DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
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STATEMENT OF

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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I. INTRODUCTION

Chairman Kohl, Senator Brownback, and members of the Subcommittee, I am Dr. Margaret Hamburg, Commissioner of Food and Drugs. I am pleased to present the President's fiscal year 2011 budget request for the Food and Drug Administration (FDA or agency). Joining me at today's hearing is Patrick McGarey, FDA's Director of the FDA Office of Budget and Norris Cochran, Deputy Assistant Secretary for Budget at the Department of Health and Human Services.

My testimony outlines FDA's FY 2011 budget request and the policy initiatives that we are advancing in our budget. I will also summarize recent developments related to FDA actions to implement the Family Smoking Prevention and Tobacco Control Act, FDA's response to the 2009 H1N1 influenza pandemic, and other initiatives at FDA.

II. FY 2010 BUDGET

The funding that you appropriated for FY 2010 shows the depth of your commitment to FDA's public health mission and the health of the American public. On behalf of all Americans who benefit from the work of the FDA, thank you for your support.

This funding allowed FDA to make progress in a wide range of areas.

For example, in the Foods Program, we are hiring and training new inspectors, improving our scientific and technical capacity, initiating a wide range of new State and international partnerships and – working with industry, consumer advocates, and others – laying the foundation for a shift to a food safety approach focused on prevention. We also started critical work on front of package labeling, an effort that will help American families better understand the nutritional content of foods.

FY 2010 funding allowed FDA to aggressively engage with our HHS partners and industry in the public health response to the 2009 H1N1 influenza pandemic. We supported the effort to rapidly develop and deploy safe vaccines, antiviral medicines, and diagnostic tests that were so vital in the public health response.

For drugs and biologics, we began the first phase of the Sentinel system, a distributed network of electronic health data that can track the safety of medical products once they reach the market and quickly investigate potential safety signals. For medical devices, we released key guidance defining a path for more efficient and effective clinical trials.

In the Tobacco Program, we established the new Center for Tobacco Products, implemented a ban on cigarettes with characterizing fruit and candy flavors, and established a program of registration and listing.

We also began a process that will make FDA much more transparent to the American public and to the industries that we regulate. The FDA Transparency Initiative responds to President Obama's Executive Order on open government and the transparency priorities that Secretary Sebelius is advancing.

As part of our Transparency Initiative, FDA held two public meetings, launched a transparency blog, and opened a docket – efforts that received more than 900 suggestions from the public.

In January, FDA launched "FDA Basics," the first phase of the Transparency Initiative. As one observer of the agency commented, "[t]he initiative can go a long way toward educating the public about what FDA does – and how – and also provide industry with real-time answers to their daily challenges, ultimately improving product quality and patient safety." Another said, "[i]t is really well put together, clear and works quite well. . . . The site is not only supportive of transparency, but is highly instructive and educational."

The next two phases of our transparency efforts are well underway, and our goal is to provide communication with the public and industry about FDA actions and the basis for FDA decisions.

We are also developing a major performance management initiative, which will provide additional access to Congress and the public about the activities and progress on more than 50 FDA offices.

III. FDA 2011 BUDGET REQUEST

Overview

The President's FY 2011 budget includes $4.0 billion for FDA programs to protect and promote public health. This represents an increase of $756 million for FDA programs, which includes $601 million for statutory increases for user fee programs in current law and four new user fees to support public health priorities.

IV. DETAILS OF THE FY 2011 BUDGET

Transforming Food Safety Initiative

For FY 2011, FDA proposes an increase of $326.3 million for Transforming Food Safety. This increase includes $87.8 million in budget authority and $238.5 million for three new user fees related to food safety: Food Inspection and Registration User Fees, Reinspection User

Fees for food facilities and Export Certification User Fees for food and feed products. The funding for Transforming Food Safety includes the budget amendment of $8 million that the Administration recommended on February 12, 2010.

The Transforming Food Safety Initiative reflects President Obama's vision of a new food safety system to protect the American public. The initiative is based on three core principles announced in July 2009 by the President's Food Safety Working Group: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

The FY 2011 resources for Transforming Food Safety demonstrate that food safety is a national priority. It reflects the consensus among consumers, industry and experts that our food safety system needs fundamental change to prevent illness and restore public confidence.

With the FY 2011 increases, FDA will set standards for safety, expand laboratory capacity and pilot track and trace technology. FDA will also strengthen import safety and improve data collection and food risk analysis. Most importantly, the FY 2011 resources allow FDA to establish a foundation for an integrated national food safety system focused on prevention.

During FY 2011, FDA will hire 718 additional full-time equivalent (FTE) staff to expand programs that protect America's food supply. The hiring by FDA food safety programs includes more than 425 new FTE in our field operations, of which 132 FTE will be new food inspectors in the field operations of our Office of Regulatory Affairs. Among those 132 FTE, three are funded by budget authority, 99 are funded by food registration and inspection user fees, and 30 are funded by reinspection fees.

When fully trained and deployed, the 132 new inspectors will annually conduct the following additional field activities, based on budget authority and user fee funding proposed for Transforming Food Safety:

- 1,900 domestic food safety inspections
- 150 foreign food inspections
- 1,000 domestic food and animal feed program reinspections
- 200 domestic tissue residue inspections for illegal drug residues in meat and poultry
- 3,000 samples for analysis in FDA laboratories.

The Transforming Food Safety Initiative will also allow FDA to fund the cost of living pay adjustment for FDA professionals that conduct food safety activities and pay higher rent and related facility costs.

In addition to the priorities listed above, FY 2011 resources for Transforming Food Safety support the following domestic and foreign activities that implement Food Safety Working Group priorities.

Prioritizing Prevention –

- **FDA will issue guidances and establish new, binding standards to help prevent foodborne illness and reduce food risks.** The standards include new controls to prevent food safety risks associated with fresh produce and other commodities, standards for food inspections, and standards for collecting and analyzing food samples.

- **FDA will conduct audits of its regulatory and public health partners.** FDA audits will evaluate inspection, investigation, sample collection and analysis, enforcement, response, recovery, and outreach activities. The audits will measure performance against FDA food safety standards. FDA will also strengthen collaboration with foreign regulatory bodies to evaluate and leverage inspection data. FDA will begin to develop an updated inventory of foreign facilities to support more foreign inspections.

- **FDA will begin to establish a modern import safety program.** FDA will develop standards to evaluate food safety systems in foreign countries. FDA will also continue third-party certification efforts and develop a registry of all importers. When fully implemented, FDA's import safety program will result in greater oversight of imported foods and provide greater assurance they meet safety standards comparable to those required for domestically produced foods.

Strengthening Surveillance and Enforcement –

- **FDA state liaisons will communicate essential information on food safety standards and priorities throughout the integrated food safety system.** FDA will also develop and implement a national food inspection and sampling work plan. Working with the states, FDA will increase surveillance and sampling of feed and feed ingredients. FDA will improve its analysis of inspection results by establishing a system to electronically exchange inspection data.

- **FDA will improve risk analysis and research for food and feed safety.** FDA will expand its ability to identify products at highest risk for contamination. FDA will use this information to better target and prioritize food and feed safety sampling and inspection. As one tool for food risk analysis, FDA will enhance the food registry used to report problems with foods.

- **FDA will expand the National Antimicrobial Resistance Monitoring System (NARMS).** Expanding NARMS means more surveillance and monitoring of commodities such as seafood and animal feed. Working with CDC and USDA, FDA will also adapt NARMS to monitor emerging pathogens in food animals and retail foods of animal origin. .

- **FDA will increase its laboratory capacity.** FDA will establish a new forensic microbiological laboratory and conduct more food safety sampling and surveillance.

Improving Response and Recovery –

- **FDA will conduct pilot studies with industry of track and trace technology.**

- **FDA will improve response and recovery with expanded lab capacity.** FDA will develop technology to reduce the time needed to screen for pathogens. We will focus our energies on priority pathogens and work to reduce screening time to one to two days, compared to the current five to ten days.

- **FDA will invest in enterprise information technology (IT) systems to transform food safety.** Funding for IT systems will also allow FDA to establish, collect and support the proposed new Food Registration and Inspection User Fees Program.

- **FDA will provide essential support to food program offices**. This support will allow food safety programs to achieve priority public health objectives.

Results for Transforming Food Safety –

FY 2011 funding for the Transforming Food Safety initiative will allow FDA to deliver the promise of improved food safety. With this FY 2011 investment, FDA will steadily reduce illnesses caused by contamination of the food supply in the years to come. In summary, Transforming safety will allow FDA to:

- Reduce the number of foodborne illnesses by heightening the focus on preventing harmful contamination
- Identify sources of risk in the food safety system through expanded data collection and analysis and collaboration with partners in other federal agencies and with, States, international agencies, and industry
- Improve industry compliance with food safety standards through more frequent inspection and expanded use of microbial testing and other modern tools
- Reduce time to detect and respond to outbreaks through improved staffing and procedures and collaboration with the Centers for Disease Control and Prevention and state, local, and international colleagues
- Establish stronger links between performance outcomes and resource investments by developing and tracking appropriate measures of progress on food safety
- Better integrate Federal, State, local, and foreign food safety efforts by removing barriers to full collaboration, leveraging of information, and expanding current partnership efforts.

Protecting Patients Initiative

For FY 2011, FDA proposes an increase of $100.8 million for Protecting Patients. This increase includes $49.4 million in budget authority and $51.4 million for two new user fees: Generic Drug User Fees and Reinspection User Fees for medical product facilities.

The Protecting Patients Initiative advances Obama Administration priorities for safe, quality health care for all Americans. The resources in this initiative support new tools and partnerships to enhance the safety of increasingly complex drugs, devices, vaccines, human tissues and America's blood supply.

This initiative will modernize FDA's approach to the safety of medical products at a time when the number of drugs, devices and biologics manufactured abroad is increasing dramatically. With these resources, FDA can act as a strong and smart regulator and address medical product safety challenges in the years ahead.

The Protecting Patients Initiative focuses on four vital areas: import safety, high-risk products, partnerships for patient safety, and generic drug review.

During FY 2011, FDA will hire 215 FTE staff for programs that protect patients and support the safety and effectiveness of medical devices, human and animal drugs, and vaccines, blood and other biologics. This includes hiring 85 FTE in FDA field operations, of which 40 will be new ORA medical product inspectors. Among those 40 FTE, 13 are funded by budget authority, 21 are funded by reinspection fees, and six are funded by generic drug user fees.

When fully trained and deployed, the 40 FTE will annually conduct more than 600 foreign and domestic risk-based inspections. This includes more than 225 inspections funded by budget authority and more than 380 inspections funded by reinspections and generic drug user fees. These include inspections of foreign and domestic drug, device, radiological health, and biologic manufacturers, as well as bioresearch monitoring inspections to protect patients and ensure data integrity in clinical trials. The Protecting Patients Initiative funds the cost of living pay adjustment for FDA professionals that conduct food safety activities. The Initiative also funds higher rent and related facility costs and provides essential support to allow medical product programs to achieve their public health priorities.

In addition to the activities listed above, FY 2011 resources for Protecting Patients support the following priorities.

Import Safety –

Thousands of critical medical products are manufactured outside of the United States. Increased funding for import safety will allow FDA to better understand and respond to the growing challenge of foreign manufacturing and globalization, including counterfeit products.

- **FDA will launch an electronic drug registration and listing system to stop imports of illegal drug.** FDA will also work more closely with trusted foreign regulators to monitor drug manufacturing facilities.

- **FDA will increase foreign inspections.** FDA will identify and inspect the highest risk foreign facilities. FDA will also protect patients through increased inspections of human subject trials.

- **FDA will review and use third party International Organization for Standardization (ISO) audits of foreign device manufacturers**. As a result, FDA will leverage device inspections conducted for foreign governments.

Safety of High-Risk Products –

Drugs, devices and biologics are becoming increasingly complex. To protect the American public, FDA will develop additional capacity to assess the safety of these medical products.

- **FDA will improve the safety of the blood supply, vaccines, human tissues, and cord blood.** To counter threats to the blood supply, FDA will improve the ability to prevent, detect and monitor for infectious agents. FDA will also improve its ability to analyze and respond to manufacturing deviations. FDA will also build additional capacity to identify and respond to adverse events and adverse reactions associated with biological products. FDA will improve vaccine safety through guidance for industry and better understanding mechanisms of adverse events.

- **FDA will begin to build a National Medical Device Registry.** FDA will begin a pilot project to link unique identifiers for medical devices with electronic health data. The result will be improved patient safety by creating a National Medical Device Registry.

Partnerships for Patient Safety –

To meet its public health responsibilities, FDA must interact and collaborate with many public and private entities in a medical system that is committed to safety.

- **FDA will expand postmarketing surveillance systems for medical product safety.** This investment includes support for the next stage in FDA's Sentinel Initiative. The goal of the Sentinel Initiative is to use large databases to fairly and quickly assess the safety of medical products.

- **FDA will partner with public and private organizations to reduce unnecessary adverse events, with emphasis on special populations.** FDA will also work with the private sector to reduce unnecessary medical radiation exposure.

- **FDA will improve pediatric drug and device safety.** Working with international and domestic partners, FDA will identify medical products that are safe for children and those that pose special risks.

- **FDA will improve the safety of animal drugs.** FDA will hire and train scientific staff to review adverse experience reports and require prompt corrective action.

Generic Drug Review –

- **FDA will Increase its Capacity to Review Generic Drugs Applications:** FDA will hire additional staff to support generic drug review.

Results for Protecting Patients –

FDA's Protecting Patients Initiative will have a significant impact on public health in the United States. This science-based strategy will build new and greater safety capabilities, resulting in:

- Reduced number of import safety emergencies
- Fewer serious adverse events linked to medical products
- Early identification of major safety problems with drugs, devices and biologics.

This initiative will permit FDA to rise to the challenge of protecting patients in the 21st century. The initiative supports critical international efforts, upgrades to FDA capacity, and essential partnerships with the private sector. With the FY 2011 resources, the Protecting Patients Initiative will lead to:

- Improved import safety program for medical products
- Increased capacity to conduct inspections
- Improved safety of blood, tissue, and vaccines
- Improved data collection and risk analysis for medical products
- Enhanced assessments of postmarket safety.

Advancing Regulatory Science for Public Health Initiative

For FY 2011, FDA proposes an increase of $25 million in budget authority for Advancing Regulatory Science. The Advancing Regulatory Science initiative is the backbone that supports all other FDA activities, including transforming food safety and protecting patients. At FDA, science is at the heart of everything we do - from keeping the blood supply safe, protecting Americans from global and emerging infectious diseases, supporting the development of new food and medical technologies, to bringing new treatments to patients.

Advancing Regulatory Science for Public Health reflects President Obama's commitment to harness the power of science to benefit America. In his April 2009 address to the National Academy of Sciences, the President declared, "science is more essential for our prosperity, our security, our health, our environment, and our quality of life than it has ever been before."

During the past two decades, U.S. research investments have dramatically expanded our understanding of biology and disease. Yet the development of new therapies has been in decline, and the costs of bringing them to market have soared. As a result, we have experienced lost opportunities to improve the effectiveness of U.S. medicine and the success of the biotechnology industry.

Today, FDA is relying on 20th century regulatory science to evaluate 21st medical products. Regulatory science is needed to provide better tools, standards, and pathways to evaluate products under development. It also serves to create efficiencies in the development process, and improve product safety, quality, and manufacturing. The Advancing Regulatory Science initiative represents the first comprehensive effort to modernize regulatory science at FDA.

Stem cells and personalized medicine are two examples of areas that could change the way we treat many diseases. Stem cells offer hope for treating patients with neurodegenerative diseases, such as Parkinson's and Alzheimer's disease. For the promise of stem cells to come to fruition, FDA must develop standards for stem cell therapies so that they can be produced reliably and safely. In the area of personalized medicine, FDA must work collaboratively to identify markers that can predict whether a patient will respond to certain cancer therapies. FDA must use cutting-edge science to validate these tests for use in clinical practice.

In addition to helping patients benefit from biomedical advances, improvements in regulatory science will also support better assessment of drug and device safety, better tools for food safety, and better understanding of how to reduce the enormous public health harm of tobacco products.

The Advancing Regulatory Science for Public Health initiative focuses on three broad themes: science leadership and coordination, core capacity, and modern standards for evaluating products.

Science Leadership and Coordination –

- **FDA will strengthen scientific leadership.** The Office of the Chief Scientist (OCS) will support FDA and its centers with dedicated and expert scientific leadership. OCS will work with the centers to prioritize, oversee, support and coordinate key scientific investments at FDA.

Core Capacities: Infrastructure, Workforce, Collaboration –

- **FDA will build core scientific capacity in the field of nanotechnology.** Nanotechnology holds great promise in many areas. Examples include targeting drugs to where they can do the most good and least harm and making improved material for medical devices. Yet, nanoscale materials may interact very differently with biological systems and require special methods to assess safety and effectiveness. FDA will support science focused on the sound evaluation of nanotechnology-based products. The goal is to realize their promise while protecting patients and consumers.

- **FDA will support the development and evaluation of products from stem cell innovation.** The FDA investment will support the transfer of stem cell discoveries from the bench to the bedside.

- **FDA will recruit next generation scientific staff.** FDA will begin targeted recruitment in essential areas of emerging science where FDA has an expertise gap.

- **FDA will address science issues that support a National Medical Device Registry.** FDA will begin a pilot project to link unique device identifiers with health-related electronic data to create a National Medical Device Registry. The Registry will improve our understanding of the risk-benefit profile of higher risk devices.

- **FDA will promote scientific collaboration through the Critical Path Initiative.** FY 2011 investments in FDA's Critical Path Initiative will allow FDA to foster partnerships that transform product development and evaluation sciences, advance personalized medicine, support meeting unmet public health needs, and better predict and prevent safety risks early in development.

Medical product regulatory standards –

- **FDA will update review standards and provide regulatory pathways for biosimilars.** FDA will establish regulatory guidance to provide a scientifically sound and safe pathway to characterize and develop biosimilars.

- **FDA will increase its ability to regulate animal biotechnology products.** FDA will hire and train staff to strengthen our knowledge base and thereby support the review and potential approval of animal biotechnology products.

- **FDA will promote development of healthy foods and encourage healthy food choices.** FDA will use data from well-designed studies to support a modernized food label to encourage Americans to eat healthier diets.

The Initiative also funds rent and related facility costs to conduct initiative activities and provides essential support to allow medical product programs to achieve their public health priorities.

Tobacco Control Act

On June 22, 2009, the President signed H.R. 1256, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), into law. The Tobacco Control Act grants FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products.

FDA's goals for the tobacco program include:

- preventing youth from using tobacco and helping adults who use tobacco to quit
- promoting public understanding of the harmful and potentially harmful constituents of tobacco products
- developing a science base for tobacco regulation
- beginning meaningful tobacco product regulation to reduce the toll of tobacco-related disease, disability, and death.

In September 2009, after a national search, I selected Lawrence Deyton, M.S.P.H, M.D., as Director of the Center for Tobacco Products. Dr. Deyton is an expert on veterans' health issues, public health, and tobacco control and prevention. He also is a clinical professor of medicine and health policy at George Washington University School of Medicine and Health Sciences.

During FY 2010, FDA made substantial progress in establishing the tobacco program and implementing initial steps under the Act.

To date, FDA has met or exceeded the statutory requirements of the Tobacco Control Act, including:

- establishing the tobacco products user fee program to support FDA's tobacco program
- issuing and enforcing a ban on cigarettes with certain characterizing flavors, including fruit and spice flavors
- publishing a guidance document related to tobacco product establishment registration and product listing and began tobacco industry registration with FDA
- publishing a guidance document describing the requirements for providing listings of all ingredients used in making cigarettes, smokeless tobacco, and certain other tobacco products and began accepting tobacco product ingredient and constituent listings
- establishing an FDA program to assist small tobacco product manufacturers
- creating the Tobacco Product Scientific Advisory Committee.

FDA is in the midst of an aggressive recruitment and hiring program, with a goal of hiring 370 FTEs in the tobacco program by FY 2011. I am pleased to report that FDA has met or exceeded the statutory deadlines in the Tobacco Control Act. During FY 2011, FDA will continue to make progress in tobacco product regulation. We will learn from the successes of our international counterparts that also regulate tobacco. We expect to implement a number of key steps in the next year. These steps will include reissuing and enforcing the 1996 rule to prevent smoking and smokeless tobacco use among young people and proposing graphic health warning labels for cigarette packages and advertising.

New User Fees

The new user fees proposed in FDA's FY 2011 Budget will facilitate the review of generic drugs and enhance FDA's ability to register and inspect food and feed manufacturing and processing facilities. New user fees will also allow FDA to reinspect facilities that fail to meet good manufacturing practices and other safety requirements and allow FDA to collect fees when it issues export certifications for food and feed.

V. FDA RESPONSE TO THE 2009 H1N1 INFLUENZA PANDEMIC

I would also like to take this opportunity to report to the committee on FDA's response to the 2009 H1N1 influenza pandemic. As we reported to you last year, FDA established an incident command approach that allowed us to work across government, internationally and with the private sector to rapidly mobilize emergency response.

Key accomplishments include:

Licensing Safe and Effective Influenza Vaccines. FDA worked to facilitate development, production, and availability of vaccines. FDA licensed pandemic influenza vaccines from all five U.S.-licensed influenza vaccine manufacturers. These pandemic vaccines were subject to the same stringent manufacturing and quality oversight processes in place for seasonal influenza vaccines. More than 70 million Americans have been immunized with these vaccines, based on CDC's coverage survey estimates. Extensive safety review involving active surveillance systems that have captured information from approximately 4 million patients has found the vaccine to have the same excellent safety profile as the seasonal influenza vaccines.

Authorizing Emergency Measures. Our physicians and scientists worked tirelessly to facilitate the availability of antiviral medications to patients. FDA authorized 13 laboratory tests, 3 drugs, and certain types or models of respirators, known as N95 respirators, to provide tools to doctors across the country to fight the novel H1N1 influenza. For example, FDA authorized the emergency of use of an unapproved intravenous antiviral drug, Peramivir, to treat certain hospitalized patients. FDA's work on dosing of Tamiflu in children under the age of one year was adopted by countries around the world. In addition, FDA authorized the use of antiviral medications that otherwise might have been thrown away because they were beyond their labeled expiration dates. Our efforts on expiring drugs helped prevent shortages of essential medicines for patients.

Cracking Down on H1N1 Fraud. FDA established the 2009 H1N1 Consumer Protection Team that conducted an aggressive, proactive strategy to combat fraudulent 2009 H1N1 products. To date, the team has sent more than 80 Warning Letters to more than 85 web sites, covering about 150 different products purporting to be dietary supplements, medical devices, drugs or biologics. These Warning Letters have resulted in a compliance rate of about 80 percent.

FDA is pleased to have worked so closely with its sister agencies under the leadership of the Department of Health and Human Services in the pandemic response. We will continue our work to pave the way for manufacturers to develop faster and more reliable vaccines, antiviral medications, and diagnostic test.

VI. CONCLUSION

The FDA FY 2011 budget of $4 billion contains important funding increases for important public health priorities: Transforming Food Safety, Protecting Patients, Advancing Regulatory Sciences and implementing the Tobacco Reform Act. Achieving these priorities is possible because of your support for the work of the Food and Drug Administration.

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