



STATEMENT OF
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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INTRODUCTION

Chairman Kohl, Ranking Member Brownback and members of the Subcommittee, I am Dr. Joshua M. Sharfstein, Principal Deputy Commissioner and Acting Commissioner at the U.S. Food and Drug Administration. I am pleased to present the President's fiscal year 2010 budget request for the Food and Drug Administration (FDA). For today's hearing, I am joined by Patrick McGarey, FDA's Director of the Office of Budget Formulation and Presentation and Norris Cochran, Deputy Assistant Secretary for Budget at the Department of Health and Human Services.

In my testimony today, I will outline FDA's FY 2010 budget request and the policy initiatives that we are advancing in our budget. I will also summarize recent developments related to the 2009-H1N1 Flu Virus outbreak and describe how FDA's budget for pandemic preparedness allowed us to prepare for and respond to the 2009-H1N1 Flu Virus.

RECENT FUNDING INCREASES

The funding that this subcommittee appropriated to FDA for FY 2008 and FY 2009 demonstrates your strong commitment to the public health mission of FDA and the health of the American public. Thank you for your support.

When I arrived at FDA, I asked each FDA center to provide examples of how they are using the recent funding increases to promote public health and achieve mission priorities. A key goal for FDA is to directly connect the investment of Federal dollars to public health outcomes.

FDA 2010 BUDGET REQUEST

Overview

The President's FY 2010 budget request for FDA includes \$3.2 billion to protect and promote the public health. The budget contains an increase of \$510.6 million for FDA programs, which is a 19 percent increase compared to the FY 2009 budget. This is an historic increase in the FDA budget and demonstrates the Administration's commitment to food safety, medical product safety, and the health of the American public.

The FY 2010 increase of \$510.6 million includes increases of \$295.2 million in budget authority and \$215.4 million in industry user fees. The FDA budget organizes these increases into initiatives for FY 2010. Our two major initiatives are Protecting America's

Food Supply and Safer Medical Products. The budget also includes \$74.4 million for statutory increases for user fee programs in current law and increases for infrastructure to support FDA's mission.

The FDA FY 2010 budget recommends four new user fees. The new user fees will facilitate the review of generic drugs, enhance FDA's ability to register and inspect food and feed manufacturing and processing facilities, 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.

The FY 2010 budget also recommends new authority for FDA to approve generic biologics through a regulatory pathway that protects patient safety and promotes innovation. Finally, the budget also includes \$5 million for FDA to develop policies to allow Americans to buy safe and effective drugs from other countries.

DETAILS OF THE FY 2010 BUDGET

Supply Chain Safety and Security

The globalization of the manufacturing and supply of foods and medical products that FDA regulates and Americans consume poses unique and demanding challenges for FDA. In the complex and rapidly changing environment driven by globalization, FDA cannot rely solely on traditional approaches – inspection and sampling at the U.S. border – to protect Americans and ensure the safety of foods. Rapid globalization requires that FDA implement new

approaches and conduct a broader range of activities to effectively regulate the supply chain for foods and medical products.

Supply Chain Safety and Security is an overarching principle that applies to both food and medical products. Supply Chain Safety and Security holds all segments of industry accountable for ensuring that their products meet U.S. safety standards.

Key components of this initiative include: identifying products and processes at high risk for earlier and more comprehensive attention; establishing reasonable and effective regulations and other standards; increasing FDA inspections; increasing effective third-party inspections; and collaborating with local, state and international partners.

Protecting America's Food Supply

For FY 2010, FDA proposes an increase of \$259.3 million for food safety activities. This increase includes \$164.8 million in budget authority and \$94.4 million in three new user fees: Food Inspection and Registration User Fees, Reinspection User Fees related to food facilities, and Export Certification User Fees for food and feed products.

To outline the key investments with the new FY 2010 resources:

- FDA will hire 678 additional full-time equivalent staff to expand programs and activities that protect America's food supply.

- FDA will fund the cost of living pay adjustment for FDA professionals that conduct food product program activities. (+\$12.9 million)
- FDA will increase domestic and foreign risk-based inspections, conduct more audits of controls designed to prevent contamination, establish three additional high volume laboratories, and conduct more food safety intervention, sampling and surveillance through our Office of Regulatory Affairs. The FY 2010 budget increase will allow FDA to hire more than 220 additional investigators. When fully trained and deployed, the new investigators will enable FDA to conduct the following additional field activities, based on the FY 2010 increases in budget authority and user fees proposed in this initiative:
 - 4,000 additional domestic food safety inspections
 - 100 additional foreign food and feed inspections
 - 20,000 additional import food and feed field exams
 - 3,000 additional samples for analysis in FDA laboratories.(+\$101.7 million)
- FDA will begin to implement a new strategic framework for an integrated national food safety system. Under this framework, FDA will build and expand existing programs and relationships with its regulatory partners: our federal, state, local, tribal and territorial partners. This will allow FDA to increase information sharing and improve the quantity and quality of food safety data that FDA receives from its food safety partners. (+\$14.6 million)

- FDA will work with all stakeholders to better ensure that food protection is built into the complete lifecycle, from food production to food consumption. (+\$6.0 million)
- FDA will improve its understanding of food and feed vulnerabilities and risks. This will include improving FDA's ability to use baseline data to measure the impact of food safety efforts and to track the status of foodborne illnesses in the United States. Achieving a better understanding of vulnerabilities and risks will allow FDA to adjust food and feed safety priorities and ensure that food programs achieve the best health benefit for the American public. (+\$4.0 million)
- FDA will improve its ability to detect signals of contamination and also improve its ability to collect and analyze adverse events for food and feed. (+\$9.8 million)
- FDA will respond more quickly to foodborne outbreaks and will improve its ability to quickly trace contamination to its source. (+\$12.2 million)
- FDA will improve risk communication during a food safety event so that the public can respond promptly to FDA alerts and protect themselves from harm.
(+\$1.6 million)
- FDA will increase the capacity of the Food Emergency Response Network by establishing three new laboratories for chemical analysis. (+\$3.3 million)

- FDA will further develop an integrated genomic data base for Salmonella and conduct research to reduce knowledge gaps. (+\$0.8 million)
- FDA will charge fees to cover the cost of reinspecting FDA-regulated facilities that fail to meet good manufacturing practices or other FDA requirements.
(+\$15.3 million)
- FDA will charge fees to cover the cost of issuing export certificates for food and feed. (+\$4.2 million)
- FDA will upgrade and integrate information technology systems, including systems that we use to screen, sample, detain and take enforcement actions against imported food and feed products that violate FDA safety standards.
(+\$49.9 million)

Safer Medical Products

There are three components of FDA's Safer Medical Products initiative. Like the food safety initiative, the first component relies on the principle of supply chain safety and security. The goal is to protect American patients from contamination or other manufacturing flaws that could harm patients. The second component will address patient-product interactions that generally do not relate to manufacturing flaws. FDA will improve the safety of human drugs, vaccines, blood and other biological products, medical devices, and animal drugs and medicated feed by hiring additional safety experts to analyze adverse events associated with these products. FDA will also identify safety problems through active surveillance of third

party healthcare data. The third component focuses on increasing access to affordable generic drugs, granting FDA new authority to approve generic biologics, and allowing Americans to buy safe and effective drugs from other countries.

For FY 2010, FDA proposes an increase of \$166.4 million for medical product safety. This increase includes \$119.9 million in budget authority and \$46.6 million for Generic Drug User Fees and Reinspection User Fees related to medical product facilities.

To outline the key investments with the new FY 2010 resources:

- FDA will hire 346 additional full time equivalent staff and expand programs and activities related to medical product safety.
- FDA will fund the cost of living pay adjustment for FDA professionals that conduct medical product program activities. (+\$16.7 million)
- FDA will improve the safety and security of foreign and domestic sources of ingredients, components, and finished products throughout the supply chain—including their eventual use by patients in America—through increased inspections and through activities conducted by the Office of Regulatory Affairs. (+\$12.2 million)
- FDA’s Center for Biological Research and Evaluation (CBER) will hire additional safety experts for its blood, tissue and vaccine safety teams. This will strengthen the ability of safety teams to analyze emerging safety threats. CBER

will modernize blood, tissue and vaccine standards to improve product safety and quality. CBER will also provide increased training to support product development and improve product safety. (+\$5.7 million)

- CBER will develop new screening tests for emerging blood-borne diseases. CBER will review vaccine and tissue data to identify safety signals. CBER will also develop quality systems for product testing and lot release of biological products and will provide additional support for safe development and manufacturing of cell, gene and tissue therapies. (+\$2.3 million)
- CBER will provide increased technical support to FDA field operations as they conduct foreign and domestic inspections of biologic products. (+\$1.3 million)
- FDA's Center for Devices and Radiological Health (CDRH) will implement safety requirements related to the FDA Amendments Act (FDAAA). To support FDAAA safety activities, CDRH will collect and analyze adverse event information related to medical devices from pediatric hospitals. CDRH will conduct a pediatric medical trials workshop to address unmet pediatric device needs. CDRH will improve device safety by hiring experts to evaluate software used in medical devices. CDRH will hire staff to provide technical support to FDA foreign offices and to support FDA field operations as they conduct foreign and domestic device manufacturing inspections. (+\$9.5 million)

- CDRH will develop new safety tests and strengthen postmarket safety reviews of ophthalmic medical devices. CDRH will also develop and validate new clinical trial methods for imaging devices. (+\$1.7 million)
- FDA's Center for Drug Evaluation and Research (CDER) will evaluate how best to use Risk Evaluation and Mitigation Strategies to minimize drug risks and promote safe drug use. (+\$3.4 million)
- CDER will also conduct research on bioequivalence standards for generic forms of novel products such as metered dose inhalers, topical drugs and complex dosage forms such as liposome products. (+\$2.5 million)
- CDER will identify and improve enforcement against Internet sites that expose consumers to unapproved products and fraud. (+\$2.0 million)
- FDA's Center for Veterinary Medicine will conduct scientific and risk evaluation of animal biotechnology products, regulate approvals for new animal biotechnology products, and coordinate U.S. and foreign regulation on animal health issues within FDA's jurisdiction. (+\$0.5 million)
- FDA's National Center for Toxicological Research (NCTR) will conduct studies to analyze the consequences of human exposure to nanoscale materials. These

studies will provide the scientific basis for issuing FDA guidance on the safe and effective use of nanoscale particles in the products that FDA regulates.

(\$1.0 million)

- NCTR will develop noninvasive techniques to better understand the risks of anesthetic use in children. (+\$0.2 million)
- FDA will develop policies to allow Americans to buy safe and effective drugs from other countries. (+\$5.0 million)
- FDA will provide greater access to affordable generic drugs and improve the productivity of generic drug review through a new user fee program.
(+\$36.0 million)
- FDA will strengthen the safety of the supply chain through a new user fee program to charge fees to cover the cost of reinspecting FDA-regulated facilities that fail to meet good manufacturing practices or other FDA requirements.
(+\$10.6 million)
- FDA will modernize and enhance information technology, including systems that we rely on to collect, store and analyze the large volume of regulatory, scientific, and risk based information necessary to assure the safety and effectiveness of medical products. (+\$40.1 million)

Legislative Initiatives for Safe, Affordable Drugs

The budget request supports greater access to affordable generic drugs, recommends new authority to approve generic biologics, and allows Americans to buy safe and effective drugs from other countries.

In the coming years, patents will expire on more than a dozen blockbuster brand-name drugs that account for tens of billions of dollars in prescription spending annually. Generic competition for these drugs will likely be very strong. It is imperative that FDA have the resources to ensure the safety, quality, and therapeutic equivalence of generic drugs and allow Americans to benefit from the savings from lower cost generic drugs. To meet this priority, FDA's FY 2010 budget includes \$36 million in new user fees to support drug review for new generic products.

The Administration will also accelerate access to affordable generic biologics by working with Congress to establish a workable and scientifically sound regulatory pathway for approval of generic versions of biologic drugs.

Current Law User Fees

FDA user fee programs facilitate enhanced premarket review performance and the timely availability of safe and effective medical devices, human and animal drugs, biological products, and other FDA-regulated products. The FY 2010 budget request includes increases

of \$74.4 million for existing user fee programs, as authorized by law. The increases expand the available options for treating and curing diseases and other health problems.

Annual Cost of Living Adjustment

FDA can only achieve its mission and fulfill its responsibilities if it has sufficient resources to pay the scientific, professional, and technical staff required to conduct food safety and medical product safety programs. The ongoing experience with the outbreak of 2009-H1N1 Flu Virus demonstrates the importance of maintaining pay rates to attract and retain top-notch scientists and professionals. The FY 2010 budget includes \$29.5 million for the annual cost of living adjustment for employees in FDA's food and medical product programs.

Delivering the FDA mission is a personnel-intensive effort. FDA performs its public health mission through a highly trained professional workforce. Personnel and related costs account for 78 percent of FDA's annual expenditures. To maintain its strong science and regulatory capability, FDA must employ, train, develop, and retain highly trained professionals to perform the mission critical work of protecting public health.

Infrastructure to Support FDA Operations

Like the annual cost of living adjustment, the FY 2010 budget increase to pay higher rental costs and other costs for the buildings that FDA occupies will allow FDA to perform its public health mission. FDA's FY 2010 budget contains \$14.0 million in budget authority for increased GSA rent and related costs of the space that we occupy.

FDA 2009-H1N1 FLU VIRUS RESPONSE

FDA plays a vital role in preparing for, and responding to, public health challenges such as the one presented by the 2009-H1N1 Flu Virus. FDA is part of the team led by the Department of Health and Human Services.

Since the beginning of the 2009-H1N1 Flu Virus outbreak on Thursday, April 23, FDA has worked closely with HHS, our sister HHS agencies, other U.S. government agencies, the World Health Organization (WHO), and foreign governments.

As soon as we became aware of the 2009-H1N1 Flu Virus outbreak, I asked Dr. Jesse Goodman, FDA's Acting Chief Scientist and Deputy Commissioner for Scientific and Medical Programs, to coordinate and lead FDA's efforts on the 2009-H1N1 Flu Virus. Dr. Goodman leads an incident management approach that includes seven substantive teams. The teams are cross-cutting and include staff from across FDA as needed. The teams include: Vaccine Team, Antiviral Team, In Vitro Diagnostics Team, Personal Protection Team, Blood Team, Shortage Team, and the Consumer Protection Team. These teams work with the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), other HHS agencies, and national and international partners.

FDA's management approach to respond to the outbreak is flexible and likely to change over time. It has already changed in response to evolving events.

Emergency Use Authorizations

Under the Project Bioshield Act of 2004 (Public Law 108-276), Congress added section 564 to the Federal Food, Drug, and Cosmetic Act. Section 564 establishes criteria that permit the FDA Commissioner to issue an Emergency Use Authorization, following a determination and declaration of a public health emergency. An Emergency Use Authorization allows the use of an unapproved product or of an approved product for an unapproved use.

On Sunday, April 26, 2009, the Acting HHS Secretary issued a determination that a public health emergency exists involving 2009-H1N1 Flu Virus. In the days that followed, the Acting Secretary issued declarations under section 564 justifying emergency use of certain antivirals, in vitro diagnostics, and personal respiratory protection devices.

Based on the Acting Secretary's actions, and using our authority under the Project BioShield Act, on April 27, 2009, FDA issued four Emergency Use Authorizations in response to requests from the CDC. Two of these Emergency Use Authorizations extend the circumstances in which two FDA-approved drugs, Relenza and Tamiflu, can be used to treat and prevent the 2009-H1N1 Flu Virus. A third Emergency Use Authorization makes available a test for diagnosing infection with the virus. The fourth authorizes the emergency use of certain personal respiratory protection devices, specifically certain disposable

respirators certified by CDC's National Institute for Occupational Safety and Health, known as N95 respirators. The emergency use authorization for N95 respirators only relates to requirements under the Federal Food, Drug and Cosmetic Act, not other requirements such as the standards for safety in the workplace administered by the Department of Labor. On May 2, FDA issued a fifth Emergency Use Authorization for a first tier test for patient specimens with suspected 2009-H1N1 infection. Taken together, these authorizations allow CDC and state and local responders to take actions that help meet the medical and public health threat.

All seven of the FDA teams are working to ensure a comprehensive response to the 2009-H1N1 Flu Virus. I would like to highlight FDA's work in two areas, developing a vaccine and protecting consumers.

Developing an H1N1 Vaccine

FDA's Vaccine Team is working to facilitate the availability of a safe and effective vaccine to protect the public from the 2009-H1N1 Flu Virus as soon as possible, in the event that a vaccine is needed to protect the American public. Members of the team are working collaboratively with CDC and other partners in efforts to grow and genetically engineer the 2009-H1N1 Flu Virus in the laboratory for possible use in a vaccine. FDA is also beginning to prepare reagents that will be essential to help manufacturers produce and test the vaccine.

In a related development, on May 6, FDA announced that it approved a new manufacturing facility to produce influenza virus vaccines. The facility, located in Swiftwater, Pennsylvania, is owned and operated by Sanofi Pasteur and will greatly increase vaccine production

capability. The facility is approved for seasonal influenza vaccine production, and the facility could also be used to produce vaccine against the new 2009-H1N1 influenza strain.

As we work to develop a safe and effective vaccine, FDA is also participating in the analysis of whether an H1N1 Flu Virus vaccine should be deployed later this year to protect the American public. Decisions about whether to deploy an H1N1 vaccine will be independent of the decision to produce a vaccine.

Protecting Consumers

FDA's H1N1 Flu Virus consumer protection team works to safeguard consumers from fraudulent and potentially dangerous FDA-regulated products or other promotions for products that claim to diagnose, prevent, mitigate, treat, or cure the 2009-H1N1 Flu Virus. Deceptive products are being sold over the Internet take advantage of the public's concerns about H1N1 influenza and their desire to protect themselves and their families. The fraudulent products come in all varieties and could include dietary supplements or other food products, or products purporting to be drugs, devices or vaccines.

FDA has an aggressive strategy to identify, investigate, and take action against individuals or businesses that wrongfully promote products in an attempt to take advantage of this current public health emergency. FDA issued warning notices to more than 30 Internet sites that we believe are wrongfully promoting products to consumers. We have also invited the public to voluntarily report suspected criminal activity, Websites and other promotions for products that claim to diagnose, prevent, mitigate, treat or cure the 2009-H1N1 influenza virus.

FY 2006 Influenza Pandemic Funding

As I mentioned in my May 7, 2009 testimony, during FY 2006 this subcommittee had the foresight to appropriate \$20 million to FDA for pandemic influenza preparedness in an emergency supplemental appropriation. FDA invested pandemic influenza supplemental funding in three key areas that are critical to America's preparedness for an influenza pandemic: strengthening our capacity to expedite the development of flu vaccines, conducting essential monitoring and inspection of flu vaccine manufacturers, and conducting FDA-wide pandemic planning and preparedness activities. This \$20 million supplemental became part of FDA's base resources and allowed FDA to achieve a higher state of preparedness for events like 2009-H1N1 Flu Virus outbreak. Because of the work begun in 2006, FDA is better prepared for today's response to the 2009-H1N1 Flu Virus.

CONCLUSION

Our FY 2010 budget of \$3.2 billion will allow FDA to strengthen the safety of the food supply and to anticipate and address safety signals that emerge from the use of the drugs, biologics and medical devices that FDA regulates. Our FY 2010 increase will allow the dedicated professionals at FDA to help ensure that Americans benefit from a safe and wholesome food supply and from medical products that sustain and improve their lives. Achieving our mission is possible because of your support for the work of the Food and Drug Administration.

Thank you very much for the opportunity to testify. I welcome your ideas and your questions.