



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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**STATEMENT
OF
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**FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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

UNITED STATES SENATE

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I. Introduction

Good morning Chairman Pryor and Members of the Subcommittee, I am Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration (FDA). Thank you for the opportunity to appear before you today to discuss FDA's fiscal year (FY) 2015 Budget request. I would like to thank the Subcommittee for its past investments in FDA, which have helped us meet the demands of our broad and increasingly complex mission. For FY 2015 FDA is requesting \$4.74 billion, which represents a modest increase to address our highest priorities.

II. FDA Plays a Vital Role in an Increasingly Complex Environment

FDA is a science-based, regulatory Agency with a public health mission. Our Agency is charged with an enormous and significant task: to promote and protect the health of the American people, and increasingly, people all over the world. This includes efforts to ensure the safety, effectiveness, and quality of human and animal drugs, biologics, medical devices, and other medical products, as well as the safety and wholesomeness of four-fifths of our nation's food supply. It also includes working to foster the scientific innovation that will lead to tomorrow's products, and more recently, regulating the manufacturing, marketing, and distribution of tobacco products while seeking to reduce the use of tobacco products by minors.

The medical and food products we regulate have the potential to sustain life, reduce suffering, treat previously untreatable diseases, and extend lives. They are products that range from those used daily, such as fruits and vegetables or medicines to treat other chronic conditions, to products that may be needed once in a lifetime, such as an automated external defibrillator, to save someone's life. FDA has a duty to make safe

and effective products available as quickly as possible, while at the same time protecting citizens from products that may cause harm. It is this dual responsibility to public health that highlights the critical nature of the Agency. The ability to prevent the outbreak of a foodborne illness is very different but just as important as fast approval of a life-changing medical product. The health of the citizens of the United States depends on both.

Many of the products we regulate are more complex than ever. Gone are the days when treating patients was based on signs and symptoms alone. Rapid developments in science and technology are making it possible for physicians to truly personalize diagnosis and treatment. For example, just last May, FDA approved two drugs for melanoma along with companion diagnostic tests that use the genetic characteristics of the patient's tumor to help determine whether a patient will respond. The ability to evaluate remarkable products like these requires FDA to stay ahead of the curve.

Scientific innovation is also driving remarkable advances in medical device development. For example, we are working hard to support the development of an artificial pancreas which would represent a huge advance in the management of diabetes. Products such as these offer great promise in reducing the burden of disease by tailoring interventions more effectively.

In addition to becoming more complex, the environment in which FDA protects and promotes the health and well-being of the American people is becoming increasingly global. Over the last ten years, the number of imported shipments of FDA-regulated products has skyrocketed – in 2013, approximately 29 million shipments of imported food and medical products entered the United States. Imports account for 50 percent of fresh fruits and 20 percent of fresh vegetables, 80 percent of seafood, and 40 percent of

the drugs on our shelves. Most of this increase in imports is coming from countries with limited regulatory oversight

A strong FDA is critical not only to the domestic and global public health, but also to the U.S. economy, the balance of trade, and homeland security. The implementation of FDA's mission promotes innovation in the industries it regulates and affects costs in the broader economic and health care systems. Innovations not only create jobs, they position the domestic industries to compete in the global marketplace. Our history shows that when there is public trust in FDA's oversight, our industries flourish. Conversely, when food and medical products cause serious harm, the result is often severe economic damage across the industry involved – to offenders and non-offenders alike.

III. We Moved Forward on Many Fronts This Year

This past year's accomplishments on behalf of public health have been as substantial as any in FDA's recent history. There were too many significant actions to list here; below are just a few of the highlights of FY 2013.

- Food Safety. FDA published seven major proposed rules that form FSMA's central framework for moving to a comprehensive 21st Century food safety system. These science-based standards are designed to keep produce safe, implement modern preventive controls in human and animal food/feed facilities, modernize oversight of imported foods, guard against intentional contamination, and help ensure the safe transport of food and feed. In August, FDA issued a final rule defining "gluten-free" for food labeling, to help the estimated 3 million Americans who have celiac disease make food choices with confidence to better

manage their health. In November, we took further steps to reduce the amount of artificial *trans* fat in processed foods

- Nutrition. FDA recently proposed updating the Nutrition Facts label on food packages to reflect new public health and scientific evidence about nutrition, obesity, and chronic disease. Serving size requirements would be updated to reflect the amounts of food people are actually eating and drinking, and the format of the label would be refreshed, with key parts of the label such as calories, serving sizes, and percent daily value displayed more prominently.
- Breakthrough Therapies. In 2012, FDASIA created a powerful new tool to facilitate the development and review of “breakthrough therapies.” In 2013, FDA’s Center for Drug Evaluation and Research (CDER) received 121 requests for breakthrough therapy designation, and has already granted the designation to 36 potentially innovative new drugs that target both rare (epidermolysis bullosa, and Waldenstrom’s macroglobulinemia) and common (cystic fibrosis, breast cancer, and hepatitis C) conditions.
- Drug Shortages. In 2013, FDA helped to prevent 170 drug shortages. In October, the Agency issued a “Strategic Plan for Preventing and Mitigating Drug Shortages,” outlining the Agency’s strategy for improving its response to early notifications of a potential shortage, as well as identifying long-term initiatives that the Agency is considering or that stakeholders could take to address the underlying causes of shortages, such as opportunities for drug manufacturers to promote and sustain quality manufacturing. FDA also issued a proposed rule that, if finalized, will expand the early notification requirements.

- Unique Device Identification. On September 20, 2013, FDA announced the final rule requiring that most medical devices distributed in the United States carry a unique device identifier (UDI). The system will be phased in over several years, focusing first on the highest-risk medical devices. Once fully implemented, the UDI system will enhance the ability to quickly identify devices when recalled, improve the accuracy of adverse event reports, and help prevent counterfeiting and diversion. It will also offer a clear way of documenting device use in electronic health records and clinical information systems.
- Drug Quality and Security Act. On November 27, 2013, the Drug Quality and Security Act (DQSA) was enacted. Within days of enactment, issued three draft guidances for industry related to how the Agency intended to implement the new requirements. As of March 6, 2014, 32 firms had registered as outsourcing facilities – and inspections have begun, focusing first on facilities that have not had a recent FDA inspection. A list of the facilities and information about what it means to register as an outsourcing facility is publicly available on FDA’s website and is updated weekly.
- New Molecular Entities. Last year marked another strong year for FDA approvals of novel new drugs (NMEs). In 2013, FDA approved 27 NMEs – about the same as the 26 average annual approvals since the beginning of this decade. Some of these medications offer new hope to patients who previously had few or no treatment options. Examples of NMEs approved this year include a “game-changing” virtual cure for Hepatitis C, a drug that attacks breast cancer cells like a “smart bomb” reducing damage to normal tissues, and four new drugs to treat

diabetes. Of the NMEs approved in 2013, one-third were identified by FDA as “first-in-class,” and one-third were approved to treat rare or “orphan” diseases. Almost three-quarters (74 percent) of the NMEs approved by FDA in 2013 were approved first in the United States before any other country.

- Public Health Preparedness. We continued our efforts in 2013 to work with U.S. government partners and product developers to facilitate the development and availability of medical countermeasures for responding to potential public health emergencies. This has resulted in the recent approval of several medical countermeasures to help protect the Nation from chemical, biological, radiological and nuclear threats, including an inhalational anthrax therapeutic, a botulism antitoxin, a next-generation portable ventilator, and several influenza diagnostic tests. For emerging infectious disease threats, such as the avian influenza A (H7N9) virus and the Middle East Respiratory Syndrome coronavirus (MERS-CoV), FDA issued Emergency Use Authorizations for diagnostic tests using new authorities created under the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013. In addition, FDA recently approved several seasonal influenza vaccines – including a vaccine manufactured using modern cell culture techniques and a vaccine made through recombinant DNA technology.
- Family Smoking Prevention and Tobacco Control Act. In 2013 we made significant progress in implementing the Family Smoking Prevention and Tobacco Control Act. We signed contracts with state and local authorities to enforce the ban on the sale of regulated tobacco products to children and teens. By January 31, 2014, approximately 258,300 inspections were conducted

resulting in about 13,400 Warning Letters being issued, and over 1,200 Civil Monetary Penalties were imposed. We launched a significant research initiative, and issued the first-ever determinations on whether certain new tobacco products were or were not “substantially equivalent” to products already on the market. Just last month we launched a national public education campaign aimed at reducing the number of young people who use tobacco products.

In addition we took important steps towards fighting the development of antibiotic-resistant bacteria, decreased the backlog in medical device applications, and exceeded our new ADUFA and AGDUFA performance goals. Our emphasis on product quality is accelerating, with the Center for Devices and Radiological Health (CDRH)’s Voluntary Compliance Improvement Program pilot, and CDER’s new Office of Pharmaceutical Quality.

FDA accomplished all this and more while costing Americans only about \$8 per person a year. FDA is a bargain -- the products regulated by FDA account for more than 20 percent of every consumer dollar spent on products in the U.S., but individual Americans only pay about 2 cents a day to ensure that those products are safe and effective. This is a small price to pay for life-saving medicines approved as fast or faster than anywhere in the world, confidence in medical products that are relied on daily, and a food supply that is among the safest in the world.

IV. FDA’s FY 2015 President’s Budget Request

The fiscal year (FY) 2015 President’s Budget Request for FDA is \$4.74 billion for the total Program Level, which is \$358 million above the FY 2014 Enacted level. Of the total funding, \$2.58 billion is budget authority and \$2.16 billion is user fees. The FY

2015 increase consists of \$23 million in budget authority and \$335 million in user fees. The growth in user fee funding stems from several new programs, along with increased collection authority for many of FDA's existing programs.

We are mindful of the larger pressures on the federal budget, and have focused our request on the most urgent needs for FY 2015. Serious product safety and quality lapses in recent years have caused serious public health situations, most notably those involving foodborne illness and the compounding of unsafe drugs, so FDA is seeking increases in order to strengthen oversight of the pharmacy compounding industry and to support food safety and implementation of FSMA. In addition, FDA must continue to advance medical countermeasures and maintain the integrity of operations and infrastructure, and is asking for small increases to support these activities as well.

Medical Product Safety

The FY 2015 Budget provides a program level of 2.6 billion, which is \$61 million above the FY 2014 Enacted level, to continue core medical product safety activities across FDA programs. Within this amount, FDA will invest \$25 million in budget authority to enhance pharmacy compounding oversight activities in FY 2015, which will significantly benefit public health and safety. It also includes \$4.6 million for proposed International Courier user fees.

In 2012, a fungal meningitis outbreak associated with a compounded sterile drug resulted in 64 deaths and over 750 cases of infections across 20 States. Since September 26, 2012, 28 firms ceased sterile operations. Since that time, FDA has learned of at least 20 compounders that may have shipped contaminated drug products, and has received at least 125 reports of adverse events, including serious infections, associated with drugs

produced by compounders. As of March 6, 2014, FDA is aware of 40 recalls by compounding pharmacies, including some recalls overseen by FDA, and others overseen by a State. . These statistics demonstrate the magnitude of the problems with compounders' sterile operations.

FDA intends to continue risk-based, follow-up, and for-cause inspections of compounding pharmacies to identify pharmacies with deficient sterile compounding practices. FDA is also encouraging purchasers of compounded products to buy from registered outsourcers, a new category of compounder created by the DQSA and that will be subject to enhanced FDA oversight and federal quality standards.

Food Safety

The FY 2015 Budget provides a total program level of \$1.48 billion for food safety, which is \$263 million above the FY 2014 Enacted level. Within this amount, FDA will invest \$24 million in budget authority to further advance recent gains in food safety modernization through implementation of FSMA. A majority of the increase is the result of new user fees, including \$60 million in Food Facility Registration and Inspection fees, and \$169 million in Food Import fees.

With the requested increase in budget authority, FDA will be able to develop guidance and provide technical assistance for industry, provide technical support for FDA inspectors, and begin to implement training for FDA and state inspectors. If the proposed user fee revenue is authorized and appropriated, FDA will be able to undertake the wider array of activities needed to fulfill the food safety modernization goals of FSMA, including retraining of the federal and state inspection force, training and technical assistance for small and mid-size growers and processors, and building the modern

import oversight system mandated by FSMA. The implementation of the broad preventive controls framework mandated in FSMA will reduce instances of foodborne illness seen recently as a result of *E. coli* O157 contamination of pre-packaged salads, *Salmonella* and *Listeria* contamination of cheese products, and *Listeria* contamination in cantaloupe, and minimize the market disruptions and economic costs inflicted by illness outbreaks and significant contamination incidents.

Infrastructure

Within the funding for medical product and food safety, and medical countermeasures, FDA requests a program level increase of \$5.8 million for infrastructure. Infrastructure includes GSA Rental Payments, Other Rent and Rent Related costs, and White Oak Consolidation.

Current Law User Fees

Within the funding requested is a \$75.4 million increase for current law user fees, which will allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry. The user fees collected will support the review and surveillance of human and animal drugs, medical and mammography devices, food and feed, color additives, export certification, and tobacco products. The request includes statutorily mandated increases for many existing programs, which will expand the available options for treating and curing diseases and will fund strategies to prevent and reduce the use of tobacco products by young people and reduce the burden of illness and death caused by tobacco products. Some of the amount requested supports infrastructure costs associated with current law user fee programs.

IV. Conclusion

FDA's oversight of our food and medical products supply is indispensable to the health and well-being of every American. We carry out our broad public health responsibilities effectively and with few taxpayer dollars – even as those responsibilities are expanding as a result of new legislation, technological advances, and a globalized marketplace. Our FY 2015 Budget targets our spending efficiently, on programs that are essential to providing Americans with the safe foods and effective medical products they expect. We look forward to answering your questions today and to working with you in the coming year.