDA is in the process of implementing Dun & Bradstreet's DUNS number as our universal business identifier for linkage and facility identification. This provides global recognition and identification of each specific business entity at a single location with a unique DUNS# and allows potential linkage of information from any source such as FDA's, other government agencies, and international regulatory authorities to the correct business entity.

107. Ms. DeLauro: Have you had any data conversion problems when exchanging data across the Agency?

Response: Yes, FDA has encountered data-conversion problems when exchanging data across FDA. FDA houses the largest known repository of clinical data consisting of unique, high-quality data on the safety, efficacy and performance of drugs, biologics and devices, both before and after approval. Unfortunately, the form, paper, electronic text, and electronic fields, structure, and terminologies for the data have been developed by those submitting the information and are not uniform. FDA has been investing in the

infrastructure necessary to support receipt of study data electronically and to develop an environment conducive to analyses of large data sets. This requires data harmonization and standardization such that comparisons between data can be made effectively.

FDA has participated in efforts and initiated pilot projects to develop data exchange and terminology standards and begin aligning its systems and mapping data sets to these standards. Clearly, in a world of accumulating data and information, FDA remains in pursuit of systems and approaches to house and analyze its vast data stores and ever increasingly complex data arriving daily. The vast data stored at FDA must be transformed into a harmonized format and organized in a common database so that it can be queried by topic and analyzed to address key questions.

108. Ms. DeLauro: At what point will the Agency achieve 100% electronic submissions in each of its centers? What technology and staff are and will be needed to achieve this?

Response: All the centers and the Office of Regulatory Affairs have the ability to accept electronic submissions via the FDA Electronic Submission Gateway for certain submission types. Sponsors of regulated products requiring or requesting FDA premarket review or notification, submit an application, usually referred to as a submission, to FDA before and during the product testing process, as applicable. FDA accepts electronic submissions through Gateway, which virtually walk external users through the process of submitting application and other information. Gateway is a centralized FDA-wide system for securely receiving submissions electronically. In 2006, FDA received approximately 60,000 electronic submissions and in 2011 over one million.

FDA is planning to accept ten additional submission types during 2012 which will help increase the submissions received to more than 1.5 million in 2012. For Gateway to accept a new type of submission, guidance must be prepared and vetted for public comment as specified by the Paperwork Reduction Act.

The technology and staff resources for current submission types and the proposed ten additional submission types, and the predicted volume increase, for 2012 are in place. To date, approximately 75 percent of the funding for this environment has been provided by PDUFA User Fees. As the types of submissions and the volume of submissions grow, resources will be required beyond what is provided by user fees. FDA requires additional capacity for the increased volume of submissions and technical updates to review tools to accommodate additional submission types.

109. Ms. DeLauro: Ms. DeLauro: Looking ahead, how will the agency improve on the multiple weaknesses noted by the HHS OIG in December 2011?

Response: To be more effective in the modern world, FDA has to improve its ability to share and integrate data with external partners.

To expand FDA understanding of partner IT systems, a Food Safety Modernization or FSMA workgroup developed a survey to provide an extensive perspective of the types of

IT systems being implemented at the state level and the integration gaps currently present.

FDA is also participating in three projects through the Partnership for Food Protection that will provide greater insight and movement towards integration. The projects comprise of the development of a tool that will assist state programs evaluate specific job and program functions from an IT perspective and identify areas for improvement, constructing a data landscape of the data points being collected by the states and FDA during a good manufacturing practice, or GMP, inspection, and conducting a Strengths, Weaknesses, Opportunities and Threats evaluation of data integration by conducting a pilot data exchange between FDA and the Pennsylvania Department of Agriculture. Last year, FDA launched several initiatives to support data integration with state partners including drafting a MARCS Partner Gateway concept paper that lays out the vision for an integrated IT system and serves as a starting point for extended electronic submission of recall audit checks by states to FDA. Another initiative provides FDA Districts and states the ability to electronically record, track, and share food contract audit results and summaries.

Microbiological Data Program

Commissioner, you may have heard of a USDA program known as the Microbiological Data Program. This program was implemented in 2001. In 2011, over 35,000 tests were performed on a range of produce commodities. In 2012, USDA intends to conduct 49,000 analyses with just over \$4.3 million appropriated for the program.

Yet, the FY2013 Budget Request eliminates this program – noting that it “is not closely aligned with the core mission of the [Agricultural Marketing Service]” but also that “the need for produce pathogen data has not diminished.”

This is clearly a valuable program, helping us understand the prevalence of foodborne pathogens and also collecting information on general microbiological contamination. Yet, it seems to be falling through the cracks that are the result of too many agencies being involved in food safety.

110. Ms. DeLauro: Does the FDA intend to absorb this program loss by creating a similar program? I did not see an indication of that in the FY2013 request.

Response: FDA does not intend to absorb the loss of USDA’s MDP by creating a similar program. Rebuilding such a network would be expensive, time consuming, and logistically difficult for FDA at a time when FDA must implement FSMA mandates.

111. Ms. DeLauro: If not, how will the Agency and Administration ensure that consumers are not at increased risk of foodborne illness because of the loss of the data and understanding of produce pathogens enabled by this program?

Response: FDA will use all of the tools under our regulatory authority to prevent foodborne illness.

Food Safety Funding and Chinese Exports to the U.S.

Ms. DeLauro: I have to tell you that I am incredibly disappointed in the Administration's FY13 request, especially as it relates to food safety funding. It is a tragedy that the health of American consumers will be at risk because of a lack of capacity at the federal level – especially when this Subcommittee has the ability to provide the Agency with the funds you need.

Nearly all of your food safety increase is because of a user fee that seems less and less likely – another letter opposing these fees was sent by some members of the industry on February 23rd. Page 25 of your testimony notes that “the simple truth is that the FDA cannot meaningfully deliver on [FSMA] mandates without sufficient funding.”

That said, what are the implications for food safety if those fees are not approved and Congress does not provide funding on top of the budget request for FDA's food program this year?

JCLERK'S NOTE: FDA did not provide a response to the question.[

112. Ms. DeLauro: The CBO estimated that FDA will need over \$400 million to implement FSMA. Do you agree with that estimate? If not, please provide the FDA's estimate for full implementation of FSMA.

Response: In enacting the FDA Food Safety Modernization Act -- FSMA, Congress gave FDA an opportunity to modernize the food safety system. In order to take full advantage of that opportunity, FDA needs adequate resources to properly implement FSMA. For FY 2011, FDA received a budget increase related to FSMA of \$61 million. In FY 2012, FDA received a budget increase devoted to FSMA of \$39 million. In FY 2013, the President's Budget recommends food facility registration user fee increases for FSMA implementation of approximately \$220 million. FDA believes that the requested increase of \$220 million to implement FSMA in FY 2013 would provide for substantial progress in building the science-based, prevention-oriented and efficient food safety system mandated by Congress.

113. Ms. DeLauro: There were predictions last year that FDA would need to hire thousands of new inspectors to implement FSMA. Is that true?

Response: FDA is not aware of the origin of the estimate that we would need thousands of new inspectors to implement the FDA Food Safety Modernization Act. The FDA FY 2013 Budget includes funding to hire 273 staff members to implement FSMA.

114. Ms. DeLauro: The only real increase and change to the food safety portion of the Agency's budget is a small amount of money to better ensure the safety of food and products imported from China. But, I have to admit that when I read your testimony, I was shocked to read that some of this money will go to "strengthen [China's] regulatory capacity to assure the safety of the food and drugs that their industries export to the United States."

Response: Capacity building helps ensure the safety of products that Americans consume. Because we cannot inspect every product at the border, having countries with sufficient capacity to regulate their internal industries results in safer products being produced and shipped to the United States to be offered for purchase by American consumers. Capacity building is a vital part of FDA's work with its regulatory counterparts around the world. Since the signing of the FDA Food Safety Modernization Act into law in January 2011, section 305 related to building the capacity of foreign governments with respect to food safety has been part of the FDA mandate. From the founding of our first overseas offices in 2008, FDA regularly and publicly highlights the capacity building work we do, not just in China, but around the world. We find this work to be especially important in our collaboration with counterparts whose regulatory systems are still developing in locations like India, Latin America, the Middle East and North Africa, Sub-Saharan Africa, as well as China.

As noted above, capacity building is a vital part of FDA's Pathway Initiative. We have worked strategically with a range of countries to strengthen regulatory capacity, and provide information, tools, and training to enhance the safety of FDA-regulated products being imported to the United States.

Specifically, regarding the proposed increase in funding for FDA's efforts in China, the vast majority of work done by new proposed staff will be in the area of inspections. It is also important to stress that any capacity-building efforts new staff perform would only serve to enhance current, ongoing capacity building FDA is already undertaking with Chinese regulators. Finally, FDA's primary goal in increasing staff in China is to enhance the compliance of FDA-regulated goods exported from China with relevant FDA regulations and requirements. Inspections can drive such enhancements in compliance, as can strategically-targeted training and capacity building, and often these two activities complement one another. In China, we have used information from investigations performed by in-country inspectors to undergird and inform our capacity-building strategy.

115. Ms. DeLauro: I find it staggering to think that we need to spend your Agency's limited resources to help increase China's regulatory capacity – why is it that unlike the other countries we trade with they cannot invest in that regulatory capacity?

Response: Capacity building helps ensure the safety of products that Americans consume. Because we cannot inspect every product at the border, having countries with sufficient capacity to regulate their internal industries results in safer products being

produced and shipped to the United States to be offered for purchase by American consumers. Capacity building is a vital part of FDA's work with its regulatory counterparts around the world. Since the signing of the FDA Food Safety Modernization Act into law in January 2011, section 305 related to building the capacity of foreign governments with respect to food safety has been part of the FDA mandate. From the founding of our first overseas offices in 2008, FDA regularly and publicly highlights the capacity building work we do, not just in China, but around the world. We find this work to be especially important in our collaboration with counterparts whose regulatory systems are still developing in locations like India, Latin America, the Middle East and North Africa, Sub-Saharan Africa, as well as China.

As noted above, capacity building is a vital part of FDA's Pathway Initiative. We have worked strategically with a range of countries to strengthen regulatory capacity, and provide information, tools, and training to enhance the safety of FDA-regulated products being imported to the United States.

Specifically, regarding the proposed increase in funding for FDA's efforts in China, the vast majority of work done by new proposed staff will be in the area of inspections. It is also important to stress that any capacity-building efforts new staff perform would only serve to enhance current, ongoing capacity building FDA is already undertaking with Chinese regulators. Finally, FDA's primary goal in increasing staff in China is to enhance the compliance of FDA-regulated goods exported from China with relevant FDA regulations and requirements. Inspections can drive such enhancements in compliance, as can strategically-targeted training and capacity building, and often these two activities complement one another. In China, we have used information from investigations performed by in-country inspectors to undergird and inform our capacity-building strategy.

116. Ms. DeLauro: Can you tell me what Chinese law requires as to the safety of food and drug exports? For example, products intended strictly for export that do not enter the stream of commerce in the US are not regulated by FDA.

Response: The government of China seeks stringent control over China's food export system. To legally export, firms must register with their municipal or provincial branch of China Inspection and Quarantine, also known as CIQ. However, many Chinese firms are able to bypass this system, and export without registering or gaining certification for their products.

To export legitimately, a local CIQ must deem a firm eligible for export through a registration process, which includes an inspection and review of information about the firm's production facility, equipment, products, the countries to which the firm intends to export, water quality, production process, employee qualification, laboratory equipment, raw material sources, and certifications the firm has already obtained. Firms that produce finished product for export, as well as farms that produce raw food materials for export, are subject to these requirements

Since 2007, the government of China has required that all shipments of exports have a certification seal from CIQ. The government also maintains a list of firms that it has deemed unfit to export based on its evaluation.

Generally, Chinese firms that manufacture drug products or active pharmaceutical ingredients, or APIs solely for export are customarily registered with overseas regulatory agencies such as FDA or the European Medicines Agency. Firms that make drugs or API exclusively for the overseas market are not required to register with China's State Food and Drug Administration, or SFDA, and thus are not regulated by SFDA. SFDA has established a system known as catalog management to regulate the production of specified exported drugs in accordance with Chinese law; this system extends regulation to exported medical products.

Under SFDA's catalog system, medical products are routinely checked before export; manufacturers must secure appropriate product registrations as well as good manufacturing practice approvals for manufacturing sites of such products. Manufacturers of specific drugs must also obtain certificates for export sale.

FDA-Approved Contraception

The line between contraception and abortion is often blurred, intentionally and unintentionally, in the course of policy discussions about birth control, including emergency contraception, and the early-abortion option, mifepristone (also known as RU 486). The distinction between the two is important.

117. Ms. DeLauro: Can you clearly describe the differences between contraception and mifepristone? Can you go through the definition of contraception that the FDA uses when considering applications for this type of product?

Response: FDA considers drug products that work as contraceptives to be intended to prevent pregnancy. Most oral contraceptives work by preventing ovulation – which is the release of an egg from the ovary. Some additionally may act to block the sperm from reaching the egg, thus preventing fertilization – the uniting of sperm with the egg – or may prevent attachment of a fertilized egg – implantation – to the uterus. The Agency does not consider mifepristone to be a contraceptive because it is intended to interrupt an established pregnancy.

118. Ms. DeLauro: Is it correct to note that FDA-approved contraception is intended to prevent pregnancies while drugs intended to induce abortions terminate an existing pregnancy?

Response: This is correct.

QUESTIONS SUBMITTED BY REPRESENTATIVE SANFORD D. BISHOP

Animal Antibiotics

119. Mr. Bishop: Madame Commissioner, there has been a growing debate surrounding the use of antibiotics on the part of animal producers here in the US and abroad, and how this activity should be managed or regulated moving forward. For example, a study in the journal *mBio*, which is published by the American Society for Microbiology, shows how an antibiotic-susceptible Staph germ passed from humans into pigs, where it eventually became resistant to the antibiotics tetracycline and methicillin. And then the antibiotic-resistant Staph learned to jump back into humans. However, good or bad, the fact is that animal producers, whether under the guidance of veterinarians or not, have come to depend on utilizing these antibiotics when needed and necessary. I'd like your thoughts on this issue, but more importantly, is FDA and the CDC working to develop a solution to this emerging problem -- a solution which would address both the potential overuse of antibiotics in animal operations, while at the same time, providing producers with realistic, reliable and safe alternatives to antibiotics? Also, are we monitoring the use of antibiotics in nations who are major suppliers of imported meat products to the US (i.e., New Zealand/Australia - lamb; Brazil/Argentina - beef)?

Response: FDA is working in collaboration with the U.S. Department of Agriculture, or USDA, the Centers for Disease Control and Prevention, or CDC, and a wide variety of stakeholder groups to develop a strategy aimed at reducing antimicrobial resistance. In June 2010, FDA released a draft guidance document explaining its recommendations, based on a consideration of available scientific information, for ensuring the judicious use of antimicrobials of human health importance in animal agriculture. "Judicious use" is using an antimicrobial drug appropriately and only when necessary. FDA's draft guidance makes the recommendation that the use of medically-important antimicrobial drugs in food-producing animals be limited to situations where the use of these drugs is necessary for ensuring animal health, and their use includes veterinary oversight or consultation. Since the publication of the draft guidance in June 2010, FDA has sought and received input from various stakeholders, including the animal pharmaceutical industry, animal feed industry, veterinary and animal producer communities, and consumer advocacy groups on approaches for implementing the proposed changes.

With respect to the monitoring of the use of antibiotics in other nations, FDA works with USDA's Food Safety Inspection Service when residues are identified in imported meat and meat products. In addition, FDA is part of international CODEX working groups that are addressing antimicrobial resistance worldwide. In terms of antibiotic use in the countries you mentioned, in Australia and New Zealand lamb production takes place on open land without the use of feedlots and there is no routine use of antibiotics for production enhancement purposes (e.g. growth promotion). When animals become sick, they are transferred to hospital pens where they can be treated individually. Similarly, Brazil and Argentina raise grass-fed beef, that is, animals on the range with no administration of antibiotics unless necessary to treat disease.

Orange Juice

120. Mr. Bishop: Madame Commissioner, I would like to take a look at the Brazilian orange juice issue for a moment. Brazil accounts for half of U.S. juice imports and the fungicide carbendazim is widely used to combat blossom blight and black spot - - a mold that grows on orange trees. As you know, we banned carbendazim from citrus in 2009, but trace amounts of the fungicide are still allowed in orange juice and 31 other foods, including grains, nuts and some non-citrus fruits. Can you share with us how FDA first found out about a potential issue with Brazilian orange juice, and was it through our inspection protocols in Brazil? And more importantly, what is the Agency currently doing to strengthen its ongoing inspection of fruits and vegetables coming into the US from Latin and South America? What happens to the FDA's planned expanded inspection program for imported fruit and vegetables, if Congress does not expand FDA's proposed new user fees?

Response: While other countries have tolerance levels for carbendazim, a pesticide chemical residue, in orange juice, there is no EPA established tolerance level for carbendazim in orange juice.

FDA was first informed of the possibility that carbendazim was being detected in Brazilian orange juice through a report made to FDA from a U.S. industry member. In response, FDA increased targeted surveillance sampling of orange juice being offered for import into the United States, initially to include 100 percent sampling of orange juice product from Brazil and then more broadly to include 100 percent sampling of all orange juice offered for import.

These increased surveillance activities resulted in the collection and analysis of more than 100 samples with nearly 30 lines of orange juice product detained or refused to date. In addition, twelve firms that offered orange juice for import, which juice was found to contain carbendazim pesticide chemical residues, have been added to an Import Alert related to the presence of pesticides in processed foods.

FDA continues its routine surveillance efforts for all fruits and vegetables, collecting samples for pesticide analysis - among other analyses - on a routine basis. Our targeted surveillance of orange juice has included sampling of orange juice from other countries as well; the results thus far indicate this is an issue specific to orange juice from Brazil.

As FDA moves forward with the implementation of the FDA Food Safety Modernization Act, the Foreign Supplier Verification Program, which will require importers to verify that the food they are importing is as safe as domestically produced food, will help strengthen our ability to assure these products do not contain non-permitted pesticide chemical residues, and are otherwise compliant with U.S. law. Obtaining user fees will help to ensure that the new Foreign Supplier Verification Program and other key components of FSMA are implemented in a timely manner.

Microbiological Data Program

121. Mr. Bishop: I would like to join my friend Ms. DeLauro, in expressing my concern regarding the potential loss, even temporarily, of the Microbiological Data Program. While it might seem like a little, small and insignificant program, the FY2013 budget for USDA proposed cutting [and essentially eliminating] this \$5 million research program -- which tests fruits and vegetables for diseases! The program's research helps the Centers for Disease Control and Prevention and the Food and Drug Administration more easily find foods contaminated with salmonella, E. coli or other pathogens. And coming from a district which is rich in the production of fruits and nuts, I am particularly concerned that this activity not be curtailed or stopped before it has a home somewhere else. How do we insure that FDA and USDA work together so that there is an orderly transfer of responsibility for administering this program?

Response: FDA does not intend to absorb the loss of USDA's MDP by creating a similar program. Rebuilding such a network would be expensive, time consuming, and logistically difficult for FDA at a time when FDA must implement FSMA mandates

122. Mr. Bishop: Follow-up: As you know, the outbreak of listeria in cantaloupes killed 30 people. We've also seen issues with alfalfa sprouts, spinach, lettuce, and tomatoes -- much of it imported, which has sickened consumers in recent years. The microbiological program was originally created as a federal-state partnership to test fresh produce for contamination, primarily pesticides. Now it mainly conducts random testing for dangerous bacteria. What role will states play if the program is halted, even temporary?

Response: We recognize that the states play an important role in administering USDA's MDP. Through cooperative agreements between USDA/AMS and 12 states—Arizona, California, Colorado, Florida, Ohio, Michigan, Minnesota, New York, North Carolina, Texas, Washington, and Wisconsin—the MDP contracts with a network of State governments to collect, analyze, and report sampling data for both domestic and imported produce. The MDP leverages the analysis capacity of these states to create a national network of food-testing laboratories, employing sophisticated technology for rapid detection of disease-causing organisms. Results from all testing States are combined to create the national baseline database. MDP also provides results and serotype data to CDC and State public health agencies to aid in ongoing epidemiological investigations or surveillance of food-related illnesses or outbreaks. We understand that the ability of the States to participate in such a program would be impacted by the loss of contact funding to support their work, given the budgetary challenges currently faced by many States.

Food Labeling for Biotech Foods

123. Mr. Bishop: During the past year, there has been concerned raised by some food safety advocates, that there needs to be more specific labeling requirements for food which is connected or derived from biotech research and development. In 2010, FDA

reiterated its authorities and policy when it stated that the method of (food) production does not, in and of itself, result in a “material” change that requires labeling, finding: “FDA has no basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any or greater safety concern than foods developed by traditional plant breeding. Is this still the FDA’s position on this matter?”

Response: FDA stated in a 1992 statement of policy on foods derived from new plant varieties and in a 2001 draft guidance that FDA was not aware of any information showing that foods derived from genetically engineered plants differ from other foods in any meaningful or uniform way, or that, as a class, such foods present different or greater safety concerns than their non-genetically engineered counterparts. As a result, FDA has concluded in the past that the method of development of a new plant variety is generally not material information within the meaning of the Federal Food, Drug, and Cosmetic Act and would not usually be required to be disclosed in labeling for food. FDA has received citizen petitions requesting that FDA require genetically engineered foods to be labeled as having been genetically engineered. FDA is currently reviewing and considering those petitions. At this time, FDA has not made a decision, in whole or in part, regarding those petitions.

Tomatoes

124. Mr. Bishop: Dr. Hamburg, the tomato farmers in South Georgia and northern Florida continue to tell me that they are still reeling from the FDA’s tomato salmonella recall debacle from a couple years ago. As you’ll recall, in Georgia alone, tomato growers loss over \$14 million from tomatoes grown, and in some cases harvested, but could not be sold since consumers were told to ‘stop buying tomatoes’ on the recommendation of FDA and the CDC. It is conservatively estimated growers nationwide lost over \$125 million from this false indictment from our own federal government. More importantly, many of the tomato producers in my district have yet to recover. The FDA Food Safety Modernization Act, which was signed into law last December, authorizes payments to producers harmed by “future” government decisions which ultimately prove to be incorrect or ill-founded. Can we find a way to provide some assistance to our tomato producers, given the precedent set under this legislation? Under the new Food Safety legislation, the FDA is required to establish, as appropriate, “a product tracing system to receive information that improves the capacity to effectively and rapidly track and trace food that is in the United States or offered for import into the United States.” Where are we on putting in place a system to trace imported food?

Response: FDA intends to cooperate with the development of the report by the Comptroller General under Section 206 of the FDA Food Safety Modernization Act—FSMA—which, in part, will consider models for farmer restitution in other nations. FDA also intends to cooperate with the U.S. Department of Agriculture should it, in turn, conduct a study of the feasibility of implementing a farmer indemnification program to provide restitution to agricultural producers for losses sustained as a result of a

mandatory recall of an agricultural commodity by a Federal or State regulatory agency that is subsequently determined to be in error.

With regard to a tracing system, Sec. 204 of FSMA, entitled *Enhancing Tracking and Tracing of Food and Recordkeeping*, has two major requirements. First, FDA, working with the U.S. Department of Agriculture, or USDA, and State agencies, must establish pilot projects in coordination with the food industry to explore and evaluate methods and appropriate technologies for rapid and effective tracking and tracing of foods. Second, FDA must publish a notice of proposed rulemaking to establish recordkeeping requirements for high risk foods to help in tracing products.

On September 7, 2011, FDA announced two product tracing pilot projects that will enhance the agency's and industry's ability to trace products through the food supply. These two pilot projects, one for processed foods and one for produce, are being conducted through an existing contract with the Institute of Food Technologists. The tomato industry, as well as many other stakeholders, is involved in the pilot projects that are currently underway.

The proposed rule that FDA develops will have a comment period, and FSMA requires that at least three public meetings be held during that comment to provide persons in different regions the opportunity to provide input.

Generic Drugs

125. Mr. Bishop: I know you're here today to primarily discuss food safety, but I'd also like to take this opportunity to look into another area of FDA's responsibility - - generic drugs. As you know, one of the most critical challenges our elderly constituents face is every increasing drug and prescription costs. If the Administration's projected revenue from expanded user fees does not pan out, what alternative plans are in place to expand the review of new drug applications for generics, as well as the inspection of generic drug facilities? Conversely, what, if any, will be the impact proposed new generic drug user-fees on the average consumer?

Response: FDA proposed a generic drug user fee program based on our extremely successful prescription drug user fee program known as PDUFA. However, FDA tailored the generic drug user fee to the challenges and features of the generics industry, with its higher number of submissions, different manufacturers of active pharmaceutical ingredients and finished dosage forms, and increasingly foreign locus. PDUFA has helped ensure a predictable, consistent, and streamlined premarket program for prescription drugs, and we expect that GDUFA will have the same result for generics. Today, more than three-fourths of prescriptions dispensed are filled by generic drugs, and yet these drugs only account for only one fourth of prescription drug spending. High quality, affordable generics have saved Americans billions of dollars.

At this time, FDA does not have alternative plans in place if the negotiated user fee for generics is not enacted and fully appropriated. Without these user fees, FDA would not be able to improve the review process of new drug applications or increase the frequency of inspections of generic drug facilities located overseas. If, however, the program is enacted as negotiated, and fully appropriated, FDA expects to be able to collect substantially the full appropriated amount of user fees, as occurs under PDUFA.

As to drug prices, the program was carefully negotiated not to raise generic drug prices, as all parties to the negotiation recognize that a critical feature of generic drugs is their affordability. In fact, the entire cost of the program, which calls for additional revenues for FDA of an inflation adjusted \$299 million per year, amounts to less than one-half of one percent of generic industry sales. As the goals letter explains, with the adoption of user fees and the associated savings in development time, the overall expense of bringing a generic product to market may decline and result in reduced costs.

Data Consolidation and Information Technology Savings

126. Mr. Bishop: Madame Commissioner, your FY2013 budget proposes to find \$20 million in savings from the consolidation your data and IT operations. The plan would be to apply these savings to meet the requirements of recent executive orders that promote government efficiency and assure environmental, energy and economic performance. FDA is also expected to reduce redundant computer equipment and achieve other IT savings. Last week, for example, Secretary Vilsack's budget proposed a \$100 million increase in IT spending for just one Agency (FSA), an Agency I might add whose responsibilities will likely change significantly whenever a new Farm bill is passed. The Department of Veterans Affairs, is proposing a 7 percent increase for IT spending, or \$216 million more than FY2012, Health and Human Services is increasing by \$179 million. Is the FDA's IT initiative a part of the President's to drive down IT costs throughout government? More importantly, how will the proposed consolidation of IT activities impact FDA's expanded food safety role activities under the Food Safety Modernization bill and should we expect to see dramatic increases in IT spending in the oncoming out years?

Response: FDA does not anticipate dramatic increases in Information Technology or IT spending in the next few years. As a result of the FDA Food Safety Modernization Act, the Agency is moving from a compliance mindset to that of optimizing quality risk based analytics and inspection by cause. This evolution requires close oversight of the Agency's IT investment portfolio to ensure that the Agency is making appropriate investment decisions and utilizing the funds in the most efficient manner. FDA's IT portfolio oversight is provided by the Commissioner, the Office and Center Directors along with the Chief Information Officer who serve on the IT Investment Review Board or ITIRB. The ITIRB is in the process of optimizing the IT portfolio and reducing redundancies Agency-wide. As a result, the ongoing modernization initiatives are realizing savings that FDA is able to reinvest in new initiatives. Additionally, FDA is making subtle target shifts rather than undertaking massive multi-year projects.

QUESTIONS SUBMITTED BY REPRESENTATIVE MARCY KAPTUR

Pet Treats Investigation

127. Ms. Kaptur: Please update the Subcommittee for the record about FDA's investigation into determining if chicken jerky products for dogs are associated with illness or death.

Response: FDA has been testing chicken jerky treats since 2007 in response to reports of illness in dogs that may be associated with the treats. FDA continues to actively investigate these reports and conduct analyses for multiple different chemical and microbiological contaminants.

During 2011 and previous years, FDA tested more than 170 samples of chicken jerky products. During the first weeks of 2012, FDA's Veterinary Laboratory Response Network tested 80 samples for which we have complete results. The results of 153 tests are still pending. In addition, several animal health diagnostic laboratories in the United States are working with FDA to determine why some of these products are associated with illness in dogs. To date, scientists have not been able to determine a definitive cause for the reported illnesses.

Jerky samples were tested for many different potential contaminants. Some samples were tested for mycotoxins (ochratoxin, vomitoxin and aflatoxin), and the results of these tests were negative. The laboratories also performed screens for drugs, poison and toxins and these tests also were negative.

Propylene Glycol was found at low levels in about half of the samples where laboratories tested for the substance, but the levels were considered to be nontoxic. Propylene Glycol is an allowed feed ingredient in pet foods.

FDA is continuing to advise pet owners who choose to feed their dogs chicken jerky products to watch their dogs closely for any or all of the following signs that may occur within hours to days of feeding the products: decreased appetite decreased activity, vomiting, diarrhea, sometimes with blood, increased water consumption or increased urination. If the dog shows any of these signs, owners should stop feeding the chicken jerky product. FDA also recommends that pet owners consult their veterinarian if signs are severe or persist for more than 24 hours.

No specific products have been recalled or implicated because the laboratories running tests have not detected a contaminant that could have caused the reported illnesses. FDA continues to actively investigate the problem and its origin. If FDA finds evidence of a contaminant that may be responsible for illness in pets that consume chicken jerky treats, FDA will take appropriate action and notify the public.

Standards for Produce Safety

128. Ms. Kaptur: Please update the Subcommittee on FDA's implementation of the FDA Food Safety Modernization Act's provision regarding safety standards for produce.

Response: The produce safety standards proposal is a high priority for the FDA and we look forward to issuing the proposed rule and continuing the dialogue on this important food safety provision.

129. Ms. Kaptur: My Congressional District is ranked as one of the highest in Ohio in production of fruit, vegetables, and nursery crops. What kind of outreach is FDA doing to inform the kind of producers in my Congressional District about upcoming safety standards?

Response: FDA has participated in an unprecedented level of outreach to producers throughout the United States in the last two years in an effort to hear directly from those who will be most affected by the produce rule.

During the past 2 years, senior FDA staff visited more than 20 farms in 13 states and interfaced with hundreds of stakeholders at various meetings across the country to develop the proposed rule.

We recognize the important role that Ohio plays in producing fruit and vegetables, and for that reason, we toured Ohio farms and had a growers' meeting in Sandusky. The Ohio farms visited included Amish farms and produce auction, and conventional, sustainable and organic farms, and a visit to the Culinary Vegetable Institute. Members of the Ohio Produce Growers and Marketers Association provided us with a wealth of information. We also participated in a full-day produce safety conference hosted by the Pew Produce Safety project in Columbus, Ohio in March 2010.

We will continue to reach out to producers across the country, including those in Ohio. We are working with the USDA's Agricultural Marketing Service, different states' departments of agriculture, farmer representatives and other entities to ensure a very broad outreach effort once the proposed rule is issued. When it issues, we will also conduct public meetings in different regions of the country.

We have also worked with partners and stakeholders to establish two produce-related alliances, the Produce Safety Alliance and the Sprout Safety Alliance, and another alliance that relates to produce packers. The Produce Safety Alliance is a collaborative project between Cornell University, USDA, and FDA. On the Alliance, Ohio is represented by five growers, a food safety consultant, a Farm Bureau member and two Ohio State University Extension Specialists.

130. Ms. Kaptur: Does FDA plan to issue any regulations impacting farmers' market or community gardens?

Response: FDA does not plan to issue regulations specific to farmers' markets or community gardens. However, growers who provide produce sold at farmers' markets may be covered under the provisions of FDA's produce safety proposed rule. The agency believes most produce grown in a community garden would be for personal consumption and therefore would not be covered by the produce safety proposed rule.

Food Imports

131. Ms. Kaptur: Given the rapid increase in food imports over the past few years, please describe some of FDA's safety initiatives that proved successful in previous years in protecting American consumers.

Response: FDA completed the transition of its import entry screening process to the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system in 2012. PREDICT utilizes information from various agency databases; information generated from previous sample collections, analyses, field exams, facility inspections; and other intelligence to generate a risk score for each line entry of FDA regulated product. As FDA continues to use PREDICT, the system will compile more data regarding the compliance and non-compliance of imported food products, resulting in a more informed entry review process through greater comprehensive risk scoring.

FDA continues to leverage its resources to take swift and effective actions when foreign facilities refuse or delay FDA inspections. Food from a foreign food facility that has refused to permit an FDA inspection is subject to refusal of admission. Currently, six foreign firms are included on an Import Alert regarding this.

FDA is currently performing pilot programs for handheld devices for use by FDA field staff during normal operations. These tools can screen imported products to determine the presence of a variety of contaminants. One tool, specific to food products, can provide an analytical screening of a product to determine if diethylene glycol may have been substituted for glycerin. These tools allow FDA to better identify products that need full analytical testing. In the future, FDA will evaluate the results from the pilot programs to determine whether nationwide deployment is advisable.

FDA continues its proactive response activities to global incidents. In response to the earthquake incident in Japan, FDA performed 31,000 examinations and collected and analyzed over 1,200 samples of Japanese products. FDA's findings provided assurance that products from Japan were free from radionuclide contamination.

132. Ms. Kaptur: What is FDA doing to build off these successes in FY 13?

Response: During the first year of its use, FDA will monitor the effectiveness of PREDICT nationwide, making operational modifications based on the continued development of risk models for all program areas as well as those indicated through practical applications. FDA will capture user and stakeholder feedback during the first year, which will be included in the development of our evaluation approach. After one

year, FDA will perform an evaluation to determine whether PREDICT is meeting FDA expectations.

FDA continues to evaluate findings from various pilot programs involving handheld devices to determine the effectiveness and efficiencies of these tools. These findings will inform FDA consideration for future nationwide deployments. In addition, pilot programs for new and innovative handhelds continue, ensuring FDA is deploying technologies that are reliable and useful in screening for or identifying potentially violative products.

Under FSMA, FDA published on May 5, 2011 an interim final rule requiring importers of a food to inform FDA if any country has refused entry to the same product. This regulation provides FDA with additional product safety information, allowing FDA to better identify imported foods that may pose a significant risk to public health.

As part of FSMA, FDA, in conjunction with the Department of Health and Human Services (HHS), Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) developed a new joint anti-smuggling strategy. Working closely, the agencies will identify import shipments that could contain smuggled foods, focusing on imported foods that pose a significant public health risk. The strategy will be implemented in a variety of ways, including joint field operations between FDA and CBP.

133. Ms. Kaptur: Please discuss the need for additional funding for food safety as it relates to importing food from China.

Response: The U.S continues to import consumable products and, as has been seen in the past, the volume of imported commodities continues to rise. In FY 2011, the U.S. received more than 9.2 million lines of human food and animal feed products from 226 countries and areas, China is one of those countries, and the volume of food and feed imports from China has risen dramatically.

With the enactment of the FDA Food Safety Modernization Act, or FSMA, FDA will be responsible for developing and implementing new rules and regulations that govern food and feed imports from China and other countries. Implementing new food and feed import programs such as the Foreign Supplier Verification Program, Voluntary Qualified Importer Program, and third party certification, will require resources. The availability of fees will affect staffing and vital operations, and will thereby affect how quickly FDA can implement FSMA for FDA's import responsibilities. Implementing FSMA will not only require staff to enforce the regulations but will also require training for FDA investigations staff and outreach and training for regulated industry. Implementing FSMA will also require updates to existing IT infrastructure and potential development of new IT systems using proposed user fees.

Successfully implementing FSMA-based programs will have a positive effect on the safety of foods imported from China and other countries.

THURSDAY, MARCH 8, 2012.

**DEPARTMENT OF AGRICULTURE—FOOD SAFETY AND
INSPECTION SERVICE**

WITNESSES

**ELISABETH A. HAGEN, UNDER SECRETARY FOR FOOD SAFETY, DE-
PARTMENT OF AGRICULTURE**

**ALFRED V. ALMANZA, ADMINISTRATOR, FOOD SAFETY AND INSPEC-
TION SERVICE, DEPARTMENT OF AGRICULTURE**

MICHAEL YOUNG, BUDGET OFFICER, DEPARTMENT OF AGRICULTURE

INTRODUCTION OF WITNESSES

Mr. KINGSTON. The committee will come to order. And I am going to abbreviate my opening statement, but certainly want to welcome the Food Safety and Inspection Service and Dr. Elisabeth Hagen, the Under Secretary for Food Safety, Mr. Al Almanza, the Administrator for Food Safety and Inspection Service, and Michael Young. And I will yield to Mr. Farr.

OPENING STATEMENTS

Mr. FARR. Well, Mr. Chairman, I will just waive. I will put in the record the remarks. But I just want to say I want to thank you for coming. This is a very important hearing, and you are a very important department in the Department of USDA because you have a heavy responsibility.

If you fail, the consequences are dire consequences, and it can lead to loss of life. So we take this hearing very seriously and appreciate you coming. We will have a lot of questions. I look forward to your testimony. And I will put my remarks in the record.

[The information follows:]

Appropriations Agriculture Subcommittee
Department of Agriculture – Food Safety Inspection Services
Congressman and Ranking Member Sam Farr
March 8, 2012

Sam Farr

Record

Opening Statement

Good morning.

I want to start by recognizing:

- Dr. Elizabeth A. Hagen, Under Secretary for Food Safety, Food Safety Inspection Service, Department of Agriculture
- Dr. Alfred V. Almanza, Administrator, Food Safety Inspection Service, Department of Agriculture
- Mr. Michael Young, Budget Officer, Department of Agriculture.

Thank you for being here today. I also want to acknowledge your work and that of your hard working staff to safeguard our nation's food supply.

The office of Food Safety Inspection Service is on the front lines of assuring that the food we put into our bodies is safe.

The work of this agency is critical to the movement of agricultural products.

And it is critical to building the consumer confidence that the goods that reach our grocery stores and corner markets are safe for our dinner tables.

This is a heavy responsibility, which must be met with the same urgency and support needed to assure that FSIS can meet their important mission.

Because, if we don't—the result comes with dire consequences.

The consequences are not lonely product, revenue and jobs lost, but more importantly lives lost.

There is simply too much on the line for us to penny pinch on the issue of food safety.

But for that same reason, we need to tediously examine the effectiveness and efficiency of how this agency is going about protecting our nation from contaminated meat.

Today, our nation needs a 21st century food safety strategy that addresses the real dangers facing our food supply.

We need to do away with practices that are decades old and do not incorporate best practices or the latest technology available to us.

And we need to increase our partnerships with food companies, so they are working with us, sharing the responsibility, and holding themselves accountable.

I understand that to an unprecedented degree, government is being questioned and scrutinized.

People want to hold their government accountable, and we have an obligation to respond and get our fiscal house in order.

But we also have an obligation to uphold one of our core responsibilities, and that is to assure the safety of the people in this country.

Today, we face that responsibility head-on.

I'll be frank; I have serious concerns about the ability of this agency to safeguard the food we are consuming.

Every single employee assigned to inspect food across the nation is dedicated to his or her job. That is no question.

-But this agency is underfunded, and inspectors cannot be everywhere at once.

Inspection services under USDA need to be funded at a level that allows them to adequately do their job, and fulfill the big responsibility that has been placed on them.

At the same time, this office needs to upgrade its protocols to reflect best practices and maximize efficiencies.

This is not an easy task, but I know it can be done.

I hope that today we can have an honest conversation about these issues of food safety.

Thank you again for being here, and I look forward to your testimony.

Mr. KINGSTON. Ms. DeLauro, do you have any statements, or do you want to recognize anybody here today? [Laughter.]

Ms. DELAURO. Thank you very much, Mr. Chairman. Thank you. And obviously, I wanted to welcome Dr. Hagen and Mr. Almanza and Mr. Young. And it is great to have you before the committee.

But I want to say a particular hello, if you do not mind, to Brian Ronholm. We spent a number of years together. And I did ask him about Nick, who is doing fine, and he is 8 years old. So it is wonderful to really have you all here today.

And I would concur with Mr. Farr. The work that you do is so critically important, and it is about life and death. There are a lot of agencies at the Federal level, but this is one that is particularly critical and important.

And really delighted to have you here today, and look forward to the testimony and to questions, and to working closely with you, obviously, on all that we agree with and on some issues in which we have questions. And none of that gets in the way of our incredible sense of support and advocacy for the good work that you do. Thank you.

Mr. KINGSTON. And Mr. Almanza has a statement, and he has submitted it.

[The information follows:]

FOOD SAFETY AND INSPECTION SERVICE

Statement of
Alfred V. Almanza, Administrator, Food Safety and Inspection Service
Before the
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration and Related Agencies

Introduction

Mr. Chairman, Ranking Member Farr, and Members of the Subcommittee, I am Alfred Almanza, Administrator of the Food Safety and Inspection Service (FSIS). I am pleased to appear before you today and appreciate the opportunity to discuss the fiscal year (FY) 2013 budget request for FSIS within the U.S. Department of Agriculture (USDA) and the status of our programs aimed at protecting public health and preventing foodborne illness.

Preventing Foodborne Illness

FSIS is responsible for the safety of meat, poultry and processed egg products. The main mission of the agency and its dedicated employees is to ensure a safe food supply, and protect consumers from foodborne illness. We take our mission very seriously and continually strive to improve the ways in which we protect public health.

Prevention is our guiding principle, and is a key element in FSIS' five-year Strategic Plan, which the Under Secretary has spoken to in more detail. It is the foundation of the modern food safety system which we are working hard to strengthen with our food safety partners. In the past few

years, FSIS has taken monumental steps to be more proactive in our approach to food safety, and adapt our policies and programs to meet modern food safety challenges.

According to the Centers for Disease Control and Prevention (CDC), every year, 48 million Americans will be affected by a foodborne illness, over 128,000 of them will be hospitalized because of it, and about 3,000 will die. Those are alarming statistics, but FSIS has taken significant steps in an effort to bring down those numbers. That's why we have been very aggressive in our fight against *E. coli* O157 through the zero tolerance policy we announced in 1994, and more recent actions on non-O157 STECs identified by the Under Secretary.

There is no question that consumers have access to safer food as a result of these testing and inspection policies. I am proud to report that we met the Healthy People 2010 goal of less than one illness per 100,000 people caused by *E. coli* O157. In fact, we met that goal in 2009, but made even further progress in 2010. And according to CDC's most recent FoodNet data, *E. coli* O157 has decreased by 44 percent since the 1996-1998 baseline. The latest foodborne illness statistics also show that we are doing better in reducing the other major pathogens associated with FSIS-regulated product, with *Campylobacter* down by 27 percent, and *Listeria* down by 38 percent.

But we also know that the current system is not perfect, and are determined to make it better. We are constantly refining our testing methods and are looking at ways to improve our strategy to combat *E. coli* O157 and other pathogens. And since the incidence of *Salmonella* infections has not declined since 1996-1998, we view reducing illnesses due to this pathogen as a high-

priority goal in the agency's Strategic Plan. In July 2011, FSIS implemented stricter *Salmonella* and new *Campylobacter* performance standards for poultry products. FSIS estimates that after two years under these standards, there will be about 20,000 fewer illnesses each year from *Salmonella* standards and 5,000 illnesses avoided from *Campylobacter*.

We expect to make additional head-way in fighting *Salmonella* and other pathogens with our recent proposal to modernize the poultry slaughter inspection system. The new inspection system is aimed at reducing the risk of foodborne illness by focusing FSIS inspection activities on aspects of the poultry production system that are most directly related to food safety. FSIS estimates that the new poultry slaughter inspection system, once implemented, would lead to as many as 4,286 fewer *Salmonella*-related illnesses and 986 fewer *Campylobacter*-related illnesses per year.

Doing More With Less

In the current budget climate, FSIS has been developing innovative ways to make more efficient and effective use of taxpayer dollars. As part of the USDA's Blueprint for Stronger Service, we have taken a number of steps to make the most of the resources provided to us by the Committee. For example, we have cut our budgets for travel, printing and supplies and are consolidating cell phone plans.

More significantly, FSIS proposed a number of office consolidations to reduce administrative costs and improve organizational efficiency. Based on a thorough review and in consideration of a number of factors, FSIS determined that we can reduce the number of our District Offices from

15 to 10. This consolidation affects management and support personnel, not inspectors, and by providing greater consistency across districts, it should only strengthen FSIS' ability to protect public health. Our inspectors will continue to provide inspection in FSIS-regulated establishments in full compliance with the law. We estimate that there will be cost-savings of about \$1 million annually when fully implemented.

The new poultry slaughter inspection system, once operational, will not only be beneficial for food safety, but will also yield savings. The President's FY 2013 Budget reflects \$13 million in efficiencies that FSIS expects to gain from the proposed inspection system. It will save taxpayers more than \$90 million over three years and lower production costs for establishments at least \$256 million per year.

We recognize that the proposed inspection system will have an impact on our workforce. Many in the inspection personnel will have the opportunity to move into upgraded positions; and other positions will be eliminated through attrition and relocations over a two to three year period. However, the proposal will move some FSIS personnel in poultry plants from work that is more related to quality assurance to work that is focused completely on food safety. We believe the proposed poultry inspection system, as well as other measures the agency has taken recently are all positive steps for our workforce, putting them in a better position to more effectively prevent foodborne illness and protect public health. A modern food safety system needs a workforce that can address the needs of the 21st century.

Empowering Our Workforce

FSIS' workforce is the backbone of our agency, and without their extraordinary work we cannot accomplish a single one of our very important food safety tasks, some of which I mentioned earlier in my testimony. We are inspectors, scientists, epidemiologists, investigators, educators and communicators stationed throughout the country, all dedicated and working toward one single purpose, protecting the health of more than 300 million Americans.

The empowerment of the FSIS workforce is imperative in our efforts to become a better food safety agency. As Dr. Hagen has said, we are only as effective as our dedicated workforce. Thus, we are committed to providing our workforce with the knowledge, tools and resources to better protect public health. This commitment to our employees is reflected in our Strategic Plan for the next five years, which the agency is working to accomplish through improved training, innovative use of technology, and offering more avenues for feedback.

Training for the FSIS workforce is a cornerstone of public health protection. FSIS can only achieve our public health mission by preparing our workforce with scientific and technical training that reflects the agency's constantly evolving approach to food safety. Our workforce training strategy includes providing entry-level training on mission-critical inspection skills to new employees, followed by additional training as policy is updated to reinforce knowledge about how to perform public health protection duties.

A good example of this approach would be how FSIS recently issued new instructions to inspection personnel in order to clarify that all non-ambulatory mature cattle must be condemned

and promptly euthanized and to ensure that they are humanely handled, regardless of the reason for the animals' non-ambulatory status. The clarification is intended to ensure that the policy is consistently applied at all FSIS-inspected establishments.

To complement the new humane handling instructions, FSIS is delivering enhanced, situation-based humane handling training. The situation-based training presents inspection personnel with realistic scenarios that they may encounter when verifying humane handling activities. It will help the agency enforce humane handling regulations more effectively and consistently. The approximately 4,000 FSIS personnel who perform humane handling verification duties at livestock slaughter establishments have completed the first training module on animal handling from truck unloading to stunning, and will complete the second and final training module, on stunning effectiveness and post-stunning considerations, this month.

In addition, FSIS offers tailored training for the various activities performed by our employees. For example, we offer a 3-week course designed for employees responsible for surveillance, investigations and enforcement activities. And for our newly hired public health veterinarians, we run a 9-week program that trains them to effectively work as part of an in-plant team in slaughter and processing establishments.

To foster career development, FSIS recently launched an initiative called the Learning Trove. One of the major goals of the initiative is to facilitate knowledge transfer by agency experts to an interested community of learners through mentorship.

Additionally, with the launch of the Public Health Information System (PHIS) last year, the agency developed and delivered PHIS training to more than 5,700 employees in the field. The course lasted two weeks and included click-by-click training on how to enter data into PHIS screens and agency policy updates. Training is a crucial component of the utility of PHIS, as the data FSIS employees enter into the system will be used by the agency to get ahead of outbreaks and recalls and better protect consumers.

PHIS, when fully deployed and functional, is technology that will empower our employees to be better prepared for the work that they do every day, as they will have a wealth of the most up-to-date data all in one place and at their finger-tips. PHIS is an intelligent system that will allow employees to use the data in the system to make more informed decisions to keep our nation's food supply safe. The agency's transition to PHIS is part of our efforts to become a more modern agency, keeping up with the latest technology and food safety challenges.

As with any undertaking of this magnitude, PHIS implementation has had its challenges, but the agency has listened to its employees, made significant improvements to the system and, as a result, has completed implementation of PHIS' domestic component to our employees.

Since the launch, we have uploaded important data to PHIS, streamlined the way that data is stored and organized to increase the speed of the system, launched a disconnected version of PHIS for inspection personnel to use when internet connection is unavailable, and transitioned to electronic sampling. We are also vigorously working to find solutions to establish solid internet connectivity for employees stationed at establishments in rural areas. At the same time, we are

making constant improvements to the disconnected version of PHIS so that it works effectively for employees in these areas.

We are already starting to see the system's benefits to public health come to fruition. With PHIS, we now know more about establishment operations, volumes, HACCP plans, and other food safety programs. There has also been an increase in the number of scheduled laboratory samples being taken at establishments as a result of PHIS' electronic sampling feature.

FSIS continues to work hard to make PHIS a useful tool for our employees, as well as our stakeholders. I can say with confidence that the agency is in a good place with PHIS implementation and we wouldn't be able to do this without the valuable feedback and contributions of our employees.

The agency is committed to engaging with our workforce and reaching out to our employees to regularly ask for feedback on significant policy and program initiatives. Their feedback has been critical for the success of these initiatives. For example, the feedback we have received from employees on PHIS has been instrumental in improving the system and completing full domestic implementation. At FSIS, we believe that keeping open channels of communication within the agency, including aggressively seeking feedback from our employees, is critical to create a workforce that is committed and unified in one mission--protecting public health.

In an effort to maintain a constant flow of information through all levels of the agency, FSIS offers various avenues to facilitate communication. In FY 2011, we held 7 all-employee town

hall meetings and 7 town hall meetings in the field, all of which have had record participation from our employees. I also have a blog, where I encourage employees to comment and give me their thoughts on a range of agency issues.

Modernizing our approach to food safety doesn't just mean an evolution in our policies and programs. It also means improving our agency as a whole, to one that empowers employees to see that they have a fundamental role in the delivery of our food safety mission.

Putting Our Plan into Action

In September 2011, FSIS unveiled our Strategic Plan for FY 2011 through FY 2016. Dr. Hagen has discussed the specifics of the plan, but let me stress that it was put together by our employees and is meant to serve as their roadmap to accomplish FSIS' mission of keeping food safe and protecting the American public we serve. The plan outlines detailed strategies and measureable goals to reduce foodborne illness. With this plan, each and every employee at FSIS is accountable to the public for protecting them from foodborne illness. But it also empowers our employees to succeed by setting out eight clear and measurable goals to support three overarching themes: prevent foodborne illness; empower people and strengthen infrastructure, and understand and influence the farm-to-table continuum.

Reinforcing the Strategic Plan is our Annual Performance Plan for FY 2012. Our employees are responsible for producing results, and meeting the corporate performance measures we have set for ourselves. In order to effectively manage and demonstrate the progress we're making with each of our eight strategic goals, we have created an online tracking tool called a Dashboard.

Designated employees from each office will go into the Dashboard on a regular basis to document the actions we are taking to accomplish our strategic goals. The Dashboard will allow the agency to assess how well we're doing on our performance measures. The progress we're making with each goal will be easily identifiable by color, with green indicating we have achieved our measures, yellow indicating we're close, and red indicating that we still have more work to do.

The Strategic Plan demonstrates our commitment to becoming a more effective food safety agency, one that focuses on prevention, adaptable to modern food safety challenges, and accountable to the American public. We have taken a number of very significant steps recently to prevent foodborne illness and protect public health, and have set very high expectations for what we'd like to accomplish in this coming fiscal year.

Conclusion

Mr. Chairman, Ranking Member Farr, and Members of the Subcommittee, thank you for your help in keeping the food supply safe and protecting the American public from foodborne illness. On behalf of the workforce I represent and serve, I'd like to thank you for the opportunity to testify before you today.

Mr. KINGSTON. And so Dr. Hagen is going to give hers, and with that, I will yield to Dr. Hagen.

OPENING STATEMENT

Dr. HAGEN. Thank you, Mr. Chairman and Ranking Member Farr and other members of the subcommittee. I am Dr. Elisabeth Hagen, the Under Secretary for Food Safety at the USDA. With me today is Al Almanza, the administrator for the USDA's Food Safety and Inspection Service. And I am pleased to be here with you today in support of the President's fiscal year 2013 budget request for FSIS.

In 2011, FSIS released a five-year strategic plan, and this plan is centered around three strategic themes: preventing foodborne illness, empowering people and strengthening infrastructure, and understanding and influencing the farm-to-table continuum.

Our first theme, preventing foodborne illness, is achievable by maximizing industry compliance, educating consumers on safe food handling, strengthening collaboration, and ensuring that inspection aligns with risk. We have been particularly successful in protecting consumers from *E. coli* O157:H7. Largely because of FSIS policies, illness rates from this deadly pathogen have dropped nearly 50 percent, and this Healthy People 2010 national health objective has been achieved.

However, as long as one in six Americans is at risk from their food, we have work to do. Our successes in targeting O157 as well as *Listeria* lead us to believe that we can make similar strides against *Salmonella* and other pathogens.

We are taking steps to encourage industry to reduce the prevalence of pathogens. Some examples of this include the implementation of stricter *Salmonella* and new *Campylobacter* performance standards, the expansion of the *Salmonella* Initiative Program, and our new policy on non-O157 STECs.

Another way that we fight foodborne illness is through public education and outreach. In June 2011, FSIS launched a national multimedia campaign with HHS to help families prevent food poisoning. The Food Safe Families campaign urges consumers to remember four key steps to food safety at home, to clean, separate, cook, and chill.

Through our partnership with the Ad Council, we have reached millions using relatively few resources. We also continue to strengthen collaboration with our food safety partners, and in January, we signed an MOU with FDA to share all public health information that we collect.

We continue to think of innovative ways to improve food safety inspection. In that spirit, FSIS has announced a proposed rule, Modernization of Poultry Slaughter Inspection, which streamlines inspection in young poultry slaughter establishments and, more importantly, facilitates the reduction of pathogen levels in poultry.

This proposed system redirects FSIS personnel to food safety-related tasks, and it will reduce product contamination and will reduce illnesses by at least 5,200 annually. It will also save taxpayers an estimated \$90 million during the first three years after implementation, and will lower production costs for the poultry industry by at least \$256 million annually.

As a regulatory agency accountable to people who are both consumers and taxpayers, FSIS is working to identify ways to streamline and consolidate, but not at the expense of our food safety goals. In order to do this, we are strengthening infrastructure and empowering employees with the tools that they need for success. This is our second strategic theme.

Last year's launch of the Public Health Information System is a key to this strategic theme. PHIS is a system which collects, analyzes, and predicts key data about public health trends and food safety violations throughout the country.

As with any undertaking of this magnitude, PHIS implementation has had its challenges, but the domestic component has now been successfully implemented. We have the ability to search and survey information in near-realtime rather than look in separate, unsearchable databases and paper documents.

The final strategic theme is to understand and influence the farm-to-table continuum. As you know, contamination can occur anywhere—at the farms where animals are raised, at the slaughter and processing establishments that FSIS regulates, and on cutting boards across America's kitchens.

We do not seek an increase in appropriated funding or expansion of our regulatory jurisdiction, but we know it is important to sponsor the conversation among a broad group of stakeholders about pre- and post-harvest food safety. We all have a stake in this, and we should together engage in a comprehensive, honest, and thoughtful conversation about how to truly make food safer.

As you know, after he took office, the President created the Food Safety Working Group. In doing so, he challenged us to create meaningful metrics to measure progress in reducing illnesses, hospitalizations, and deaths. We have made progress in doing just that. One of our key corporate performance measures at FSIS now is a reduction in illnesses attributable to the products that we regulate.

While measuring food safety success is something that we strive for, our greatest successes are often what does not happen. How do you measure a product that was not contaminated and a recall that did not happen? These things can be difficult to measure, but are just as important to our success.

So I want to recognize the FSIS employees who work every day to improve our food supply—ensuring the humane treatment of livestock, identifying regulatory violations, using science to detect unsafe product, solving outbreaks, and educating consumers. This seemingly routine work constitutes an awful lot of our success.

Guided by the strategic plan, we are inspired to work together as one team toward a common goal, preventing foodborne illness. So thank you all for your support in ensuring the safety of meat, poultry, and processed egg products, and for this opportunity to be with you today. And I look forward now to answering your questions.

[The information follows:]

FOOD SAFETY AND INSPECTION SERVICE
Statement of
Dr. Elisabeth Hagen, Under Secretary for Food Safety
Before the
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration and Related Agencies

Introduction

Mr. Chairman, Ranking Member Farr, and other Members of the Subcommittee, I am

Dr. Elisabeth Hagen, Under Secretary for Food Safety. With me is Al Almanza, Administrator of USDA's Food Safety and Inspection Service (FSIS).

I am pleased to appear before you today in support of the President's fiscal year (FY) 2013 budget request for FSIS, and to discuss the status of FSIS programs. The President's FY 2013 budget request for FSIS includes \$995,503,000 in appropriated funding, a net decrease of \$8,924,000 from the FY 2012 appropriation of \$1,004,427,000. With this funding level, I am confident that FSIS will maintain the effectiveness of its core mission.

In 2011, FSIS released a 5-year Strategic Plan, which details the Agency's goals for FY 2011-2016, and outlines the framework for achieving these goals. The full plan can be found on the FSIS website (http://www.fsis.usda.gov/about/Strategic_Plan_2011-2016_Summary/index.asp). FSIS' Strategic Plan is divided into eight goals based on the following strategic themes: preventing foodborne illness, empowering people and strengthening infrastructure, and understanding and influencing the farm-to-table continuum.

Preventing Foodborne Illness

The first strategic theme, preventing foodborne illness, is achievable through the following goals: maximizing industry compliance with food safety policies; reaching out to and educating the public to improve food-handling practices; strengthening collaboration among stakeholders to prevent foodborne illness; and ensuring that inspection aligns with risks.

Every policy and program that we implement in the Office of Food Safety is designed to prevent foodborne illnesses. We have been particularly successful in protecting consumers from *E. coli* O157 since the implementation of Hazard Analysis and Critical Control Point (HACCP) and our zero tolerance policy. Between 2000 and 2010, FSIS helped our nation meet the Healthy People 2010 goal to reduce *E. coli* rates by 50 percent, largely because of strengthened beef safety policy and enforcement.

However, until every illness is prevented, we have more to do. While *E. coli* O157 illnesses have been cut almost in half, *Salmonella* illnesses – which according to the Centers for Disease Control and Prevention (CDC) cause more hospitalizations and deaths than any other type of bacteria found in food – have not declined. That is why we are constantly applying new methods to protect consumers from emerging foodborne hazards. Our successes in targeting O157 have led us to believe that we can make similar strides against *Salmonella*, non-O157 Shiga-toxin producing *E. coli* (STEC), and other pathogens found in FSIS-regulated products. Over the last fiscal year, FSIS has taken steps to do just that.

Maximizing Industry Compliance with Food Safety Policies

One of the ways that FSIS combats foodborne illness is to encourage industry to reduce the prevalence of pathogens in slaughter and processing establishments. The Agency implemented stricter *Salmonella* and new *Campylobacter* performance standards for poultry products, which are expected to prevent as many as 25,000 foodborne illnesses annually.

In July 2011, we announced the expansion of the *Salmonella* Initiative Program (SIP), which provides public health benefits by encouraging establishments to test for microbial pathogens, a key feature of effective process control. The voluntary, incentive-based program will grant participating establishments waivers of regulatory requirements with the condition that establishments test for *Salmonella*, *Campylobacter*, and generic *E. coli*, and share this internal food safety data with FSIS.

In the past year, we declared the six serogroups of pathogenic *E. coli*, the serogroups of greatest public health concern, as adulterants in non-intact raw beef. FSIS personnel will soon test beef for these six serogroups, and will ensure that raw product that tests positive for any of these strains will be diverted from commerce. While more than 100 Shiga-toxin producing *E. coli* (STEC) serotypes have been associated with human illness, these six serogroups cause between 70 and 83 percent of confirmed non-O157 STEC illnesses, and the CDC estimates that nearly 113,000 foodborne illnesses occur in the United States from these pathogens annually. Thus, combating these six serogroups can make a huge public health impact. FSIS will launch its non-O157 *E. coli* testing program on June 4.

In the past year, we also announced and asked for comment on a new “test and hold” requirement for the meat and poultry industry. By requiring industry to hold products subject to FSIS microbiological testing until the tests determine they are safe to release in commerce, consumer exposure to unsafe food will be reduced significantly. This approach could have prevented 22 recalls during FY 2009 and FY 2010. We expect this policy to result in fewer recalls by industry, fewer illnesses, and increased consumer confidence in the safety of the food supply.

Public Education and Outreach

Another way we fight foodborne illness is through public education and outreach to improve food-handling practices. We can help people understand and adopt the preparation and cooking practices that will make their families safer.

On June 28, 2011, FSIS launched a joint national multimedia campaign with Health and Human Services (HHS) to help families prevent food poisoning: the Food Safe Families – Check Your Steps campaign. The campaign urges consumers to remember four key steps to food safety: clean (surfaces, utensils and hands), separate (raw meat and poultry from other foods), cook (to a safe temperature), and chill (raw and prepared food). We have reached millions using a variety of donated media, including television, radio, print, and social media tools and the Internet. During the 2011 Thanksgiving season, I participated in a Food Safe Families media tour that generated more than 190 television and radio segments nationwide, reaching 20.3 million people. In addition, the Ad Council’s “separate” television spot ran on Wal-Mart Checkout TV, reaching

50 million shoppers in a 2-week period. Our partnership with Ad Council has enabled us to reach millions of consumers using very limited resources.

On May 5, 2011, FSIS launched Mobile Ask Karen, a web-based smartphone application that gives consumers another way to access the only U.S. government-sponsored food safety virtual-representative. Ask Karen had a self service rate of 98.8 percent for 2011, representing a savings of the time and money that would have otherwise been required for FSIS employees to respond to consumer questions.

As a mother and a doctor, I recognize the importance of developing good health habits at an early age. That is the purpose of our Food Safety Education Camps at schools and the Food Safety Discovery Zone, which visits grocery stores, schools, and community events. A significant part of our outreach programs target children and parents of young children, because children are among the most vulnerable population groups impacted by foodborne illness. Ultimately, though, our efforts reach all consumers because everyone can benefit from knowledge of safe food behaviors.

Strengthening Collaboration

In order to be successful in our battle with foodborne illness, we must also continue to strengthen collaboration with our food safety partners. In January of this year, USDA and the Food and Drug Administration (FDA) signed a memorandum of understanding (MOU), in which we committed to sharing information we have collected related to foodborne pathogens, contaminants and illnesses. As partners in ensuring food safety and furthering the efforts of the

President's Food Safety Working Group, we are also working with FDA to facilitate implementation of the Food Safety Modernization Act, which calls for increasing coordination and consultation between the two agencies.

Ensuring Inspection Aligns with Risks

We must also continue to think of creative ways to improve food safety through more efficient and effective inspection and verification activities. As part of that effort, OFS has announced a proposed rule – Modernization of Poultry Slaughter Inspection – that would facilitate the reduction of pathogen levels in poultry and streamline slaughter inspection in young poultry slaughter establishments. Inspectors would still perform a critical appraisal of each carcass, as mandated by law. In addition, the proposed system would direct FSIS personnel to off-line food safety-related tasks, such as verification of the establishments' HACCP systems, verifying that establishments are controlling their production process, and sampling for pathogenic microorganisms. It would also require that establishments address contamination before the chiller, in order to reduce the occurrence and levels of *Salmonella* and *Campylobacter* on the finished carcasses. This new system is expected to prevent over 5,000 foodborne illnesses per year. As reflected in the President's budget request, we estimate that this proposal also will save taxpayers more than \$90 million during the first three years after implementation and lower production costs for the poultry industry by at least \$256 million per year.

Empowering People and Strengthening Infrastructure

FSIS is working continually to identify ways to streamline operations and consolidate staff and resources, but not at the expense of our food safety goals. In order to do this, we must strengthen

infrastructure and empower employees with the tools they need to achieve success. The President's FY 2013 Budget includes an increase of \$4 million to purchase, install, and maintain time clock hardware and software for 3,300 employees in 500 industry plants. This will enable FSIS to capture more accurately the time and attendance of inspection personnel working in slaughter facilities as well as reimbursable overtime, and to electronically prepare establishment bills for that overtime.

As part of the USDA's Blueprint for Stronger Service, the Department proposed a number of office closures and consolidations to reduce administrative costs and improve organizational consistency and efficiency. FSIS has determined that it can streamline resources by reducing the number of district offices from 15 to 10. We are working with employees to limit the impact on affected employees and their families. This will not have an impact on inspectors in the establishments. We estimate that ultimately this would reduce costs by at least \$1 million annually, when fully implemented, while more evenly distributing the circuits, establishments covered, and FSIS employees that each district office oversees.

In April 2011, we launched the Public Health Information System (PHIS), a modern system that collects, analyzes, and even predicts key data about public health trends and food safety violations at the more than 6,000 FSIS-regulated plants across the country. As with any undertaking of this magnitude, PHIS implementation has had its challenges, but the Agency has listened to its employees, made significant improvements to the system and, as a result, has completed implementation of PHIS' domestic component to our employees. PHIS has made daily business more efficient, and given us a greater understanding of the larger food safety

picture. Since PHIS was launched, we know more about establishment operations, volumes, HACCP plans, and other food safety programs. We have increased the number of scheduled samples being taken and lowered the discard rates of unused samples because sampling is more targeted. We also have a pilot program that provides industry with access through PHIS to inspection results and noncompliance reports, allowing for more direct communication. Most importantly, we now have the ability to search and survey information in near real time, as opposed to having to look in separate, unsearchable databases and read paper documents.

Understanding and Influencing the Farm-to-Table Continuum

Contamination can occur anywhere: at the farms where animals are raised, at the slaughter and processing plants that FSIS regulates, and on cutting boards in kitchens. This means that we must be vigilant in working with our food safety partners across the farm-to-table continuum to protect consumers from harmful pathogens.

Everything we do at FSIS is affected by what happens before animals are brought to slaughter, and we can always do more to ensure that the food on consumers' tables is safe. We do not seek an increase in appropriated funding or expansion of our regulatory jurisdiction to the farm, but we think it is important to sponsor a conversation about pre- and post-harvest food safety. I think it is important that all of us with a stake in food safety – producers, packers, public interest groups, and regulators as well as consumers– engage in a comprehensive, honest, and thoughtful conversation about how to truly make food safer. That means examining every opportunity from farm to table, gaining a better understanding of foodborne illness, and implementing effective science-based policies that respond to existing and emerging risks.

In November 2011, FSIS held a joint public meeting with USDA's Animal and Plant Health Inspection Service and Agricultural Research Service on "Pre-Harvest Food Safety for Cattle." During the meeting, we discussed the latest thinking on how pre-harvest pathogen control strategies for animals presented for slaughter can reduce the likelihood that beef could become contaminated with *E. coli*, *Salmonella*, and other pathogens. FSIS is already promoting on-farm practices that can reduce and control pathogens at the pre-harvest stage. The Agency is also working on ways to trace contaminated food to the source before the product enters commerce.

Foodborne Illness Attribution and Measuring Success

Progress has been made in the President's challenge to Food Safety Working Group members to create meaningful metrics to measure progress in reducing illnesses, hospitalizations, and deaths from contaminated food.

However, the Government Accountability Office reported in its February 2011 High-Risk Series Update that food safety agencies have not developed a government-wide performance plan that includes results-oriented performance measures, which could be used to guide corrective actions and monitor progress. In response to that, FSIS developed a Strategic Plan that will help strengthen collaboration with our regulatory partners to prevent foodborne illness, and measure our progress to that end. As part of this effort, FSIS has made attribution estimates of the total number of illnesses from meat, poultry, and processed egg products and developed a key corporate performance measure of our progress. We calculated between FY 2007-2009 that there

were 436,401 *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7 illnesses attributable to FSIS-regulated products. By FY 2016, we hope to reduce this number to 363,547.

Conclusion

While measuring food safety success is something we always strive for, our greatest successes are often what does not happen. How do you measure product that was not contaminated, and a recall that did not happen because product was detained? You probably are not able, but these immeasurables are key to marking our successes. I would like to recognize that FSIS employees work every day to improve the safety of our food supply, ensuring the humane treatment of livestock, identifying regulatory violations, and using science to detect and detain unsafe product, solving outbreaks, and educating consumers.

This seemingly routine work constitutes the majority of our successes, and these successes only serve to inspire us to do more. I believe that the Strategic Plan will inspire us to work together as one team toward a common goal – preventing foodborne illness – and will measure our progress as we do so.

Thank you for your support in ensuring the safety of meat, poultry, and processed egg products and for the opportunity to testify before you today. I look forward to answering your questions.

FSIS STRATEGIC PLAN

Mr. KINGSTON. Thank you very much, Dr. Hagen. And I am glad that you started out talking about the strategic plan, and I just wanted a little bit of clarification because sometimes you never know, with the subtleties of this town, but the administrator has a statement on the plan, but you do not. And I was wanting to find out, is there anything that we need to read into that? Do you own it, or does he own it, or are you enthusiastic about it?

Dr. HAGEN. Yes. Thank you for the question, Chairman. As with everything that we are doing, we own it together. Al and I are a team. This entire group behind me is a team. And this process started not long after I came into the job in the fall of 2010. We wanted to take a fresh perspective on things, and the most important thing to us was to make sure that everybody in our organization got it and could see themselves clearly aligned in their work every day with the mission that we have.

And so the fact that there is no statement in there from me certainly does not reflect anything about whether I am behind it or not. I am absolutely behind it, and everything that Al is doing.

GOVERNMENT-WIDE STRATEGIC PLAN

Mr. KINGSTON. Now, one criticism from the GAO has to do with a government-wide strategic plan. And while you rightfully have outlined a good strategic plan, it is still for only one Agency. And so I do not know if the GAO would be satisfied with it. What is your reaction to that? Does this take care of their criticism, do you think? Because you—

Dr. HAGEN. Well—go ahead, sir.

Mr. KINGSTON [continuing]. Would be in the lead, I suppose.

Dr. HAGEN. We actually did have a chance to discuss this plan with GAO recently, and I think they were impressed with the direction that we are taking. Having a government-wide strategic plan has its challenges, I think. FDA and the other agencies involved in food safety operate under different statutes, within different statutory constraints, and there are limitations to what we can do.

But that is what the Food Safety Working Group is about. That is what the collaboration that we have been engaged with FDA is all about. I think that collaboration is at an all-time high. I think that we share a lot of common goals. Some of them are laid out very specifically.

We share a priority goal in Salmonella reduction, for instance. We have made foodborne illness attribution a shared priority and put resources behind that. So there are a lot of places where we can collaborate and we can agree on common goals. But to this point, we do not have a government-wide performance plan, per se, on food safety.

SALMONELLA ILLNESSES

Mr. KINGSTON. On Salmonella, 1.3 million illnesses, according to the CDC. And do you know how many of those would be from FSIS-related products that you could say you have jurisdiction over them?

Dr. HAGEN. I think we do have that number. I do not have it with me today, Chairman, but we can certainly get back to you on it. One of the things that we look at as one of our most important measures is what we call our all-illness measure.

So we look not just at salmonella, but we look at *Salmonella*, *Listeria*, and O157 from all the products that we regulate. And we have a goal of reducing from somewhere around 494,000 attributable illnesses in fiscal year 2011 to around 391,000 attributable illnesses by the end of fiscal year 2013. But we can get you that specific pathogen information.

[The information follows:]

The number of *Salmonella* illnesses from FSIS-regulated products is approximately 440,000 for FY 12. We calculated this by using case-rate data from CDC of the number of domestic, foodborne illnesses per 100,000 people, then use other CDC data to determine the fraction of those illnesses that come from FSIS-regulated products. Finally, we apply additional factors such as U.S. population and published, peer-reviewed scaling factors (Scallan, et. al., 2011) to come up with our final estimate. These numbers demonstrate that we have not been meeting our targets so far. *Salmonella* is the main reason we are not meeting our All Illness targets, which is the reason why that particular pathogen is such a high priority for us. It is important to note, however, that we continue to work closely with our food safety partners at FDA and other agencies to seek ways that we can reduce this and all foodborne illnesses.

Mr. KINGSTON. And then if there would be some gaps, we would probably want to know, outside of your jurisdiction, who is supposed to be stepping forward and if they are moving in the same direction that you are.

EDUCATIONAL OUTREACH

On Check Your Steps, the goal is to go from a 75 percent consumer participation to 79 percent, and you are using radio and internet and all kinds of public information systems. What do you think is keeping people from moving in the right direction? They just have not heard the message, or laziness, or—and how many people are we talking about, going from 75 percent to 79 percent? Do you have a number on that?

Dr. HAGEN. Well, I certainly do not think that what is preventing people from practicing these behaviors is laziness. I think people have heard these messages before, but we realize that they are not processing them for whatever reason.

People get a lot of information, and one of the things that we did when we designed this campaign was try to find a way that we could break through the hundreds and thousands of messages that people seem to receive in a week, so to do it in a way that would be eye-catching.

I think part of it is raising awareness. I think when you tell a mom that one in six people get sick from the food that they eat, that 3,000 people will actually die from foodborne illness, I do not think people are aware of those kinds of statistics. So part of it is raising awareness. I think part of it is making people believe that this is doable, that there are simple steps that can be taken to help reduce your risk.

So I think what we are doing here is innovative, and I think it is the right direction to be on. We have a lot of metrics that we are looking at in terms of success for this campaign, and we can certainly get those for you for the record.

Some of the other things that we look at are, how many people are talking about food safety? How many people are now going to the fulfillment website, foodsafety.gov? Or how many people are using our online databases and resources since we launched this? And we have seen really a very impressive increase in the traffic to those types of tools.

Mr. KINGSTON. Yes. My time is up, but I think we would be interested in knowing where you get the most bang for your buck. [The information submitted by USDA follows:]

Perhaps the best example is USDA's joint national multimedia campaign with Health and Human Services (HHS) to help families prevent food poisoning: /the Food Safe Families—Check Your Steps campaign. Our partnership with Ad Council has enabled us to reach millions of consumers using very limited resources. We estimate that the initial multimedia news release, in English, and Spanish, launched on June 28, 2011, reached more than 26 million consumers by the end of FY 2011. Broadcast coverage, including the Satellite TV and Radio media tour, resulted in more than 200 segments reaching more than 13 million people. As a result of the campaign launch, traffic to FoodSafety.gov, the campaign fulfillment site, increased significantly, from 85,000 visitor sessions in May 2011 to more than 92,500 within the campaign's first month, and more than 146,000 in August. FSIS's virtual representative, Ask Karen, saw page views increase from 4,133 views per month to 29,717 views less than two months after the campaign was launched, an increase of 619 percent. The Check Your Steps campaign videos on YouTube were viewed 12,560 times during the two months after the campaign launch.

Mr. Farr.

Mr. FARR. Thank you, Mr. Chairman.

LABELING RULE FOR ADDED SOLUTIONS

I am impressed that you are wanting—and I represent a lot of the fresh vegetables in the Salinas Valley, and the Leafy Green Marketing Order, and all the concerns they have had. I find that the industry, particularly that industry when it comes to growing all fresh stuff, that they are very interested in working with the regulators to make sure that it works.

And we will never have enough Federal inspectors to inspect everything. We have in California the County Agricultural Commissioners and Sealers Association; each county in the State has these professional folks who are the—they are the government of agriculture and in consumer protection as weights and sealers officials, empowered by law to do all the inspections.

They are concerned and talked to me about essentially the added solutions to chicken, added liquids, which represent a high percentage of product weight. And they petitioned the Department some time ago to revise the rule because they have determined in a California study that an estimated \$246 million in solutions are added to ready-to-cook poultry.

And assuming that California is approximately 12 percent of the U.S. market share, the nationwide impact is projected to cost about \$2 billion annually for just the added solutions for the weight. And they are required under the California Business Professions Code to inspect and provide equity in the marketplace.

And so their petition to you—and I think you are in the process of revising the rule. And I understand that you have issued a proposed rule to provide more accurate labeling requirements on packages of poultry and meat products that fully informs consumers of the contents of the package, including the fluids.

We find in this committee that people are very concerned about value cost. What am I buying for my buck? And we think this labeling would be very important now that people do not have as much money to spend.

So could you tell me when you are going to issue the Final Rule?

Dr. HAGEN. Thank you for the question, Congressman. Yes. The comment period for that rule closed in January, and we did receive a lot of comments because, as you say, people are, I think, more concerned than ever about what is in their food and what they are buying, and what they are getting for what they are paying for.

So we are in the process of analyzing the comments. And then when we finish those, we will move on to the next step in the rule-making process.

Mr. FARR. Just roughly, when does that occur? When does the end come and the rule gets proposed? I know the industry is not going to like those changes, but consumers will.

Dr. HAGEN. We never want to put a strict timetable on how long it is going to take with notice and comment rulemaking. But we do have somewhere over 800 comments that we need to analyze at this point. So that can take 60 days; it can take longer. So we are not making—

Mr. FARR. But it is going to be done this year?

Dr. HAGEN. That is our intent.

Mr. FARR. Well, by the end of this year.

COORDINATION WITH THE FOOD AND DRUG ADMINISTRATION

Let me also ask you, on page 5 of your testimony, you mention the memorandum of understanding that you signed with FDA in January of this year, sharing on foodborne contaminants and illness. And on page 5 of your testimony, you mention the Food Safety Modernization Act calls for increasing coordination and consultation with FDA and FSIS.

Could you discuss your hopes for the MOU, and also what work has been done since the passage of the Food Safety Modernization Act to improve coordination and consultation between your Agency and FDA?

Dr. HAGEN. Surely. Thank you for the question. The MOU is important. There have been, I think, sometimes sort of structural and bureaucratic reasons, things that get in the way of information-sharing between two Federal agencies when it ought to be more simple than that.

Sometimes there are concerns about commercial confidential information, things like that. But this really aims to break down those barriers because we all ought to be working together, particularly when it comes to issues of public health.

The MOU was signed, incidentally, not only between FSIS and FDA but other mission areas within the USDA as well. So it is really an effort to share information broadly across the board.

And as far as our collaboration with Food Safety Modernization Act implementation, as you said, the legislation does call for a lot of consultation with the Secretary of Agriculture, a lot of collaboration on the work. We have worked with them on developing their preventive controls, on really a lot of different pieces of that implementation. And that is going to continue as well.

Mr. FARR. Have you done anything since you signed the MOU? I mean, has there been any product of that, or just organizing the——

Dr. HAGEN. We actually just finalized it in January, so we have not had a chance to take any new steps since it has been signed. But I think it is going to be really good for all of us.

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

Ms. DeLauro.

E. COLI VARIANTS

Ms. DELAURO. Thank you again, Under Secretary. We are pleased to have you here. And I will just say one more word about Brian. We loved your work for me, and I know you are doing great work for the Secretary as well. I mean that.

I am going to try to do two questions in this round. One has to do with STEC and E. coli, and the other with regard to HIMP. So I am going to try to be brief, and I will ask you to do the same.

I was encouraged by the announcement last year that testing for the big six E. coli types we know to be as dangerous as O157:H7 and meeting the legal definition of an adulterant, would be required. Though I was disappointed in the delayed implementation, I am glad that you are moving forward with implementation as soon as possible.

Can you tell me about the science that confirms the label of adulterant for these pathogens in ground meat? How did the Agency reach the decision to require testing for these six?

Dr. HAGEN. Sure. Thanks for the question. You know, when we started out, we looked at whether we can and should see these pathogens in the same way that we see O157:H7. And the case law in that instance points us toward a couple of key factors, things like the fact that they are resistant to what we call everyday or normal cooking; they have a heat resistance issue. A very low infectious dose is required to make people sick, and make people very sick.

These are the types of things that we looked at from a legal basis, and also through our risk profile, at whether we could consider them and should consider them in the same way that we do a O157:H7. We are very confident in the science——

Ms. DELAURO. In the science basis of this effort?

Dr. HAGEN. Yes.

HACCP-BASED INSPECTION MODELS PROJECT

Ms. DELAURO. Let me move to HIMP. On January 7th, the Agency published a proposed rule related to poultry slaughter inspection. I understand that some see this as a step forward in modernizing meat and poultry inspection, and I look forward to working with you to ensure that we modernize this antiquated system while improving food safety and ensuring worker safety is protected.

Was the risk assessment for the HIMP rule peer-reviewed? If so, if you can provide my office with that review, the reviewer, feedback, and how FSIS addressed that feedback. Central to HIMP is the reduction of inspectors in the facility and the ability to increase the line speed before the chiller, up to 175 chickens a minute.

The Agency has indicated that expanding the HIMP model to allow all poultry plants will prevent 5,200 illnesses per year. If you can explain how that figure was calculated, specifically what the Agency expects to happen to illnesses associated with *Campylobacter* in HIMP plants. I understand that the study included in the proposed rule has not been started and will take one year to complete, plus there appear to be difficulties in confirming plant participation.

A couple of additional questions. Why should participation in this study not be required for plants that opt to transition to HIMP? And is FSIS prepared to wait until this study is conducted and the data is in before imposing this new rule? If FSIS is not prepared to wait until this data is available, how are you going to integrate NIOSH's findings?

Dr. HAGEN. Thanks. I will try to get to as many points as I can, and give you the rest for the record.

Your question on peer review, yes. The risk assessment was peer-reviewed. And I think, just to try to address all of it at once, this rule is about food safety, and it is about modernizing. The commitment that I made when I came into this job was that we would look at the way we do things and we would find ways to do them better than we have done them before. And that is what this is about. It is, first and foremost, about safer food and safer consumers.

You know, as far as the line speed issues, we are, I would say, going outside of our statutory mission to look at the impact on worker safety. Our first concern is food safety, and if we have the opportunity to modernize the system to produce safer product, we will do that.

But we are concerned about unintended consequences that might occur because of this modernization. And that is why we have partnered with the National Institute for Occupational Safety and Health—NIOSH. We have been in discussion with the Occupational Safety and Health Administration—OSHA—and we are going to take these findings very seriously.

As you know, we did submit a line speed report to Congress in 2010 in which we looked at all of the available data on line speed and worker safety. And we were not able to conclude at that time that there was any increased risk to workers at that time.

But it is important that we look at this, and——

Ms. DELAURO. 5,200 illnesses per year?

Dr. HAGEN. Yes, ma'am.

Ms. DELAURO. How was that calculated, and how are you going to deal with *Campylobacter*?

Dr. HAGEN. Right. So that is——

Ms. DELAURO. Because that is going up. That is increasing.

Dr. HAGEN. Yes.

Ms. DELAURO. *Salmonella* is going down, but *Campylobacter* is going up.

Dr. HAGEN. So 5,200 illnesses a year, that figure comes from the risk assessment itself. When we looked at this rule, we looked at it from a common sense standpoint, having people focused on the things that matter most in food safety in 2012.

We looked at our experience with the HIMP model in which we have plants performing better than they are performing in the non-HIMP style in terms of product contamination rate and meeting performance standards. And then we had a peer-reviewed quantitative risk assessment that actually looked at specific public health impacts when we moved people off line and focused them on these critical verification activities.

So that is where the 5,200 comes from. About 4,200 of that is salmonella, and about a thousand of that is Campylobacter.

Mr. KINGSTON. Your time has expired.

Ms. DELAURO. If I can just ask—I would like to get the peer review material. And then, really, because there was a study asked for in 2005 with regard to integrating NIOSH, et cetera, that, as far as I know, has never been done.

So I am anxious to get the information on how we are really going to integrate NIOSH, and your view as to whether or not we should wait until the study is conducted before we impose the rule, and shouldn't we be requiring plants before they opt into this to participate in the study. I understand there is only one plant that has agreed to participate in the study. So we need to figure out how we can do this.

Thank you, Mr. Chairman.

Dr. HAGEN. Sure. We will get that for you.

[The information follows:]

The updated FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection is published at: http://www.fsis.usda.gov/science/risk_assessments/index.asp.

It is important to note that the 2005 GAO report you reference was aimed at OSHA, and recognized that FSIS's role should properly be aimed at verifying food safety. Although that report did not discuss NIOSH, we are nonetheless working with NIOSH as we implement poultry slaughter modernization. The GAO report can be found at: <http://www.gao.gov/assets/250/245042.pdf>

Ms. DELAURO. Thank you.

Mr. KINGSTON. Mr. Nunnelee.

FSIS EMPLOYEE ILLNESSES

Mr. NUNNELEE. Thank you, Mr. Chairman. Thank you for being here. Probably more importantly, thank you for the work that you do. If anything, I think Americans probably take you for granted.

I have got to confess I am a freshman here, and there are times I deal with agencies and find us talking about how to do something better or how to do something more efficiently, and I find myself asking the question why are we even doing this thing at all, but I do not have that question with your agency. I think you perform a very vital service to Americans. I want to thank you for it. It is one of those things we do not notice or appreciate until we see headlines somewhere.

But I guess I want to start with talking about your employees, particularly those that are out there in the field. They are doing really some of the dirty work that has to be done in order to have a safe, reliable food supply. But in the process, they are going to be exposed to Salmonella and E. coli and a lot of other foodborne illnesses.

So I guess how often do those employees have an adverse reaction as they come in contact with some of these things?

Dr. HAGEN. Do you want to take that question?

I am going to defer that to Mr. Almanza.

Mr. ALMANZA. Being that I started my career working on the slaughter line, I think I can speak to that. Our front line inspectors are our most valuable tool. I will say that right up front, our inspectors that stand on the slaughter line, be it poultry and/or red meat, but it is not as if they start that job every single day, and so they know the routine of how to avoid those types of situations. I mean, it is one of those things that when you work on the slaughter line every single day, you understand there are certain things you do. You wash your hands as you do in any type of food handling business.

So it is not as significant as it appears from the outside.

Mr. NUNNELEE. Do you ever use the sickness of an employee as an indicator of a potential outbreak?

Mr. ALMANZA. I do not know that we have ever crossed that bridge to this point, but whenever our employees or company employees have a communicable disease, they are not allowed to work in the establishment.

Mr. NUNNELEE. I am not worried about them having a disease getting into the food. It is more if there is disease in the slaughter process that they contracted and that is an indicator that there is a problem with what they are inspecting.

Mr. ALMANZA. No, I do not recall us having that problem as of yet.

CATFISH RULE IMPLEMENTATION

Mr. NUNNELEE. All right. Let me move to catfish. A couple of weeks ago my colleague, Representative Aderholt, asked Secretary Vilsack about the status of the proposed rule to determine the definition of catfish. I understand the rule is still pending with OMB. The 2008 Farm Bill was pretty clear asking that the program be completed within 18 months of passage, and here we are in 2012, and we still do not have a definition of catfish.

So can you give me some kind of timeline as to when we are going to have that completed?

Dr. HAGEN. Thank you, Mr. Nunnelee. I thought you might ask a question about catfish.

The rule is actually not with OMB any longer. The rule was proposed, and we are in the process of analyzing the comments at this point. There are a lot of comments as you will recall. There was a lot of vigorous debate about this entire issue, and particularly about the definition of catfish. So we are still in the process of analyzing the comments, and then we will move forward with a final rule when we are done with that process.

Mr. NUNNELEE. Under what kind of time line?

Mr. ALMANZA. I cannot guarantee you a timeline. I would expect, you know, we are looking to hopefully have the program begin to implement in fiscal year 2013.

Mr. NUNNELEE. I think that has got it. Thank you.

Mr. KINGSTON. Mr. Graves.

FSIS EMPLOYEE COMPENSATION

Mr. GRAVES. Good morning, Dr. Hagen. I want to bring to your attention and maybe get some clarification of an issue I received from a constituent. As you know, I am a free market guy, and I believe individuals should be able to purchase beef from wherever they choose, however they choose, certainly as long as it is safe. And a glaring issue that has come up in my district, and it was brought to me from a constituent and I am sure it is not limited to the State of Georgia, and this is a small, all natural beef producer. He uses two different USDA inspected processors, and their cost of doing business shoots up dramatically many times or it is inhibited each day when there is a federal holiday, and as it relates to the pay.

Now, our Commissioner of Agriculture, Gary Black, he does a great job of making sure that Georgia Agriculture stays on the cutting edge, and he has made an effort to rehire fully qualified inspectors that are retired in order to provide inspection services during the normal 40-hour week.

But it is my understanding when these or any other inspector works hours that are outside of the normal 40-hour week or during a federal designated holiday it is the processor that gets billed for that overtime, even if the inspector involved has not worked 40 hours.

Is there truth to that or how does that work? Maybe you could help explain that.

Dr. HAGEN. I am going to defer that question to Mr. Almanza if I may.

Mr. GRAVES. Sure.

Mr. ALMANZA. The way our system works is an establishment gets eight hours of free inspection per day, which comes out to 40 hours per week. Some establishments choose to work ten-hour days, and so they get Monday through Thursday, ten hours a day. Some do the five days, but any time outside of those free hours of inspection, the establishment is billed be it for a quarter hour all the way up to four hours a day.

Mr. GRAVES. So is there a case in which an inspector works on a federal holiday, but has not worked any other hours during a week, and that would be charged as overtime to the processor?

Mr. ALMANZA. I would say that that could be the case, though normally the inspector has to be on duty the day prior to the holiday in order for them to be eligible to work on the holiday. Otherwise, the person that is assigned to that position during the week, that would be the person that would be assigned to that position.

Mr. GRAVES. So it is possible then that somebody is being billed for overtime when the inspector has, in fact, not worked 40 hours.

Mr. ALMANZA. Just hypothetically, if the inspector was on annual leave, say, they were on vacation and they were willing to return to work for that holiday and the person that was assigned to that position did not want to work, then, yes, hypothetically, yes, that could happen.

Mr. GRAVES. The reason I am bringing this up, I mean, our job as appropriators right now is to look for where we can save Amer-

ican taxpayers money, and every dollar that I see in your budget, I see it as coming out of the pockets of taxpayers.

But then there is also the side of the business community and the economy itself, and what are the barriers to these small business owners doing better.

In your opinion, is there an opportunity in which these small business owners should not have to pay for overtime when, in fact, an inspector has not worked overtime? They just happen to work on a day that was designated by the Federal Government to be recognized as a certain day when, you know, Americans all across the country are still working on that day. They are not getting paid overtime.

Just thinking about the small business owner and the growing amount of bureaucracy that is placed on him, and now I see an additional cost that may be hurting their business or preventing them from being more successful.

Mr. ALMANZA. Regardless of who works that assignment, they are going to be billed, and I understand your line of questioning, but what we try to do is we try to share the overtime billing. So if multiple establishments are working, one establishment is not billed for eight hours, say, if there are other establishments that that inspector is in charge of overseeing.

So they split it up depending on the number of establishments, but to your question, I mean, that is the way the system works, is that they are going to be billed for the time that they work on be it a holiday or a weekend.

Mr. GRAVES. And can you direct me to where that derives from? Is it law? Is it a rule? Is it labor laws? I mean, where does that occur that overtime pay can be paid to somebody that has not worked 40 hours?

Mr. ALMANZA. I do not know exactly, but I will submit it for the record.

[The information follows:]

As set out in the Code of Federal Regulations on Overtime and Holiday Inspection Service, 9 CFR 307.5 and 9 CFR 381.38, establishments, importers, and exporters are required to reimburse FSIS for the cost of inspection services furnished on Federal holidays or for more than eight hours in a day, or for more than 40 hours in an administrative workweek. Also, the Poultry Products Inspection Act (21 USC 468) and the Act of June 5, 1948 (21 USC 695) provide that the cost of inspection rendered under this chapter shall be borne by the United States, except the cost of overtime and holiday work performed in establishments subject to the provisions of this chapter at such rates as the Secretary may determine shall be borne by such establishments.

Mr. KINGSTON. Mr. Farr.

Mr. FARR. Thank you.

Let me just tell you what I am feeling on the ground, and it is beyond just poultry and meat inspection. What is happening in our area in California, we have a lot of organic growers and now a lot of ranchers who want to follow in the organic movement or at least have their grass fed beef that are raised totally on their ranch to be able to sell those to local markets and farmer's markets.

ECONOMICS OF SMALL PRODUCERS

The problem is you say, look, down the street guys grow grapes and put them in a bottle and put their name on it and can sell it to anybody that comes and visits their vineyard.

My cattle ranch, I have home stays and people come, but I cannot sell them my beef with my label on them because of the whole difficulty and cost of transporting to the slaughterhouse and getting that back. So what we have been trying to do is work with the inspectors to see if we could create economy of scale. It is not just the slaughtering. It is the packaging as well.

And there has always been kind of a bureaucracy here, and I think part of it was raised, you know, in payment time, overtime, but I think it would be really helpful if we could get the attention of the department to try to work out something that you could really develop a linear experience of where we could line it up so that it is cost effective to be able to get an inspector to be at a place.

For example, we have a mobile slaughter, and that seems to work, but I am not sure it is an economy of scale that they need right now. There are some slaughterhouses in Santa Barbara, California right now that are going under and others are interested in buying them. You know, it's a whole new movement coming out of this sort of what we call the field to fork movement in the vegetable area, but it is also starting to apply to poultry and to cattle where people would like to be able to bring local cattle into the local market and have not been able to do so because of the difficulty of meeting all of the regulatory needs.

You know, we do not have that many slaughterhouses and packaging companies. So I do not have a specific question other than just we would love to work with the department to see if there are regulations that need to be looked at and waivers given or even the State to come up with an inspection program.

I know you have certified some States to do the inspections for the federals, and it is a whole field that I am very curious about working on.

FEDERAL REGULATIONS VS CORPORATE RULES

And the last thing that I have, and what is happening in the fresh vegetable area, and I do not know whether this is happening in the meat and poultry, but in the fresh vegetables, when the E. coli break came, what we saw is corporate risk managers, essentially the lawyers of the corporation came down and started telling farmers how they had to grow.

We lost the ability to have the federal preeminence in using science and regulations to be the trusted entity. So all of a sudden growers say, "You are buying all my lettuce."

I am McDonald's. I am buying everything you can grow, but you are going to grow it my way, and I do not want that riparian vegetation there."

And the grower says, "That is federal law. I cannot just go in and take that."

"I want you to put fences up everywhere." I mean, it is not going to keep E. coli out.

And you see these applications that having been made cost to the farmer only because they have to meet that corporate demand because the Federal Government has lost the ability to say, "Hey, you know, trust us. We are in this field. We regulate, and you do not need to go beyond our regulations."

So I think you are going to continue to see this, the liability of health risks and the litigation over it, sort of usurp your authority in the field. It is something we have got to work at and be concerned about.

But that is my observation.

Mr. KINGSTON. Forty-three seconds.

DETERMINATIONS OF EQUIVALENCE

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

Dr. Hagen, I spoke a bit about this issue with Secretary Vilsack when he came before the Subcommittee, and you and I have had the opportunity to talk about Chinese poultry products in the past. So I continue to be concerned that the outcome of the equivalency process has been decided before the audits and reviews have been completed.

So a couple of questions here. Is FSIS participating in the recently announced trade mission to China, being headed up by Acting Under Secretary for Farm and Foreign Agricultural Services Scuse?

Dr. HAGEN. I do not believe that we are participating in that, no.

Ms. DELAURO. You are not. Because it is my understanding as well that the equivalency decision is a decision that should be made by FSIS. What role is the Foreign Agricultural Service playing in the equivalency determination issues related to China?

Dr. HAGEN. I do not believe that they are really playing a role. You know, we are still following the same process that we follow for equivalency determination for any country, and in fact, we are not at that point yet with China. There are still a number of requirements that need to be satisfied.

Ms. DELAURO. But I have a copy of a letter. Oh, so it is not mine. I will get back to this.

Mr. KINGSTON. We will get back to it.

Mrs. Lummis.

Mrs. LUMMIS. Thank you, Mr. Chairman.

Ms. DELAURO. Yes, that is fine. Thank you.

Mrs. LUMMIS. Good morning.

Dr. HAGEN. Good morning.

Mrs. LUMMIS. Mr. Young, you have occupied that chair for several weeks, and you must be getting kind of tired of this.

Ms. DELAURO. Never.

Mr. YOUNG. I appreciate the opportunity.

DUPLICATIVE PROGRAMS ACROSS AGENCIES

Mrs. LUMMIS. Excellent. Well, as you know I tend to focus on those GAO reports on duplicative programs at the Federal Government, and one of them discusses creating a single food safety agency because of the number of redundant agency regulatory schemes. For example, the FDA deals with chicken eggs to make sure they

are safe, wholesome and properly labeled, whereas the USDA is responsible for the safety of eggs processed into egg products.

And as I have said before in these hearings, that just sounds so backwards to me. You would think it would be the USDA that would be dealing with the whole egg, and it would be the FDA that would be dealing with the processed product. So I think that there has over time grown to be some sort of bizarre consequences of having an FDA and a USDA food safety division of responsibilities.

So my question is this. I know there is a Memorandum of Understanding to reduce duplication across agencies. What steps are laid out in that MOA for USDA and FDA?

Dr. HAGEN. I am not sure if I am clear on exactly which MOA that you are referring to, Congresswoman. I am sorry.

Mrs. LUMMIS. Do you know is there a Memorandum of Understanding?

Dr. HAGEN. We have a number of Memoranda of Understanding with FDA, including one that we signed recently about sharing of information, and then we have other agreements in terms of how we work in dual jurisdiction establishments and things like that.

Mrs. LUMMIS. Well, last year it was mentioned that a Food Safety Working Group meets to discuss reducing overlap. So maybe we should attack it this way.

What progress has been made over the last 12 months?

Dr. HAGEN. And I agree with you. I think if we started from scratch, we might go about things differently, and things have gotten more complicated, I think, as the years have gone by. But we do have different statutes. We have constraints that come with those statutes, and I think that we have done a pretty good job of protecting the American consumer.

I am particularly proud of the work that we are doing at USDA over the last few years to protect American consumers, but we have focused more on collaboration through the Food Safety Working Group. One of the things we talked about earlier was we share a goal on Salmonella reduction, for instance. So FDA looks at it from an egg standpoint. We look at it mostly from a broiler standpoint and see, you know, how we can hit public health based targets there.

We have this MOU that we recently shared. We have collaborated with them and consulted with FDA a lot on the limitation of Food Safety Modernization Act as they write their regulations there.

REALIGNMENT OF FOOD SAFETY ROLES

Mrs. LUMMIS. Is it time to divide food safety and put it in USDA and drug safety it—and put it in FDA and get the drug administration out of food so they can really concentrate on getting prescription drugs vetted as quickly as possible, not to mention medical devices?

So let them concentrate on drugs and medical devices. Let the USDA concentrate on food safety. Would that not make more sense?

Congress has done this. It is not you. You are just trying to do what the statutes tell you to do, but just in terms of policy, would

it not make more sense if USDA had food and the FDA had drug and devices?

Dr. HAGEN. Thank you. Thank you, Congresswoman, for your question and thank you for acknowledging that we are operating under the laws that we are operating under.

You know, I do not know whether one system is better than two or better than a few. I do know that this system needs to be accountable to the consumer that it is there to protect. I know that it needs to be more seamless to the industry that it regulates than it has been in the past. So I think there is a lot of room there for us to each grow and improve in our own missions and for us to collaborate to a much greater extent than we have before.

Mrs. LUMMIS. And are you making progress on this Food Safety Working Group?

Dr. HAGEN. I think we are. Some of the things that I mentioned earlier are examples of that, and we have also focused on a shared goal on foodborne illness attribution, knowing that that helps guide our policies and our resources.

We have improved the National Residue Program in terms of how that is governed and how we protect consumers there.

We have a joint incident command structure for when we have kind of a dual jurisdiction related to outbreak, and we have an ongoing collaboration through things like FoodNet that actually help us track from year to year what our progress is on foodborne illness.

So I think collaboration with FDA is very good right now. I think there is still more work to do there.

Mrs. LUMMIS. Thanks.

Mr. Chairman, if we have another round, I have a question about Homeland Security and border food safety issues, but I will hold that.

Mr. KINGSTON. We will have another round. How long does that question take?

CBP INFORMATION SHARING

Mrs. LUMMIS. It is short.

Mr. KINGSTON. I will yield you one minute.

Mrs. LUMMIS. Thank you, Mr. Chairman.

Has Customs and Border Protection taken steps to communicate time of arrival information to your screening system?

Dr. HAGEN. Yes, I know we have worked with Customs and Border Protection on improving food defense and food security there at the border. I do not have an answer specifically to that question for you. I am happy to get that for you.

[The information follows:]

When the Public Health Information System (PHIS) is fully operational, it will interface with the Automated Commercial Environment (ACE). At that time, Customs entry data will automatically populate PHIS when the entry is filed, so FSIS will be aware that the shipment has arrived at the port of entry. PSIS is also interested in when the shipment will arrive at the official import inspection establishment. While this information is currently not collected by Customs and Border Protection (CBP), CBP has developed a set of data elements specific to FSIS that may lead to increased collaboration between the agencies.

Mrs. LUMMIS. That would be great.

Mr. Chairman, I will submit that for the record just so you have that validation in writing, and I yield back. Thank you.

Mr. KINGSTON. Well, thank you.

Let me mention also on Mrs. Lummis' question and the theme of Ms. DeLauro, there are about 1,400 plants which might make something like sandwiches or soups that have meat in them or pizzas that have meat in them, and you have a USDA presence and an FDA oversight jurisdiction. So perhaps you and Ms. DeLauro, working with Dr. Hagen or whoever, could get together and we could move towards some report language or something that would address that because it would certainly save money, but not jeopardize food safety, I would hope.

FOREIGN PLANT EQUIVALENCY DETERMINATIONS

So I also just wanted to make that statement, and then I am going to yield the balance of my time to Ms. DeLauro, but I want to tee it up on the equivalency issue with Chinese chicken. While she and I may disagree on the importation of Chinese chicken, we are together on the equivalency and thorough inspection, and I am really surprised that you guys are not at the table. That might be ordinary in terms of working these out. It does not surprise me that the U.S. Trade Representative does not put you in there, but one of the great concerns that we have shared on this is we do not want the wish for trade and commerce to override your role on food safety, and we also know that you can have one Chinese plant that looks great and another one that might not look great.

So I want you to say for the record if this is the case. You are inspecting this on a plant-by-plant basis for equivalency and not a processing company-by-company basis. In other words, you would inspect every facility.

And so I am going to yield the balance of my time to Ms. DeLauro, but perhaps in this discussion you can address that plant-by-plant question and why you all are not at the table.

Ms. DELAURO. Thank you, Mr. Chairman.

SINGLE FOOD SAFETY AGENCY

I would just say, and I listened carefully to what my colleague Mrs. Lummis has said about food safety, we have 15 agencies today that deal with food safety at the federal level, and it was in 2007 that the GAO talked about moving, if you will, toward an independent food safety agency and Government-wide performance standards.

I understand what you are talking about with food at USDA and with drugs at the FDA, and I would love to continue our conversation as well with the Under Secretary.

Today there is no single agency or person who is in charge or responsible for food safety at the federal level. We need, in my view—a single, and it has bothered me for years, and I have introduced a single—people are laughing here because they know—a single food safety agency who has the total jurisdiction and should be independent of both FDA and USDA, and I would look forward to continuing conversations on that, and I will send you a copy of the bill.

AGENCY ROLES IN EQUIVALENCY DETERMINATIONS

Okay. The second question I was asking is: what role is the Foreign Agriculture Service playing in the equivalency determination issues that are related to China?

I make reference to a letter from the Secretary that addresses or talks about FAS going to Beijing, et cetera. So I am curious, and you have said, as the Chairman pointed out, that you are not part of this trade mission that is going, and so what role is FAS playing in this regard?

Dr. HAGEN. Well, Congresswoman, I think that we have other trade priorities and trade concerns with China, and so FAS is going to have a role there.

I do think there is a respect for the line that needs to be drawn between food safety, food equivalency, food inspection, and trade priorities, and I think that out of respect for that, that is why they have left us out of that. But they are not playing a role in the equivalency determination per se.

INITIAL EQUIVALENCY DETERMINATIONS

Ms. DELAURO. Well, I get very concerned that the outcome of the equivalency process has been decided before those audits and reviews have been completed as the Chair talked about, and we know what equivalency means. We had charts up here in the past about what some of the audits have shown.

If it is equivalency, it is not plant by plant. They can pick out two or three plants. Once equivalency is granted, any plant can then send whatever they want to send here, and we have no way of trying to deal with the safety of that product, including, you know, on the processed side of this.

And now we are looking at the importation of China's poultry, et cetera, and in a nation that has dealt with a myriad of violations of food safety laws, and—

Mr. KINGSTON. My time has expired, but it is your time now anyway, but I would like you to answer that question. If it is plant by plant, location by location, or is it processor by processor?

Then it is your time.

Ms. DELAURO. Just to reinforce that, once equivalency is determined, we do not inspect every plant. The produce just comes in; is that not right? So it is not plant by plant.

Dr. HAGEN. Well, the initial equivalency determination is made on a subset of plants, and you are correct that once equivalency is determined, that that country—but I think it is important to state on the record that there are a lot of pieces to this.

The very first thing we do and what takes often the longest is we need to be comfortable that the country as a whole has a statutory and regulatory structure and the ability to produce or to guarantee the safety of the food products that come out of that country. So we start there.

Then we do the audits, and remember we have re-inspection of the border, and then we have recurrent audits once a country had gained equivalency. So it is not as if the process stops just by that initial equivalency determination.

But the characterization is correct, that it is done using a subset of plants from the country.

Ms. DELAURO. Is it my time now, Mr. Chairman?

Mr. KINGSTON. Yes.

Ms. DELAURO. What happens after equivalency is granted?

It is a subset. It could be four. It could be three. It could be six. It certainly does not go beyond a great number of plants.

And your first point though was about the regulatory structure of the country that we are granting equivalency to, and quite frankly, when the Secretary was here last week, we talked about a portion of our dollars is going to prop up China's regulatory system when we need to be trying to deal with our own set of circumstances here like a microbiological program which helps to look at pathogens and foodborne illnesses. For \$5 million we are going to eliminate that program.

But the fact is here that China is notorious about having an unsafe system and a poor regulatory system. So we are trying to get to the point upon what basis is equivalency granted and then what happens after you grant equivalency and what is coming in plant by plant.

Dr. HAGEN. Well, the equivalency process is complex, and it is extensive. And as you know, we have been submitting reports to Congress on a regular basis about the deliberations over equivalency. We are happy to provide even more detail about what components are looked at when we determine equivalency, but your question about what happens afterward is that they are able to start exporting products to the United States.

And to my point earlier, we go back and we audit countries on a regular basis. We re-inspect products at the border. We have enforcement capabilities. Countries can be suspended. Plants can be de-listed. These things can and do happen.

So we do have enforcement capability once equivalency has been determined, and we have numerous examples of suspended nations and de-listed plants that have occurred over the years.

[The information follows:]

FSIS ensures the equivalence of the exporting country's food safety system before trade is allowed, then conducts its own inspection of product when product is presented at import facilities. This includes product examination and random testing. After establishing the equivalence of a Nation's system, FSIS also conducts annual audits of that system to make sure it continues to be equivalent.

FSIS' system of establishing country-by-country equivalence makes the foreign country accountable for its own food safety system and the establishments within its borders. This is an efficient, effective, and globally-accepted approach.

To export product regulated by FSIS to the United States, foreign governments must have a food safety system determined by FSIS to be at least equivalent to the U.S. system. The equivalence determination process begins with an examination of the country's statutes and regulations to determine whether the country's food safety officials have sufficient authority to be equivalent. FSIS staff then visit the country to ensure that actual procedures and resources are deployed consistent with the documents reviewed. Once the foreign country system is deemed equivalent, specific establishments in the country must be certified before those establishments can export to the United States.

When FSIS makes an initial equivalence determination, a proposed rule is published for comment in the *Federal Register* setting forth the determination and the reasons for the determination and seeking public comment. FSIS reviews comments submitted and, if appropriate, publishes a final rule to add the country as eligible to export meat, poultry, or processed egg products to the United States.

FSIS verifies the effectiveness of foreign systems through re-inspection of product at the border. Every shipment of meat, poultry, or processed egg products, with few exceptions, must be presented to an FSIS inspector at one of the approximately 120 official FSIS import establishments located at major ocean ports of entry and land border crossings.

Every import shipment is re-inspected for documentation irregularities, evidence of tampering, transportation damage and proper labeling, to ensure that the product was produced in an eligible establishment in an approved country.

More intensive inspections are completed on about 10 percent of shipments, including product examinations. Approximately 5 percent of shipments are sampled and the samples analyzed for microbiological contaminants.

Ms. DELAURO. How many plants in terms of this equivalency process will be inspected for China? Is it proportional to the number of plants that they have that produce a product, that produces product?

Last time I just will tell you we had for slaughtering and we had for processing, and the reports were abysmal. We had people here saying on this side of the table that they would have shut down plants in the U.S. if they had found such circumstances.

So how many? Is it proportional? And do we have the capability to do something that is proportional?

Dr. HAGEN. We actually do not yet know how many plants will be included. We are still in an earlier phase of the equivalency determination. So we do not yet know how many plants are going to present for that.

Ms. DELAURO. How many plants are there in China?

Dr. HAGEN. I do not know, Congresswoman.

Ms. DELAURO. We should know that, and we should know in what proportion we should be looking at.

And I will just say to you you ought to find out what FAS is doing, and you ought to be very much engaged and be at that table as FSIS in making the determination on what product is coming into the United States from China in this effort, both on the process side and on whether or not, in fact, we are going to accept Chinese poultry into our markets here.

I am going to run out of time. I would just preface this. This is about mechanically tenderized beef products, and essentially it is about labeling. I read the article yesterday about lean beef trimmings. What we need to do is to label products so that consumers in school districts can make informed choices about the purchases.

But a 2008 Journal of Food—well, my time is up, Mr. Chairman. Are we going to do another round or what are we doing here?

Mr. KINGSTON. We will, and Mr. Graves.

SINGLE FOOD SAFETY AGENCY RESPONSIBILITIES

Mr. GRAVES. Thank you, Mr. Chairman.

I guess still sticking with the small business themes, as a small business owner, those great Americans that are creating jobs, and to add to this great agency consolidation accord we are hearing about, I wanted to ask about seafood and meat and poultry inspectors.

Is that two different agencies as well? Is that another area in which these two fine ladies could bring into their accord and have a conversation about? Because it appears that whether it is a local grocery store or a butcher, that there are two different inspectors coming in potentially. Is that the way it lays out today?

Dr. HAGEN. Congressman, at the federal level, the safety of seafood is not managed by the USDA, although we are in the process of developing a catfish inspection rule.

Mr. GRAVES. When it is defined, yes.

Dr. HAGEN. When it is defined, yes. And then there are different jurisdictions at the retail level as well. So, yes, these are done separately currently.

Mr. GRAVES. Would that be something you would want to see brought into the discussions that Mrs. Lummis and Ms. DeLauro are thinking of, or do you see that it is working the way it is now?

Dr. HAGEN. Well, as I said to Congresswoman Lummis, I think we have done a remarkable job given the statutory constraints that we do operate under. I think there is a lot more progress to be made, and I think that making this make more sense to the average American consumer is really important, and I think that making it less burdensome on the industries that are regulated while still preserving food safety is also very important.

Mr. GRAVES. That is a very diplomatic answer there.

LABELING PROCESS FOR SMALL PRODUCERS

Shifting to labeling a second, again, small business owners out there trying to do the best they can, and when they go through the labeling process, you know, they spend a lot of money. They have to hire a company to help navigate the process, and as they go through the FSIS, is there one point of contact for them?

Because it appears that you may go through the process a little bit and you hear from constituents, well, then they kicked me back, but I resubmitted, but then this person might have said something different was required, but this person had already previously approved.

In a business owner context in regards to labeling, do they have one person they are working with through the process from conception to completion when it comes to labeling?

Dr. HAGEN. Congressman, it is a pretty small staff, and our staff processed over 68,000 label applications in fiscal year 2011. So they are working pretty hard.

But labeling is one of those places where we really are always looking for process improvement. We know how important this is to businesses. So we are always looking for ways that we can cut down the amount of time that it takes, make things simpler for the Applicant, but while still protecting consumers and making sure that the information that they are getting is accurate.

So I certainly take your suggestion and will consider it seriously.

Mr. GRAVES. So it is possible that there are different expectations being made potentially if they are working with multiple folks, and maybe with that you could explain the process and what the average time is.

Dr. HAGEN. I think we certainly strive for consistency. Again, it is a pretty small staff, but you know, there will always be, I think, anecdotes where people might have found that they got inconsistent information.

I think if I can defer to Mr. Almanza, I think he wants to jump in on something here.

Mr. ALMANZA. Yes, the normal time for a label approval is ranging in the 23 days, and so what we are striving for is around 15, but we have a new electronic label approval system that will kick in in April that will help that process and hopefully capture some of the challenges.

Mr. GRAVES. So does it provide a template for individuals to work through? Because I imagine a lot of new business owners, proprietors, they do not know. So it gives them a tool to work with?

Mr. ALMANZA. Yes, yes.

Mr. GRAVES. Okay. Well, thank you for working with the small business owners.

Thank you, Mr. Chairman.

Mr. KINGSTON. Mr. Farr.

Mr. FARR. Thank you, Mr. Chairman. I will yield to Ms. DeLauro.

Ms. DELAURO. Thank you, Mr. Farr.

SINGLE FOOD SAFETY AGENCY

Let me say again to my colleague, Mr. Graves, as I said to Mrs. Lummis, I believe the goal should be a single independent food safety agency with someone who has a direct responsibility for food safety. As I mentioned, 15 agencies none of who end with regard to seafood. That is under Commerce and Fisheries, and a lot of varied interests in terms of trade and what is coming into the country with regard to seafood.

So I would love to talk to you about that and elicit your support for a single, independent food safety agency.

Thank you.

MECHANICALLY TENDERIZED BEEF LABELS

I was talking about the mechanically tenderized beef products. In 2008, the Journal of Food Protection noted that 94 percent of the beef processors surveyed used mechanical tenderization to improve their product quality. A number of studies have indicated that mechanical tenderization transferred foodborne pathogens from the surface of the meat product to the interior of the meat, yet there was no labeling, just the distinction between true whole meat cuts and those that had been mechanically tenderized, leaving customers to be both unaware and potentially at risk.

I am not making a comment on mechanically, you know, tenderizers, on that view, but I do believe that we have got another grilling season that is coming up. So I want to ask the agency when the agency is going to act to provide consumers with the information that they need. That is with regard to the preparation of the food and at what temperature you grill it. Because by the standards, you do a whole cut without this tenderized process at 145 degrees Fahrenheit, but when it has been tenderized at 160.

Now, once people know that, they need to take the responsibility for the safety of the product after that, but if we do not tell them that it is mechanically tenderized or that it has to be grilled at a certain temperature, then there are going to be risks.

So is the agency going to act to provide consumers with the information that they need to deal with safe preparation and cooking temperatures for these beef products before May, before October when people are getting involved in it?

Dr. HAGEN. Thank you for the question, Congresswoman. You know, I think we have had a huge push, a huge emphasis during our time together in this work on consumer information, consumer education, making sure that people have the tools that they need, empowering them to make good choices and to take the steps that they need.

We do believe that mechanically tenderized beef should be labeled for consumers, and in fact, we have some history with this. We tried to get this into the food code a number of years ago. We were unsuccessful in doing that, although we were able to produce guidance on it.

So we do believe that they should be labeled. This is important information for consumers to have. We are developing a proposed rule on this. I cannot give you an exact time frame as to when that proposal will be out.

Ms. DELAURO. As far as I know, you are right. Since 2009, there have been a number of exchanges on that. So are we talking about this year?

Dr. HAGEN. I cannot give you a guaranteed date, but it is definitely something that we are working on, and it is pretty high on our priority list.

I am hearing from my colleagues that we are hoping to have the proposal out by this summer.

Ms. DELAURO. Terrific. Thank you.

TRANS-PACIFIC PARTNERSHIP

I want to find out about FSIS' role in the negotiations of our free trade agreements, specifically FSIS' role in the current negotiations of the Trans-Pacific Partnership. Can you tell us a bit about who is overseeing the negotiation process related to food safety and when you are involved?

For example, is USTR leading the talks? How and when are you involved from the food safety point of view?

Do you believe that FSIS has the capacity and the resources to deal with increased imports that are likely to be generated by the TPP?

Do you believe that you will have the ability and the resources, for example, to enforce the comprehensive catfish inspection rule?

And in full disclosure, I will tell you I was opposed to catfish moving from FDA to USDA. I lost that fight, but you mentioned earlier and I asked about the resources because you mentioned earlier and I did not see funding for enforcement to implement the rule in the Fiscal Year 2013 request.

Catfish inspection was transitioned three and a half years ago, and we are just talking still about the definition.

REGULATORY COOPERATION COUNCIL

Can you also explain the substance and the status of the discussions involving FSIS and the Canadian Food Safety Authorities related to the Canada-U.S. Regulatory Cooperation Council? For example, will we be relaxing any food safety standards or procedures to facilitate trade between Canada and the United States?

Now, I know there are a bunch of questions. My time is out, and I am still hopeful that we will come back around again, Mr. Chairman.

Mr. KINGSTON. Mr. Nunnelee.

FUNDS FOR TRADE IMPEDIMENTS

Mr. NUNNELEE. Thank you, Mr. Chairman.

We talked about imports. I want to shift now and talk about exports. Exports are pretty important to Mississippi, particularly poultry exports. Your budget request is \$9 million less than the 2012 level. I commend you for that. You are moving in the right direction, but I want to make sure that with the resources you have requested that you are going to have the adequate level of funding and staffing to address any trade impediments that might exist.

Dr. HAGEN. Thank you for the question, Congressman.

You know, again, our focus really is on food safety, and at FSIS, we are not focused on market access and things like that. Our colleagues at the Foreign Agricultural Service do have that as their primary mission.

I feel that what we have put in the budget, what we have requested is adequate to meet all of our mission priorities and statutory mandates.

Mr. NUNNELEE. Thank you.

I think that is all I have got, Mr. Chairman.

Mr. KINGSTON. A lot about catfish today for you just to be yielding back, but I do not think anybody is going to complain.

CATFISH RULE

Mr. NUNNELEE. Well, the main thing I heard about catfish is that a mandate that the U.S. Congress had in 2008 to get done in 18 months if we are lucky may get done by 2013. I am from Mississippi, but in my math that does not add up, but we are going to still be——

Ms. DELAURO. Would the gentleman from Mississippi yield for a second?

Mr. NUNNELEE. Why sure.

Ms. DELAURO. I would just for a second. I tried to persuade my colleagues on both sides of the aisle, from Mississippi, Alabama, and other folks, that this probably was not the right move, that we should have kept this rule at the FDA. So I sympathize with your concern.

Mr. NUNNELEE. Well, I just thought that somebody read in the code and saw where it said 18 months, and they thought it really meant 18 years.

Mr. KINGSTON. How many species of catfish are you considering to be catfish?

Dr. HAGEN. Mr. Chairman, I believe that when we got into the analysis of this, there are perhaps 39 different species, although that may be——

Mr. KINGSTON. Thirty-nine suspects.

Dr. HAGEN. Yes. So that debate still continues, and we really have not. As you know, the law provided for the Secretary to define what catfish would be, and when we proposed the rule, that was one of the things that we wanted to take comment on, and that is one of the things that will be in the final rule.

Mr. KINGSTON. How many of those are domestic and how many of those are foreign?

Dr. HAGEN. I am sorry. I do not have the answer for your today, but I am happy to——

Mr. KINGSTON. I would be interested in that.

And do you remember the scientific name for them? I remember that——

Dr. HAGEN. We will begin reciting them now. [Laughter.]

Mr. KINGSTON. It took me five days to learn to pronounce it. Now I am blanking out. Do you remember?

[The information follows:]

In the taxonomy of fish, the order Siluriformes (common name “catfish”) consists of 36 different families. Among these families are Ictaluridae, which includes North American channel and blue catfish, the principal U.S. farm-raised species; and Pangasiidae, which includes basa, tra, and swai, commonly raised in Southeast Asia. According to data from the National Marine Fisheries Service and the National Agricultural Statistics Service, about 203 million pounds of Siluriformes were imported into the United States in 2011 (of which about 7.5 million were Ictaluridae and the remainder mostly Pangasiidae); and approximately 167 million pounds of Ictaluridae were produced domestically.

Ms. DeLauro.

Ms. DELAURO. Thank you, Mr. Chairman.

TRANS-PACIFIC PARTNERSHIP NEGOTIATIONS

Let me just quickly, this is on the trade. FSIS’ role in the current negotiations of the Trans-Pacific Partnership; who is overseeing the negotiation process related to food safety, and when are you involved?

Does FSIS have the capacity, resources to deal with the increased imports that are likely to be generated by TPP?

And in that regard, there is no line in the budget with regard to enforcement on implementation of the catfish rule.

And will there be any relaxing of food safety standards or procedures to facilitate trade between Canada and the U.S.?

Dr. HAGEN. Thank you, Congresswoman.

I will try to handle them in the order that I remember them. USTR is leading the effort on the Trans-Pacific Partnership. FSIS does have the opportunity to have substantive input into that. I am not personally currently involved in those negotiations.

Ms. DELAURO. Is there anyone from your staff involved?

Dr. HAGEN. From our Policy Office, our international policy team.

Okay. So moving on, I am sorry. I have forgotten what the next set of questions were.

Ms. DELAURO. Resources——

Dr. HAGEN. For catfish?

Ms. DELAURO. Well, the capacity to deal with increased imports that are going to result from the TPP.

Dr. HAGEN. Well, that is one of the things that we are going to have to look at and to make sure that we can handle them and to make sure that we can still insure food safety.

Ms. DELAURO. Is there anything, in terms of your budget, et cetera, that reflects, you know, this agreement? It does not at the moment with regard to catfish and to be able to enforce that; is that right?

Dr. HAGEN. We do not specifically ask for anything in regards to the Trans-Pacific Partnership. We do anticipate spending around \$800,000 on the catfish program in fiscal year 2013, although that may not be laid out specifically within the budget. It is about the same amount that we plan to spend during this fiscal year.

Ms. DELAURO. Will we be relaxing any food safety standards or procedures to facilitate trade between Canada and the U.S.?

Dr. HAGEN. We will not be relaxing any food safety standards. There is interest in pilot programs, for instance, when it comes to re-inspection of product. So we have agreed to a limited scale pilot program that is truly a pilot program to see how something like this would work, but we know how important it is that the products coming into this country are just as safe as the products that are produced here in the United States. So we do not have any intention to relax food safety standards in relation to either the Beyond the Border or the Regulatory Cooperation Council, RCC, whatever it is called.

Ms. DELAURO. Just a quick question on your role in the negotiations. I just want to know what the nature of that role is. USTR is driving the negotiation. What kind of, if you will, acceptance, rejection of process; what level of input are you having in this process?

And do you have any veto power in anything that they have come up with? If it is in your mind that this is something that would jeopardize food safety, do you have any veto power?

Dr. HAGEN. Well, if there are issues, such as sanitary measures, that come up during these negotiations, then we are present at those meetings, and we are able to provide our input, but as far as more specifics, I think it is probably best if I get you some more detailed information for the record because I can tell that you want more detailed information.

[The information follows:]

As a member of United States Trade Representative's (USTR) Sanitary Phyto-sanitary (SPS) issues team, FSIS actively engages in any trade negotiations involving the products FSIS regulates. FSIS routinely attends USTR led inter-agency meetings and discussions on proposed text, and also has a physical presence at the many actual negotiation sessions. The Agency regularly provides comments, guidance, and feedback to USTR on proposed text in advance of and during negotiation sessions on issues of particular interest to FSIS in order to ensure food safety issues are addressed in a manner consistent with U.S. laws and FSIS policies.

Ms. DELAURO. No, I truly do because what happens when these trade agreements are completed, when we begin to look at what the imports are and the potential nature of difficulty here and we have a treaty, then the individual countries can go to the WTO. If we try to change what we are doing, then they go to the WTO and say that we are now dealing with protectionism, et cetera, when what we need to do is at the front end of these agreements lay out and instead of trade being the byword here, and trade is important, but in terms of, you know, our obligation to protect the public health in the United States.

So I really do want to know very specifically about your role in what is happening with this treaty which is coming up very soon and there is a big push to move forward on it.

I have one last question. Well, I actually do not. I have two questions, but my time. Do you want to move forward?

Mr. KINGSTON. You have ten seconds.

Ms. DELAURO. Thank you so much. I appreciate that.

PHIS IMPLEMENTATION

This is on the Public Health Information System. I continue to hear that inspectors are still encountering problems with the new system. Can you lay out for us what those problems are?

How have inspection assignments been altered because of the data captured by PHIS?

Dr. HAGEN. Thank you for the question.

I am going to go ahead and give you sort of a top line answer and then ask Mr. Almanza to walk us through some of the details.

As I alluded to in my testimony, this is a big undertaking, and we have encountered some real challenges with implementation, and we listened to the feedback. We listened to what we were hearing. Al and I have been out all over the country doing town halls, talking to our inspectors, and we listen to what we are hearing.

So at one point during this summer, Mr. Almanza decided to put things on hold and put a team in charge of fixing what was wrong and really a task force being out there, being very responsive to the inspection force and the concerns that we were hearing, and there were a couple of key areas that seemed to be coming up over and over again.

So we put a lot of emphasis on being responsive and on getting this thing right and on slowing it down if we had to in order to get it right because it does impact the work that we do, and it certainly impacts the daily lives of our inspectors.

So I think if I can have Mr. Almanza walk us through a little bit more about specifically what has happened.

Mr. ALMANZA. Yes. Well, PHIS was an enormous challenge and one that I, not being an IT type person, as you can understand, you kind of think, well, this is certainly something that is going to be beneficial to our inspection workforce, and I have to tell you having worked in the field and having gone through that data mining trying to get stuff, and some of the data that you all request is very labor intensive, and so when PHIS was presented as an idea, I thought this is exactly what our field needs because it is real time data that they will be able to act on and be proactive, and I think that, that is what you all want. You all want us to be proactive rather than reactive.

So as our inspection workforce is performing tasks on a daily basis, taking samples for O157:H7, for Salmonella, for Listeria monocytogenes—LM, and having that data available to them as they are gathering it—

Ms. DELAURO. What are some of the problems? That is what I want to try to get at so we can help you with this. What are some of the problems?

Mr. ALMANZA. Okay. Well, some of the problems have been connectivity problems, and so we are addressing those, having our IT people go out and sit in some of the town hall meetings with us.

The other one was the scheduling of tasks. Some of our inspectors were saying it takes too much time. It is taking us four, five, six hours because they kept getting knocked off the system.

Ms. DELAURO. Okay. System, so it is system related.

Mr. ALMANZA. Yes, and so those are things that we are dealing with and trying to mitigate those by bringing on different softwares that will address some of those issues.

But I have to tell you compared to the number of complaints that we were getting at the beginning, they have really, really tapered off.

Ms. DELAURO. Have inspection assignments been altered because of the data?

Mr. ALMANZA. Inspection?

Ms. DELAURO. Tasks?

Mr. ALMANZA. Well, one of the things that we are doing is, you know, when they would schedule their own task, well, now they are going to have an option of having some of the tasks laid out for them so that they can opt for using a template, if you will, so that they do not have to generate all of those tasks for themselves.

Ms. DELAURO. I understand sifting out the bugs. What is your time frame? I do not want you to make a guess. I want to know when this process is going to be in order because it is risk based, and it is based on this data.

Mr. ALMANZA. Right. I hope to have all of the kinks and the bugs out of it by the end of this calendar year.

Ms. DELAURO. End of this calendar year. Okay. Thank you.

LINE SPEED ANALYSIS

Is that ten seconds?

Mr. KINGSTON. That was five.

Ms. DELAURO. Okay. HIMP, and this is a truly last question. Has the agency considered requiring poultry plants that transition to HIMP model to participate in the NIOSH study related to line speed? If not, why not?

How will you work to insure industry participation in the study so that it is a valid study?

It sounds like you are going to move ahead in implementing this rule without waiting for results of the NIOSH study, and so how will you integrate those findings?

Are you going to require poultry plants to participate in the study?

Dr. HAGEN. We are not going to require that. We do require that any plants that want to join the Salmonella Improvement Project—SIP—expansion participate in the NIOSH study. They are in the process of finalizing their questionnaire and getting ready to go into the first plant. We will be working with them throughout the study, not just at the end of the study, and if there are adjustments that need to be made because of the data that comes out of that study, we have the ability to make those adjustments in an interim or a final rule.

Mr. KINGSTON. Mr. Farr.

PAY COSTS

Mr. FARR. In your budget, you point out that you are requesting to realign \$2.9 million, almost \$3 million from agency programs to fund the .5 percent pay increase, and then you point out that you are going to offset these reductions with cuts in food safety, cuts

in State food safety and cuts in international food safety and some from Codex Alimentarius. There is no other information on this.

Can you give us exactly how those cuts to each one of those programs is going to be implemented?

Dr. HAGEN. I can certainly give you more exact data in a written response for the record.

Mr. FARR. Yes.

Dr. HAGEN. But if we need to do that, we are just going to have to find the money within the program dollars that we have now. I will say that the agency over the last couple of years has developed a really impressive governance process for dealing with really every financial decision we make, every policy decision that we make.

So we have a process for looking at what are high priority, mid-priority, and low-priority unfunded mandates and unfunded requests, and it would go through a process like that, and that is how we arrived at that kind of an answer.

We still do not know whether that is something that we will need to be able to do, but we would be happy to give you some more detailed information about that if you would like.

Mr. FARR. Yes, I think we would like to have that. I mean, we have to authorize this transfer.

Dr. HAGEN. Right.

Mr. FARR. We would like to know what the impacts are going to be.

Dr. HAGEN. That is why we wanted to be up front about it.

[The information follows:]

We had to fund the pay raise out of our existing funding level for all accounts which is why you say the decreases in several funding lines. Funding for the pay raise would primarily come from not filling vacancies. However we will continue to ensure that we uphold our commitment to protect the public health.

Mr. FARR. Thank you. I have no further questions.

Mr. KINGSTON. Mr. Nunnelee.

FSIS USER FEES

Mr. NUNNELEE. Thank you, Mr. Chairman.

I did run across one other question. It looks like your budget proposes establishing some type of food safety user fee. Is this just another way to supplant a cut in appropriated funds?

Dr. HAGEN. There are two components to the user fees, Congressman, that we put up, and I think one of them is very easy for people to understand, and that is what we would call sort of a performance based user fee. When bad things happen and when, you know, holes happen in the food safety system and consumers are impacted so that we have a large outbreak, we have a recall, those are taxpayer dollars that are used to pay for, you know, extra time in the plants, extra sampling, food safety assessments. That all comes out of the taxpayer's wallet, and I do not think that that is right.

So this kind of performance based user fee, I think, is something that is easy for most people to understand. The other component of the user fees that we put up have to do with everything outside of that basic statutory mandate, which is inspection, eight hours per day that you get under the law.

So you know, in 2012, the work that we do requires a lot of other support, so risk assessments, things like this that support the work of inspection. So I do not think it is just asking for a supplement or trying to make up for a loss in appropriated funds. I believe that there is a real purpose behind this.

Mr. NUNNELEE. So do you have a plan in place to decide which items are going to be chargeable and which will not be chargeable, particularly on the second phase that you talked about?

Dr. HAGEN. There is a legislative proposal being developed on all of this, and I am not sure of the timing of when that might make its way up here to the Hill, but those kind of things will be detailed.

Mr. NUNNELEE. And then my final concern would be impact that any of these user fees might have on smaller producers. So I will ask you to keep that in mind and take that into account.

Dr. HAGEN. We will certainly keep that in mind, sir.

Mr. NUNNELEE. Thank you.

Mr. KINGSTON. Thank you, Mr. Nunnelee.

Ms. DeLauro.

HIMP RISK ASSESSMENT

Ms. DELAURO. I just have one question, and we can be in touch. I really am concerned on this transition to HIMP and the line speed without getting some sense of what this means in terms of actually because the description from some of the inspectors already looking at what is happening or not happening, and I can get that to you about what they are finding with fecal matter, and this is prior to going to the chiller, what they are finding in the feather process, bile, et cetera. It is pretty gross, but that is what is being found in terms of those measures that have been set up, in terms of the criteria, a couple of food safety criteria, and then there are other concerns. This is really fairly explicit of what they are finding.

So I understand moving from just a visual piece of this, but when you are moving from was it either 75 or 90 chickens up to 175 per minute, and I know there is flexibility in the inspectors and now they can go up and down, you are not seeing what is there at that rate.

I also think worker safety is involved in that, and then I see nowhere else how we are dealing with microbiologically looking at where contamination might occur. There are some pieces, and so without some sort of study or the integration of that study in the plants who want to opt for this 175 chickens per minute, that they do not have to be part of a study, it seems to me that we are not providing the best effort in terms of safety, the overall food safety.

So I will get more explicit and write that up and let you know because I need the answers to those questions.

FSIS AND TRADE NEGOTIATIONS

And I would just say one final thing. I want you at the table in those trade negotiations. I will just tell you because you are dealing with food safety, and oftentimes and my colleagues have heard me say this, it is trade that trumps safety. We need you at that table,

and I am going to fight for FSIS to be at that table on those trade agreements.

Mr. KINGSTON. I have no further questions. Do you, Mr. Farr?

Mr. FARR. I have no further question, Mr. Chairman.

Mr. KINGSTON. With that, Dr. Hagen, we stand adjourned, and we thank you and we will look forward to getting a follow-up from you on some of these questions, and some will be submitted also. So it is good to see you again.

Dr. HAGEN. Thanks.

Mr. KINGSTON. Do not be a stranger on the Hill, either one of you all.

Dr. HAGEN. Thanks for having us.

Mr. KINGSTON. We stand adjourned.

CHAIRMAN JACK KINGSTON
QUESTIONS FOR THE RECORD
USDA FOOD SAFETY AND INSPECTION SERVICE FISCAL YEAR 2013 BUDGET REQUEST
MARCH 8, 2012

OIG/GAO REPORTS

Mr. Kingston: Provide for the Committee the OIG/GAO recommendations, and the current status of the open recommendations that were included in these OIG/GAO reports:

Report No. 24601-8-AT, Food Safety and Inspection Service In-Commerce Surveillance Program;
Report No. 24601-6-AT, Food Emergency Response Network;
Report No. 24601-9-KC, FSIS Sampling Protocol for Testing Beef Trim for E. coli O157:H7
GAO-11-801, Antibiotic Resistance Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals; and
GAO-11-376, School Meal Programs

Response: Provided below are the recommendations made in OIG and GAO reports relevant to USDA's Food Safety and Inspection Service (FSIS), as well as the current status of each recommendation.

1. Report No. 24601-8-AT, Food Safety and Inspection Service In-Commerce Surveillance Program;

Recommendation 1: Develop and implement a selection methodology for in-commerce surveillance reviews that prioritizes risk considerations among and within risk tiers.

Current Status: FSIS expects to close this recommendation within six months with issuance of a revised in-commerce surveillance directive; all other requirements necessary to close these recommendations are complete.

Recommendation 2: Enhance and implement a better search capability in the In-Commerce System (ICS) or develop additional guidance for investigators on how to identify irregular records and to eliminate duplicate entries in ICS. We also recommend that FSIS formalize its guidance for documenting firms that need to be deleted from ICS or marked as inactive.

Current Status: FSIS expects to close this recommendation within six months with issuance of a revised in-commerce surveillance directive; all other requirements necessary to close these recommendations are complete.

2. Report No. 24601-6-AT, Food Emergency Response Network;

Recommendation 1: Through discussions with senior management at FDA, draft and propose an updated charter and memorandum of understanding that include a clear strategy for how the two agencies are to work together to accomplish FERN's mission. Formalize the charter and memorandum of understanding when agreements are reached on the draft proposals.

Current Status: Implemented. A closure request and supporting materials are under Department review.

Recommendation 2: Through discussions with senior FERN management at FDA, draft and propose standard operating procedures for all of the network's critical functions. Formalize and implement the standard operating procedures when agreements are reached on the draft proposals.

Current Status: FSIS on track to meet original estimated completion date. A closure request with supporting materials is being compiled to submit to the Department in late March.

Recommendation 3: Evaluate and rank non-CAP laboratories in terms of their importance (e.g., testing capability and capacity), reliability (e.g., demonstrated performance), and other factors relevant to FERN's effective operation.

Current Status: FSIS is on track to meet original estimated completion date. A closure request with supporting materials is being compiled to submit to the Department in late March.

Recommendation 4: Develop tiers based on rankings determined in response to Recommendation 3 and develop guidance for activating non-CAP laboratories during an emergency.

Current Status: FSIS is on track to meet original estimated completion date. A closure request with supporting materials is being compiled to submit to the Department in late March.

3. Report No. 24601-9-KC, FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7

Recommendation 1: Develop a plan with specific timeframes and milestones to prioritize and perform necessary baseline studies of beef trim and ground beef in order to determine the estimated prevalence rate of *E. coli* O157:H7 for redesigning FSIS' sampling program. The plan should include how often the prevalence should be reassessed.

Current Status: A draft of the Federal Register Notice that would close this item is under Departmental review.

Recommendation 2: Re-evaluate its sample parameters (size and confidence level) and redesign a sampling program for *E. coli* O157:H7 in beef trim that provides higher confidence in FSIS accurately detecting contaminated product in order to effectively verify process controls at beef processing plants across the nation.

Current Status: A draft of the Federal Register Notice that would close this item is under Departmental review.

Recommendation 3: Thoroughly document the scientific support and rationale for FSIS' revised *E. coli* O157:H7 sampling program design, including the contamination level that will be associated with the new sample parameters and how the estimated prevalence rate impacts the new design. Publish FSIS' revised *E. coli* O157:H7 sampling design with its support and rationale for public comment, and consider any recommended changes before implementing the new sampling program.

Current Status: A draft of the Federal Register Notice that would close this item is under Departmental review.

Recommendation 4: Develop a detailed operational plan with specific timeframes and milestones to implement an inspection system that focuses *E. coli* O157:H7 sampling and testing resources primarily at plants that are likely to be of higher risk, and consider the use of specialized sample collection teams.

Current Status: A Federal Register Notice that would close this item is under Departmental review.

4. GAO-11-801. Antibiotic Resistance Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals;

Recommendation: To enhance surveillance of antibiotic-resistant bacteria in food animals, we recommend that the Secretaries of Agriculture and Health and Human Services direct agencies to modify the National Antimicrobial Resistance Monitoring System sampling, consistent with their existing authorities, to make the data more representative of antibiotic resistance in food animals and retail meat throughout the United States.

Current Status: No final decisions have been made regarding making changes to the FSIS *Salmonella* verification program which currently submits isolates to NARMS for resistance testing. FSIS and FDA are still evaluating various options for changes to the program.

Note: This GAO report contained six recommendations, three of which were directed at HHS. The remaining three recommendations were all directed at various USDA agencies, and only one was applicable to FSIS.

5. GAO-11-376, School Meal Programs.

This report contained no recommendations directed at FSIS. The Food and Nutrition Service took the lead in responding to the GAO report and coordinating corrective actions with various other USDA agencies.

OFFICE COSTS

Mr. Kingston: Provide the FY 2011 actual, and FY 2012 and FY 2013 estimated costs for each of the following offices: Headquarters; 15 district offices; Policy Development Division; 3 laboratories; Financial Processing Center; and the Human Resources Field Office.

Response: The actual costs in FY 2011 and the estimated costs for FY 2012 and FY 2013 are as follows:

	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>
	<u>Actual</u>	<u>Estimated</u>	<u>Estimated</u>
Headquarters	\$111,551,156	\$111,551,000	\$111,551,000
15 District Offices	19,793,856	19,794,000	19,998,000
Policy Development			
Division	3,116,966	3,117,000	3,117,000
3 Laboratories	27,426,315	27,426,000	27,426,000
Financial Processing			
Center	2,277,750	2,278,000	2,278,000
Human Resources Field			
Office	<u>6,116,537</u>	<u>6,117,000</u>	<u>6,117,000</u>

Total	<u>170,282,580</u>	<u>170,283,000</u>	<u>170,487,000</u>
-------	--------------------	--------------------	--------------------

UNFILLED POSITIONS

Mr. Kingston: How many unfilled positions did FSIS have at the end of fiscal year 2011?

Response: FSIS has 173 unfilled positions.

Mr. Kingston: Where are these positions located?

Response: Twenty-four of these positions are in Washington, DC, and 149 of them are in the field.

Mr. Kingston: Does FSIS have a plan to fill these positions?

Response: Yes, FSIS expects to fill these positions.

FSIS MOTOR VEHICLE FLEET

Mr. Kingston: Last year, the FSIS budget justification display on motor vehicles estimated that the annual operating cost for its vehicle fleet was \$13.8 million and 1,946 vehicles for fiscal year 2012, but according to the fiscal year 2013 budget justification the cost was \$12.8 million, and 2,072 vehicles. What is the explanation for the change?

Response: The increase in number of GSA vehicles is due to high-mileage inspection program personnel who previously used POVs now requesting GSA vehicles because the General Services Administration's (GSA) reduced Personally Owned Vehicle (POV) mileage reimbursement from 28.5 cents per mile to 19 cents per mile. Roving inspectors are requesting GSA vehicles instead of using their POVs and getting mileage reimbursement.

Mr. Kingston: How was the FSIS able to procure more vehicles than estimated at a significantly lower cost?

Response: FSIS replaced their vehicles with smaller, subcompact sedans that cost less to lease.

Mr. Kingston: According to the fiscal year 2013 budget justifications the FSIS is projected to spend \$13.9 million on its vehicle fleet of 2,147 in fiscal year 2013. What is the reason for adding 175 new vehicles between FY 2011 and FY 2013?

Response: More employees are requesting GSA vehicles versus using POVs due to reduced mileage reimbursement per GSA.

Mr. Kingston: How much of the increased cost to operate this fleet is due to the higher cost of alternative fuel vehicles?

Response: None, because we have not increased the number of alternative fuel vehicles.

Mr. Kingston: What is the cost to lease an alternative fuel vehicle versus the cost of a traditional vehicle?

Response: For FY 2012, the cost to lease an alternative fuel vehicle is \$174 per month and 15 cents per mile versus gasoline fuel vehicles, which cost \$163 per month and 13.5 cents per mile (subcompact that meets the requirements of Section 141 of the Energy Independence and Security Act).

Mr. Kingston: How many alternative fuel vehicles are in the fleet?

Response: As of March 8, 2012, there are 928 alternative fuel vehicles in the FSIS Fleet.

Mr. Kingston: What is the total cost of the alternative fuel vehicles in the fleet?

Response: The cost of leasing alternative fuel vehicles for FY 2011 was \$4.7 million.

Mr. Kingston: How many gasoline fuel vehicles are in the fleet?

Response: As of March 8, 2012, the FSIS Fleet includes 1,119 gasoline vehicles.

Mr. Kingston: What is the cost of the gasoline fuel vehicles in the fleet?

Response: The cost of leasing gasoline fuel vehicles for FY 2011 was \$6.4 million.

Mr. Kingston: How much of the \$1.2 million increase is due to the increase in the size of the fleet?

Response: Approximately \$800,000 of the increase from FY 2012 to FY 2013 would be for increasing the size of the fleet. The remaining \$400,000 is for the anticipated increase in the cost of leasing GSA vehicles.

Mr. Kingston: How does the agency dispose of vehicles?

Response: FSIS leases their vehicles from GSA. GSA has set criteria for the replacement of their vehicles. When the criteria are met, GSA will order a new vehicle and the older vehicle is returned to GSA in exchange for the newer one. Should a vehicle no longer meet the Agency's needs, it is returned to GSA, and re-assigned to another Agency.

Mr. Kingston: Specifically, how much of the vehicle cost increase is due to the reduced use of privately owned vehicles by roving inspectors?

Response: Since the GSA POV reimbursement rate was decreased in January 2011, we estimate that 276 inspectors switched from using POVs to using GSA vehicles. The estimated annual lease cost of these vehicles is \$1.2 million.

PUBLIC HEALTH INFORMATION SYSTEM (PHIS)

Mr. Kingston: Provide the Committee with a current update of the PHIS. What is the status of the implementation?

Response: FSIS launched PHIS in the spring of 2011, following months of hands-on training in the field. Since the launch, we uploaded important data to PHIS, streamlined the way that data is stored and organized to increase the speed of the system, launched a disconnected version of PHIS for inspection personnel to use when internet connection is unavailable, and transitioned to electronic sampling. We are also vigorously working to find solutions to establish solid internet connectivity for employees stationed at establishments in rural areas. At the same time, we are making constant improvements to the disconnected version of PHIS so that it works effectively for employees in these areas.

In January 2012, FSIS completed implementation of PHIS' domestic component to its employees in the field and is now working on the launch of the import component of the system due to be released May 29. The Agency also recently completed a six-week pilot of PHIS to approximately 18 industry users, to test PHIS' industry functionalities.

Mr. Kingston: How much did FSIS spend on PHIS in fiscal year 2011, and what are the estimates for fiscal years 2012 and 2013?

Response: FSIS spent \$7.3M in FY 2011 and expects to spend \$4.1 million in FY 2012 and \$3.5 million in FY 2013 on developing PHIS.

Mr. Kingston: Provide the Committee with an update on the expansion of the Performance Based Inspection System.

Response: FSIS is not expanding the Performance Based Inspection System (PBIS). PBIS is a legacy system that has been replaced by PHIS.

Mr. Kingston: Why is FSIS expanding a legacy system while implementing PHIS?

Response: FSIS is not expanding PBIS. PBIS is in operation and maintenance mode only and the system will be shut down once all required PBIS functionality is migrated into other FSIS systems, primarily PHIS.

Mr. Kingston: When will FSIS complete training of all field employees about PHIS?

Response: FSIS completed PHIS domestic component training for field employees on February 16, 2012.

Mr. Kingston: Is the domestic phase of PHIS fully implemented?

Response: Yes, FSIS completed implementation of PHIS' domestic component to its employees in the field in January 2012.

Mr. Kingston: What is the timeline for FSIS to rollout PHIS to State Programs and Importers?

Response: FSIS expects to launch PHIS to importers May 29, 2012. As for state programs, FSIS will begin a rolling implementation in September 2012, with the expectation of having a full implementation completed by the end of the calendar year.

PUBLIC HEALTH DATA COMMUNICATION INFRASTRUCTURE (PHDCI)

Mr. Kingston: FSIS has completed approximately 642 broadband connections for field locations. How many FSIS personnel do these 642 connections cover?

Response: The 642 broadband connections cover approximately 1,600 employees in the field.

Mr. Kingston: What is the significance of providing Evolution Data Optimized cards for second shift inspectors and in-plant inspection program personnel working in federally inspected establishments?

Response: In processing plants, first and second shifts of FSIS inspection program personnel may differ in their makeup. Evolution Data Optimized cards are provided to second shift personnel in a single-inspector assignment when the day shift inspector has only one plant, but the night shift inspector has multiple plants. This allows the second shift personnel

to plan appropriately as their assignment coverage can vary from plant to plant.

Mr. Kingston: What was the cost for PHDCI in fiscal year 2011, and what are the estimates for fiscal years 2012 and 2013?

Response: FSIS had \$26.158 million in FY 2011 and estimates \$34.58 million in FY 2012 and \$34.58 million in FY 2013 for Public Health Data Communication Infrastructure.

STUDENT LOAN REPAYMENTS

Mr. Kingston: How much did FSIS spend to grant 85 student loan repayments?

Response: For FY 2011, FSIS funded 85 student loan repayment incentives at a cost of \$895,878.

Mr. Kingston: How much do you plan to spend in fiscal years 2012 and 2013?

Response: For FY 2012, FSIS will fund 25 Student Loan Repayment incentives at a cost of \$264,125. These were all final payments on multi-year incentive commitments. No new commitments have been or will be made for FY 2012. For 2013, the Agency will not fund any incentives.

FSIS RECALLS

Mr. Kingston: Provide the Committee with an update on FSIS recalls that were conducted in 2011.

Response: During calendar year 2011, FSIS oversaw 103 recalls. Of those recalls, 40 were due to undeclared allergens; 13 were due to possible *E. coli* O157:H7 contamination; 11 were associated with *Listeria monocytogenes*; 10 were associated with *Salmonella*; 5 due to extraneous material; and 24 were because of other issues, such as mislabeling and product in commerce without the benefit of inspection. For more information on recalls of FSIS-regulated products, visit:
http://www.fsis.usda.gov/Fsis_Recalls/.

ASSURANCE NET/IN-COMMERCE SYSTEM (ICS)

Mr. Kingston: According to the justifications, FSIS implemented nearly 150 enhancements to ICS. Provide the Committee with the details of those enhancements. Also, provide the details of the new risk-tier structure for in-commerce businesses. How does this improve FSIS' ability to protect the public health and improve food safety?

Response: In FY 2011, FSIS implemented enhancements to the ICS System. The enhancements included changes to improve system functionality, management controls, and reporting for FSIS and State investigators. A substantial component of the enhancements included new requirements to provide the system capacity for State meat and poultry inspection program investigators, compliance officers, and supervisors to gain access to and use the ICS system, providing similar functionality to FSIS investigators, as well as the

ability to refer investigations to and share information between FSIS and State programs.

Other enhancements included those to improve the use of ICS for supervisory oversight of field personnel through the in-plant and out-of-plant performance systems, to provide additional system access and functionality to import surveillance liaison officers, and to realign the Agency's field investigative team from five to four regions to reduce supervision and improve program execution. The updates also included development of new user guides, system instructions, and computer-based training.

Another central component of the enhancements included reclassification of the ICS business tier system, based on input from the National Academies of Science (NAS), to enhance FSIS surveillance of in-commerce firms and better allocation of limited surveillance resources to firms based on food safety and public health risk criteria. Substantial enhancements were made to system functions and data fields to improve execution of FSIS mission across multiple program areas, including for administrative enforcement reports, investigations, evidence documentation, enforcement activities, case management, confidentiality of investigation and enforcement data, and foreign inspection equivalency determinations.

This new public health risk-tier structure, recommended by NAS, was also implemented in FY 2011. In 2009, NAS reviewed the risk criteria that FSIS used to classify 13 in-commerce business types into several risk tiers, and concluded that surveillance by other authorities may be the primary risk consideration. NAS consequently recommended that FSIS devote most of its not-for-cause surveillance resources to the several business types where FSIS effectively has "sole jurisdiction" in order to maximize the effectiveness of our public health efforts. Our resulting new tier structure placed just three business types (warehouses, distributors, and transporters) into Tier 1, left a few business types in Tier 2, and moved all others into a "for cause" Tier 3. Those Tier 1 businesses types that FSIS believes offer the greatest potential for public health protection by our surveillance activities are targeted to receive approximately 85 percent of our not-for-cause surveillance efforts.

RISK ASSESSMENT

Mr. Kingston: Provide the Committee with the details on the 15 risk assessments that FSIS completed in 2011, the 8 risk assessments that were updated, and the 8 risk assessments that FSIS initiated.

Response: In FY 2011, FSIS led the development of 15 risk assessments and related analyses, eight of which are new. The new analyses include:

- A risk assessment to evaluate the public health risks associated with industry controls for *E. coli* O157 during beef slaughter, designed to inform FSIS policies to incentivize industry adoption of more stringent pre- and post-evisceration food safety measures, and to guide the allocation of FSIS inspection resources among beef slaughter establishments;
- A risk assessment to evaluate the effectiveness of beef slaughter interventions in mitigating human cases of salmonellosis in the United States (an expansion of the aforementioned *E. coli* O157 beef slaughter

risk assessment that considers the broader public health benefits of mitigations addressing more than one pathogen in a food product);

- A risk assessment called "Estimating Changes in Public Health Following Implementation of Hazard Analysis and Critical Control Point in the United States Broiler Slaughter Industry" which evaluates the effectiveness of FSIS policies in combating salmonellosis from broilers in the United States (<http://online.liebertpub.com/doi/pdf/10.1089/fpd.2011.0951>);
- An overall approach to conducting rapid risk evaluations during food safety emergencies by utilizing farm-to-table exposure data from prior food safety emergencies;
- Risk-based sampling approaches to threat agents, including establishment of the level of detection needed, to inform Food Emergency Response Network activities during food-related emergencies;
- Two risk assessment models - one for *Listeria monocytogenes* in ready-to-eat meat and poultry products, and another for *Salmonella* and *Campylobacter* in poultry, respectively - that link performance objectives and microbial criteria to specific public health outcomes, according to the Codex Alimentarius Commission's risk management metrics;
- A risk assessment intended to establish "levels of concern" for environmental contaminants in FSIS-regulated foods for the purposes of decision-making during emergencies, and for presentation to FDA as a case study for addressing chemical residues without tolerance limits.

FSIS revised another seven analyses in response to independent, regulatory review; public comments; or scientific data garnered by FSIS, including:

- A "Draft Risk Profile for Pathogenic Non-O157 Shiga-toxin Producing *E. coli* (STEC)" (http://www.fsis.usda.gov/PDF/Non_O157_STEC_Risk_Profile.pdf), which provided the scientific basis for FSIS' decision to declare that six non-O157 STEC serotypes are adulterants;
- Two risk assessments - one on salmonellosis and the other on campylobacteriosis associated with the consumption of chicken and turkey - that estimate the public health benefits of the proposed rule on "Modernization of Poultry Slaughter Inspection";
- A "Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish" (http://www.fsis.usda.gov/PDF/Catfish_Risk_Assess_Dec2010.pdf), which focused on exposure to *Salmonella*;
- A "Draft Comparative Risk Assessment of *E. coli* O157:H7 for Intact and Non-intact Beef," which informed FSIS' draft proposed rule on the "Descriptive Designation for Needle or Blade Tenderized (Mechanically Tenderized) Beef Products."
- The model for the "Interagency Retail *Listeria monocytogenes* Risk Assessment," which will further inform FSIS retail policy strategy; and
- A "Risk Assessment for Guidance of Generic *E. coli*, *Salmonella* and *Campylobacter* Performance Standards," which provided the basis for sanitation performance standard options for chicken and turkey in the proposed rule on "Modernization of Poultry Slaughter Inspection."

COUNTRIES ELIGIBLE TO EXPORT

Mr. Kingston: Provide a list, for the record, of the 34 countries that were eligible to export FSIS regulated products to the U.S. throughout 2011.

Response: The following 34 countries are eligible to export one or more FSIS-regulated products to the United States. A detailed list, containing information on the types of products that these 34 countries are eligible to export, can be found on FSIS' website at:
http://www.fsis.usda.gov/pdf/Countries_Products_Eligible_for_Export.pdf.

1. Argentina
2. Australia
3. Austria
4. Belgium
5. Brazil
6. Canada
7. Chile
8. China*
9. Costa Rica
10. Croatia
11. Czech Republic*
12. Denmark
13. Finland
14. France
15. Germany
16. Great Britain
17. Honduras
18. Hungary
19. Iceland
20. Ireland
21. Israel
22. Italy
23. Japan
24. Mexico
25. Netherlands
26. New Zealand
27. Nicaragua
28. Northern Ireland
29. Poland
30. Romania*
31. San Marino
32. Spain
33. Sweden
34. Uruguay

* The eligibility of each of these three countries has been suspended, pending equivalence re-verification, for all of the FSIS-regulated products that they are eligible to export. Thus, they cannot currently export FSIS-regulated products to the United States.

STRATEGIC PLAN - SALMONELLA

Mr. Kingston: According to the information in the plan, Salmonella is the leading known cause of bacterial foodborne illness in the U.S. causing an estimated 1.3 million illnesses, and somewhere between 400-500 deaths. According to the Strategic Plan, the FY 2011 food safety priority goal seeks a 4.5 percent reduction in the rate of Salmonella illnesses from FSIS regulated products between the 2007-2009 average baseline and the end of FY 2011. Based on this year plan, this is a reduction of 22,600 illnesses.

Of the 1.3 million illnesses that CDC attributes to *Salmonella*, how many of those are from FSIS regulated products? Or, in other words, how many of the 436,401 illnesses in your 2007-2009 baseline, are attributed to *Salmonella*?

Response: Out of the 436,401 illnesses calculated from the FY 2007-2009 average baseline for the FSIS All Illness Measure, 413,965 are from *Salmonella*.

Mr. Kingston: Did the FSIS meet its goal of reducing 22,600 *Salmonella* illnesses from FSIS regulated products by the end of FY 2011?

Response: No, FSIS did not meet its goal of reducing 22,600 *Salmonella* illnesses by the end of FY 2011. Our goal for FY 2011 was to reduce *Salmonella* illnesses to 482,242, and FSIS reported approximately 536,000 *Salmonella* illnesses associated with FSIS-regulated products. *Salmonella* is the main reason that FSIS is not meeting its All Illness Measure, and that is why *Salmonella* is such a high priority for the Agency.

STRATEGIC PLAN - CHECK YOUR STEPS CAMPAIGN

Mr. Kingston: The testimony alludes to the "Check Your Steps" campaign that you are conducting with HHS. The steps being clean, separate, cook, and chill. Your performance measure for this is the average number of consumers who follow these four key food safety practices. The baseline for this measure was a 75 percent rate from 2006 and the target is 79 percent by 2016. According to the testimony, FSIS is now reaching millions using donated television, radio and print and social media and the Internet.

Why does it appear to be so difficult to get consumers to adapt to such basic guidelines?

Response: I think that people may have heard these messages before, but they are not necessarily applying them. People get a lot of information, and one of the things that we did when we designed the Check Your Steps Campaign was try to find a way to reach people in a meaningful way. And I think that we have.

For our target audience, parents of young children who prepare at least four meals per week at home, the hectic pace of life can often get in the way of being "food safe." The campaign ads are designed to get people's attention with a humorous, hyperbolic approach to a serious message. The ads personalize the CDC foodborne illness estimates by reminding people that one in six Americans get sick each year. That brings the message closer to home. The ads also portray food preparation situations that the average American can relate to, and thus, make the risks real to them. Over time, as we are able to gather more specific information about which foods are hazardous in which situations, we will be able to increase the specificity and gravity of food safety educational messages. For this round of public service announcements, we are collecting "pre and post-wave" consumer response data to gauge public awareness of the campaign messages and their response to them.

Mr. Kingston: How many consumers are we talking about that it would take to move that number to 79 percent by 2016?

Response: Based on extrapolations from 2010 U.S. census data, results from the FDA's 2006 Food Safety Survey indicate that 75 percent of U.S. adult consumers (or approximately 176 million people) routinely practice at least one of the four key food safety best practices: clean, separate, cook, and chill. Based on this data, we would reach our target of 79 percent of U.S. adult consumers, or approximately 185 million people, if approximately 9 million more people adopt these best practices by FY 2016.

FSIS' \$4 MILLION INCREASE FOR TIME CLOCKS

Mr. Kingston: FSIS proposes a \$4 million increase to install time clocks at about 500 [covers about 3300 employees] of the largest Federally-inspected facilities across the country. Current time and attendance system is paper-based, and data is entered into the pay system. The clocks will allow FSIS to track reimbursable overtime and bill industry only for actual time worked instead of current practice of rounding up in 15 minute increments.

How much of the \$4 million is for the purchase of the actual clock?

Response: The Agency is reviewing the technology that is currently available in order to determine the most cost effective and efficient way of recording time and attendance and overtime. Our initial estimates show that \$1.2 million would go toward purchasing clocks or similar sophisticated input devices that are able to: 1) record actual start and stop time, 2) provide authentication security to withstand legal challenges from industry (for billing purposes) and employees, 3) separate unbillable time and reimbursable time, 4) accept accounting codes to allow charges for reimbursable overtime and voluntary services, and 5) interface with our timekeeping and billing systems.

Mr. Kingston: How many clocks will you be purchasing with the \$4 million if it is approved?

Response: If the \$4 million is appropriated, FSIS will purchase 582 clocks.

Mr. Kingston: How much of the funding is for technical aspects such as installation and internet connections?

Response: Technical costs would total \$1 million, including \$200,000 for planning; \$300,000 for installation; \$100,000 for training, materials, and travel; \$100,000 for IT support; and \$300,000 for internet connections.

Mr. Kingston: How much of the increase is for enhancement of accounting and billing, reprogramming of software, etc.?

Response: \$1.8 million is for accounting and billing enhancements and software reprogramming.

POULTRY SLAUGHTER INSPECTION PROPOSED RULE

Mr. Kingston: On January 20th, FSIS proposed a rule for modernizing young chicken and turkey slaughter inspection that will save money for businesses and taxpayers by focusing FSIS inspection resources on the areas of the poultry production system that pose the greatest risk to food safety.

FSIS budget request assumes \$12.9 million in savings in fiscal year 2013, and 500 FTEs, based upon a final regulation being in place by October 2012.

What will FSIS inspectors do differently under the proposed rule, and how will that improve food safety?

Response: The FSIS proposed rule for "Modernization of Poultry Inspection" would streamline slaughter inspection in young poultry slaughter establishments, and yet facilitate the reduction of pathogen levels in poultry products.

Currently, some FSIS inspection program personnel in poultry establishments perform activities that are unrelated to food safety, such as identifying visual defects. The proposed new inspection system would redirect FSIS personnel to food safety-related tasks, such as sampling for pathogenic microorganisms and verifying that establishments are maintaining sanitary conditions and controlling food safety hazards at critical points in the production process. FSIS will continue to conduct carcass-by-carcass inspection, as mandated by law.

The rule also proposes to require that establishments address contamination before the chiller in order to reduce the occurrence and levels of *Salmonella* and *Campylobacter* on the finished carcasses, which will provide another layer of protection for consumers.

Mr. Kingston: How many facilities does the proposed rule cover?

Response: The proposed rule would allow for voluntary implementation at all young chicken and turkey slaughter establishments. However, the assumption in the proposed rule was that only the 175 large and small (not the very small) slaughter facilities that are not currently participating in the HACCP-Based Inspection Models Project would convert.

Mr. Kingston: What are the costs to the agency to implement the rule for items such as training, relocations, pay raises, lump sum payments, etc.?

Response: While the costs and savings may change once the rule becomes final and the program is implemented, the estimated first-year (FY 2013) costs of the program total \$13.7 million (including \$5.1 million for salaries and benefits for upgraded positions plus lump sum payments, \$4.8 million for training, and \$3.8 million for relocation). These costs will be outweighed by savings of \$26.6 million (including \$26.4 from eliminated positions and \$139,567 from local travel reduction). Thus, the estimated net savings are \$12.9 million in the first year.

Mr. Kingston: How will the public benefit when the proposed rule goes into effect?

Response: As a regulatory agency accountable to people who are both taxpayers and consumers, FSIS is working to identify ways to streamline operations and consolidate staff and resources, but not at the expense of our food safety goals. The proposed poultry slaughter inspection system is expected to prevent more than 5,000 foodborne illnesses per year. As reflected in the President's budget request, we estimate that this proposal also will save taxpayers more than \$90 million during the first three years after implementation and will lower production costs for the poultry industry by at least \$256 million per year.

Mr. Kingston: The budget request assumes that the final rule will be in place by the beginning of fiscal year 2013 in order to achieve savings of \$12.9 million. When will these FTEs have to be off the books in order to achieve this level of savings?

Response: The proposed rule estimate assumed a phased implementation from October 2012 through June 2013, with the last employee off the books by July 2013.

SHIGA TOXIN-PRODUCING *E. COLI* (STECs)

Mr. Kingston: On September 20, 2011, FSIS published the Final Determination announcing that six additional STECs would be deemed adulterants in certain beef products. In January, USDA's National Institute of Food and Agriculture (NIFA) announced that it was awarding a \$25 million grant to the University of Nebraska-Lincoln to conduct research on STECs. Among the projects is one that involves conducting a quantitative microbial risk assessment. Specifically, the project provides that:

"Input from scientists, economists, and industry will develop a risk assessment model that encompasses the complete beef supply chain. Predictive analyses, such as the Process Risk Model, can help estimate the risk of pathogen prevalence and concentration throughout the food manufacturing process. Among other things, the model will identify current data gaps and uncertainties attributable to STECs as a foodborne disease while fostering the design of cost-effective strategies to protect public health."

Why was this risk assessment not done before FSIS published the final determination? Wouldn't the process be better served to have all the necessary scientific data collected before starting regulatory action?

Response: FSIS has developed a risk profile to assess the risk of non-O157 STEC illness from beef consumption in the United States, which was used to inform the policies targeted towards its control. The risk profile was independently peer reviewed and is the most appropriate format by which to assess the risk of this foodborne hazard. At this time, the Agency is confident that the prevailing science supports our decision to move forward with the declaration of six additional STEC serotypes as adulterants.

In funding the STEC Coordinated Agricultural Project, NIFA recognized that "Shiga toxin-producing *E. coli* are a serious threat to our food supply and public health" and that cattle and other ruminants play a role in STEC illnesses and outbreaks. One aim of this research grant led by the University of Nebraska-Lincoln is to develop useful information to assist the industry in reducing the risks from non-O157 STEC in beef products throughout production and processing. The research projects and risk assessment associated with the NIFA grant are not intended to evaluate whether non-O157 STEC serotypes are significant public health threats.

STECs AS PRIORITY PATHOGENS

Mr. Kingston: As far as I know there has only been one documented outbreak attributable to these additional STECs in beef. In addition, the strategic plan recently issued by the CDC/FDA/FSIS Interagency Food Safety Analytics Collaboration did not include these STECs among its "priority pathogens."

Given the fact that the Interagency Food Safety Analytics Collaboration did not include STECs among its priority pathogens, why is FSIS implementing this policy before the risk assessment is finished?

Response: FSIS assessed the scientific data on the risk posed by non-O157 STEC, and determined that this risk is potentially equivalent to that posed by *E. coli* O157:H7. The Agency risk profile examined the risk presented by non-O157 STEC from beef products. The risk profile is an internationally recognized risk assessment technique, and it is the appropriate tool for assessing the risk of these human foodborne pathogens in this situation, according to the Codex Alimentarius Commission and the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement Article 5, paragraph 2: http://www.codexalimentarius.net/download/standards/10741/cxg_063e.pdf). The risk profile presents all available information on the public health challenge posed by these organisms.

As stated in the *Federal Register* Notice published on September 20, 2011, a risk assessment would not provide any added value to FSIS regarding the modeling of risk mitigation strategies. Rather, the available information within the risk profile was sufficient for FSIS to declare the six non-O157 STEC serotypes as adulterants in certain raw beef products. FSIS has determined that the six additional non-O157 STEC serotypes are adulterants of certain raw beef products, and therefore, FSIS has no intention of implementing a risk mitigation strategy different from that for O157 STEC.

Mr. Kingston: I understand that during the Interagency Food Safety Analytics Collaboration meeting on January 31, 2012, when asked why the six additional STECs were not included as priority pathogens, a CDC official said:

"We reviewed the estimates of foodborne illness, major pathogens and specified sources, papers for the volume of data, severity of illness, our ability to measure change, and we concluded that the non-O157 E. coli, at this point in time, was not on par with the other pathogens as far as understanding and implementing interventions to reduce them." Dr. Mark Hoekstra, CDC, CDC/FDA/FSIS Foodborne Illness Source Attribution Meeting, January 31, 2012.

Do you agree with this statement? If not, why not?

Response: I agree with Dr. Hoekstra that we do not have as much data on non-O157 *E. coli* as we do on other pathogens of public health concern, such as *E. coli* O157:H7, *Salmonella*, *Listeria*, and *Campylobacter*. Because non-O157 STECs are emerging pathogens, there is less available data compared to established pathogens, limiting our ability to perform in-depth analysis regarding attribution. However, the available scientific literature on non-O157 STEC indicates that they present a significant public health threat, and the evidence for this is presented and analyzed in the Agency's risk profile. We also expect that some of the same interventions currently used by FSIS and industry to combat *E. coli* O157:H7 will be effective against non-O157 *E. coli*. As a food safety regulatory agency, FSIS is committed to preventing illnesses before they happen, and this new policy will do just that.

LACK OF COMMERCIAL TEST KITS

Mr. Kingston: Another project under the NIFA grant will develop and validate methods for detecting, isolating and enumerating the targeted serogroups/serotypes of STECs. The September 20th announcement seems to suggest there is a test method available for industry use, but several governments and organizations expressed concern in their comments about the availability of a commercially viable test method.

Is there a commercially viable test method? If so, what is the false positive rate and what is the confirmed positive rate using that method?

Response: Commercially available screening tests for non-O157 STECs exist. FSIS is aware that multiple additional testing methods are in the later stages of development or validation and should be on the market soon. To date, FSIS has provided "no objection" letters for at least two different STEC screening tests, and preliminary data shows comparable performance to the official FSIS regulatory method. Method validation is done under controlled situations, with known negative and known positive samples. Vendors have conducted validation studies on their methods.

FSIS cannot provide an established false positive rate for commercial methods until a large sample of commercially sourced material has been analyzed.

Mr. Kingston: If there is such a test, why is NIFA funding research to "develop and validate cultural, immunological, and molecular methods for the detection, isolation, and enumeration" of the serogroups being studied?

Response: FSIS, the Agricultural Research Service (ARS), and NIFA continue to promote research and refinement of testing methods for a variety of foodborne pathogens, including *E. coli* O157:H7, *Salmonella*, and *Listeria monocytogenes*. The NIFA-funded STEC initiative covers a broad range of STEC public health issues, including development of additional STEC testing strategies and technologies in the future. According to the STEC Coordinated Agricultural Project document "Improving Beef Safety: Shiga Toxin-Producing *Escherichia coli*: Prevention, Recovery, Characterization, and Control Across the Beef Chain," one project of this NIFA-funded grant aims to further develop test methods and tools "for use throughout the beef production and processing continuum," including the on-farm environment. The testing methods investigated will not be limited to methods for testing cattle feces and hides and beef products, but will include methods for testing soil, water, feed, flies, and purge from combo bins. FSIS encourages the development of any testing methods that will assist the beef industry in identifying and controlling the target non-O157 STEC serotypes.

BASELINE TESTING FOR STECS

Mr. Kingston: Dr. Hagen, when you were a deputy administrator of FSIS, you said, "FSIS will soon begin testing ground beef and ground beef components for the presence of the selected non-O157 STECs, the six serogroups ... Now, the primary objective, initially, is going to be to determine the magnitude of the issue. Once we get a handle on that, we can determine whether a regulatory program is warranted and how we would go about implementing such a program."

Was this baseline testing done?

Response: FSIS traditionally designs its baseline studies to determine the presence and levels of specific pathogens in a particular food product; to determine a national prevalence estimate; and to develop performance standards, guidance, and risk assessments. We determined that a baseline was not necessary to implement the FSIS verification sampling and testing program.

Mr. Kingston: If not, why was it not done before the September 20th publication declaring STECs to be adulterants?

Response: FSIS does not believe that a baseline is necessary to implement the FSIS verification sampling and testing program because we already know that these organisms are present in beef products in the United States; the evidence for this is presented in the risk profile. Data obtained at slaughter establishments by ARS and in retail establishments is considered by FSIS to be adequate for identifying the potential prevalence of non-O157 STEC in the United States. The available information, referenced in the FSIS risk profile, provides information about the presence of non-O157 STEC in the U.S. beef supply.

QUESTION FOR THE RECORD SUBMITTED BY REPRESENTATIVE CYNTHIA LUMMIS

CUSTOMS AND BORDER PROTECTION (CBP) COLLABORATION

Ms. Lummis: The GAO report on duplicative programs recommends that CBP ensures their new screening system communicates time-of-arrival information to FDA and FSIS. Has CBP taken steps to communicate time-of-arrival information to FSIS's screening system?

Response: When the Public Health Information System (PHIS) is fully operational, it will interface with the Automated Commercial Environment (ACE). At that time, Customs entry data will automatically populate PHIS when the entry is filed, so FSIS will be aware that the shipment has arrived at the port of entry. FSIS is also interested in when the shipment will arrive at the official import inspection establishment. While this information is currently not collected by Customs and Border Protection (CBP), CBP has developed a set of data elements specific to FSIS that may lead to increased collaborations between agencies.

WITNESSES

	Page
Almanza, Alfred	255
Cochran, Norris	1
Hagen, Elisabeth	255
Hamburg, Margaret	1
McGarey, Patrick	1
Young, Michael	255

INDEX

Food and Drug Administration

	Page
Animal Antibiotics	245
Approval Pathways	63
Biosimilars	161, 210
Budget Scenarios	216
Center for Tobacco Products.....	78, 224
China:	
FTEs	35
Exports.....	56, 241
Inspections.....	75, 242
Cigars	66
Cosmetics User Fee.....	39, 211
Counterfeit Drugs	35
Data Consolidation/IT Savings	72, 250
Dialogue with USDA	64
Drug Shortages.....	45, 65
FDA Approved Contraception	244
Food and Veterinary Medicine Strategic Plan	76
Food Establishment Registration Fee	42, 52, 57
Food Imports	253
Food Labeling.....	60, 247
Food Safety Modernization Act.....	43, 45, 54, 56, 64, 89, 227, 241
Fresh Produce Testing	228
Front of Pack Nutrition Rating System	230
FY 2013 Budget Request	1
GAO/OIG Reports	104
GAO Report, FDA–USDA Roles	58
Generic Drugs.....	160, 249
Generic Drug User Fee	47
Glaucoma and Eyelash Products	38
GSA Rent	74
Heparin	35
Import Equivalency	227
Imports	36
Fast Track	229
Information Technology Systems	41, 237
Medical Countermeasures	4, 51
Medical Countermeasures initiative (MCMi)	108
Medical Devices	49, 57
510(k) Process	55, 70, 232
Approval and Recall Rates	230
Innovation	62
Medical Device User Fee Reauthorization	162

	Page
Menu Labeling	40
Requirements	213
Microbiological Data Program.....	240, 247
New Dietary Ingredients	215
Nicotine Replacement Therapy	223
Off-Label Uses	39
Opening Statement, Dr. Hamburg	2
Infrastructure	3
Innovative Drugs	3
Food Imports	3
China	3
New Laboratories	4
Orange Book	162
Orange Juice	246
Pathway to Global Product Safety and Quality	84
Pay Awards and Bonuses	165
Pay Cost	78
Pet Treats Investigation	251
Pilot Project to Expedite Imports	212
Plan B	36
Post Market Surveillance and REMS	234
Prescription Drug User Fee Act (PDUFA)	48
Produce Safety	252
Quantifying Risk	228
Questions for the Record:	
Mr. Aderholt	212
Mr. S. Bishop	245
Mr. Farr	227
Mr. T. Graves	216
Mr. Kingston	72
Mrs. Emerson	210
Mrs. Lummis	215
Ms. DeLauro	232
Ms. Kaptur	251
Reagan-Udall Foundation.....	68, 83
Recalls	70
Refusal of Inspections	44
Registration Tax	52
Risks and Benefits	63
Seafood	67
Secure Supply Chain Initiative	213
Sodium Intake	61, 75
States' Roles in Food Inspection	44
Tanning Beds	40
Targeting Resources	68
Third Party Resources	214
Tobacco	219
Lack of Enforcement	221
Tomato Recall.....	58, 248
Trade and Food Safety	233
Transparency	88
User Fees	50, 55, 155
Voluntary Qualified Importer Program	214
White Oak Consolidation	73
Witness Statement, Dr. Hamburg	5

	Page
Witness Statement, Dr. Hamburg—Continued	
FY 2013 Budget Summary	11
FDA Budget Authority	12
FDA User Fees	15
Conclusion	33

Food Safety and Inspection Service

	Page
Assurance Net/In-Commerce System	319
Catfish Rule	304
Implementation	289
Commercial Test Kits, Lack of	328
Countries Eligible to Export	321
Customs and Border Protection:	
Collaboration	330
Information Sharing	295
Duplicative Programs across Agencies	293
E. coli:	
Baseline Testing for STECs	328
SHIGA Toxin-Producing E. coli	326
STECs as Priority Pathogens	326
Variants	286
Educational Outreach	283
Employee Compensation	290
Employee Illnesses	288
Equivalence:	
Agency Roles in Determinations	297
Determinations	293
Foreign Plant Determinations	296
Initial Determinations	297
Federal Regulations vs. Corporate Rules	292
Food and Drug Administration, Coordination with	285
Food Safety Roles, Realignment of	294
HACCP-Based Inspection Models Project	286
Risk Assessment	310
Introduction of Witnesses	255
Labeling Process for Small Producers	301
Labeling Rule for Added Solutions	284
Line Speed Analysis	308
Mechanically Tenderized Beef Labels	302
Motor Vehicle Fleet	316
Office Costs	314
OIG/GAO Reports	312
Opening Statements:	
Mr. Almanza	260
Mr. Farr	256
Dr. Hagen	270
Pay Costs	308
Poultry Slaughter Inspection Proposed Rule	324
Public Health Data Communication Infrastructure	318
Public Health Information System	317
Implementation	307
Questions for the Record:	
Mr. Kingston	312
Ms. Lummis	330

	Page
Recalls	319
Regulatory Cooperation Council	303
Risk Assessment	320
Salmonella Illnesses	282
Single Food Safety Agency	296, 302
Responsibilities	300
Small Producers, Economics of	292
Strategic Plan	282
Check Your Steps Campaign	323
Government-Wide	260
Salmonella	322
Student Loan Repayments	319
Time Clocks	324
Trade Impediments, Fund for	303
Trade Negotiations	310
Trans-Pacific Partnership	303
Negotiations	305
Unfilled Positions	315
User Fees	309
Witness Statement	272