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 HOUSE OF REPRESENTATIVES

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I. Introduction

Good morning, Chairman Aderholt 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 the President's fiscal year (FY) 2016 Budget Request for FDA. 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 2016, FDA is requesting $4.9 billion to support our essential functions and priority needs.

On a personal note, I'd like to thank the Committee for its continuing commitment to these issues during my six years as Commissioner. As you know, I will be stepping down at the end of this month, so this will be my final appearance before this Subcommittee. I will miss the constructive dialogue we have enjoyed over the years to address matters of mutual concern. My decision to leave FDA was not an easy one, as there is always more to be done, and I remain dedicated to the vital work and mission of the Agency. But, I am confident that I leave the Agency stronger and more effective than when I began, and better positioned to meet the challenges of the 21st century. And, I know that with your commitment, FDA will continue to move forward in fulfilling its critical responsibilities to the American public.

II. FDA Plays a Vital Role in America's Public Health System

FDA is a science-based regulatory agency charged with an enormous and significant public health mission: to promote and protect the health of the American people. Our goal in carrying out our mission is to ensure the safety, effectiveness, and quality of medical products, as well as the safety and security of the vast majority of our

nation's food supply. The Agency also regulates the manufacturing, marketing, and distribution of tobacco products and seeks to reduce the use of tobacco products by minors. FDA plays a unique and vital role in facilitating the availability of safe and effective products, while also protecting citizens from products that may cause harm.

FDA's important work promotes innovation in the industries it regulates, creates jobs, and positions domestic industries to compete in the global marketplace. History shows that when there is public trust in FDA's oversight, the industries we regulate flourish. Conversely, when food and medical products cause serious harm, the result is often severe economic damage across the industry involved.

Congress has recognized the dynamic role that FDA plays and the increasingly complex and global environment in which we operate. As a result, FDA has been tasked with a multitude of new responsibilities and authorities in the public health arena, including the Drug Quality and Security Act (DQSA); the FDA Safety and Innovation Act (FDASIA); the FDA Food Safety Modernization Act (FSMA); and the Family Smoking Prevention and Tobacco Control Act. While FDA has stepped up to meet these essential public health challenges under current funding levels, successful implementation of these new authorities requires significant additional resources.

III. FDA Has a Proven Track Record of Success

FDA's accomplishments over the past year have been as substantial as any in the Agency's recent history. Across the areas of food safety and nutrition, medical product safety and innovation, tobacco control, and other areas of our work, our accomplishments demonstrate our ability to respond to evolving needs and opportunities – including the embrace of new approval pathways, innovative technologies, and cutting-edge science.

Moreover, especially given the importance of our work, 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 per day to ensure that those products are safe and effective. This is a small price 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.

FDA's Innovations Improve and Protect America's Food Supply

Food Safety Modernization. FDA published seven major proposed rules and, based on stakeholder input, four supplemental proposals to implement FSMA. The Agency also completed 8,607 high-risk food establishment inspections in FY 2014, exceeding the target of 6,507 inspections by 32 percent. FDA also released a FSMA Operational Strategy Document that focuses on how we can implement FSMA by prioritizing prevention, voluntary compliance, risk-based oversight, and expanded collaboration across the food safety community.

Genome-Based Food Pathogen Detection. FDA established GenomeTrakr, the first national pilot network of whole genome sequencers (WGS) for pathogen identification to trace where outbreaks start – even at the level of a single farm or food facility – based on whole bacterial genomes. FDA is already utilizing this innovative technology, such as in the identification and closure of a cheese facility connected to a *Listeria monocytogenes* outbreak, to take quicker, yet more targeted, action and likely prevent a larger number of illnesses.

Nutrition Labeling. On December 1, 2014, FDA published two final rules requiring that calorie information be listed on menus and menu boards in chain

restaurants and similar retail food establishments, and on signs for vending machines. Americans eat and drink about one-third of their calories away from home, and this is an important public health step to help consumers make informed choices for themselves and their families. FDA also proposed important updates to the Nutrition Facts Label, such as more prominent calorie declarations, to bring it up to date with current diet and health concerns.

Promoting Innovative Medical Product Development

Medical Product Application Review. FDA's rapid drug reviews and use of expedited programs has helped provide meaningful new products to U.S. patients. In 2014, FDA approved 51 new molecular entities and biological products, more than in any single year in almost 20 years. Among the 2014 approvals are treatments for cancer, hepatitis C and type-2 diabetes, as well as the most new drugs for "orphan" diseases since Congress approved the Orphan Drug Act more than three decades ago. Seventeen of the new approvals are "first in class" therapies, which represent new approaches in the treatment of disease, and almost two-thirds were approved first in the U.S. In addition, important biological products approved in 2014 include a number of groundbreaking vaccines for meningitis B, the flu, and certain types of Human Papillomavirus.

From 2011 to 2014, the median number of days for FDA to approve investigational device exemption (IDE) submissions decreased from 442 to only 101, cutting the time it takes to bring a new medical device to market by nearly a full year. In addition, improvements to the de novo program have resulted in a 70 percent reduction in the average total time to decision for these submissions.

These developments are a testament not just to expanding understanding of human biology and the molecular mechanisms that drive the disease process, but also to FDA's innovative approaches to help expedite development and review of medical products that target unmet medical needs, while adhering to the established standards for safety and efficacy.

Abuse-Deterrent Opioid Medications. FDA continues to make progress in its efforts to help reduce prescription drug abuse, while remaining committed to ensuring that patients with pain have appropriate access to medicines they need. In 2014, FDA approved three new opioids with abuse deterrent features to give physicians effective new treatment options with less risk of abuse. To help encourage the development of more abuse-deterrent formulations of opioids, the Agency hosted a public meeting to discuss scientific and technical issues related to development and assessment of abuse-deterrent opioid products and is working diligently to finalize its guidance on this topic this spring. We also approved a new dosage form of naloxone with an autoinjector to allow for the emergency treatment of opioid overdoses in community settings.

Drug Quality and Security Act**.** During FY 2014, FDA conducted over 90 inspections of compounding facilities, issued warning letters, and worked with DOJ to bring criminal and civil enforcement actions. The Agency also continued to develop a framework to implement the new law. FDA has issued numerous policy documents to implement Federal Food, Drug, and Cosmetic Act section 503A, as amended by the DQSA, as well as section 503B, as added by DQSA, concerning outsourcing facilities. In addition, on February 23-24, 2015, FDA held the first meeting of the Pharmacy

Compounding Advisory Committee to provide advice on scientific, technical, and medical issues concerning drug compounding.

FDA Works to Reduce the Impact of Tobacco on the Public Health

Family Smoking Prevention and Tobacco Control Act. FDA published the proposed "deeming rule" to extend FDA's tobacco authority to additional tobacco products, including e-cigarettes, and is reviewing over 135,000 comments the Agency received in preparation of the final rule. Public health-based regulation of these products can help reduce the death and disease toll from tobacco use. FDA also closely monitors retailers' compliance with restrictions on tobacco product marketing and sales to youth – and takes strong corrective action when violations occur. In addition, the Agency launched a major public education campaign targeting youth about the dangers of tobacco products, with the goal of reducing or preventing use in future generations.

FDA Tackles Emerging, Unique, and Complex Challenges

Combating Antimicrobial Resistance. FDA has made important strides in confronting the growing resistance of some bacteria to antimicrobial drugs. In 2014, FDA approved four novel systemic antibiotics to expand the pipeline of new medical products available for identification, prevention, treatment, and/or cure of bacterial infections. In contrast, only five new antibiotics had been approved in the previous ten year period. In addition to working on the human medical product side, FDA has made great progress on its initiative to fight antimicrobial resistance by restricting the use of medically important antimicrobials in food animal production to legitimate animal health purposes. All 26 drug companies with affected products have committed in writing to remove animal production uses from their FDA-approved labels and bring the remaining

medical uses under veterinary supervision by the end of 2016. FDA is working closely with USDA, producers and drug companies to support implementation of these important changes and gather data to verify their effectiveness in reducing antimicrobial resistance.

Ebola Outbreak Response. In response to the Ebola epidemic in West Africa, FDA has acted aggressively to help expedite the development and availability of investigational medical products for Ebola, including by: providing regulatory advice and guidance to commercial developers and U.S. agencies; helping to facilitate access to investigational medical products for patients with Ebola when requested by clinicians; and authorizing the use of eight investigational diagnostic tests for Ebola under FDA's Emergency Use Authorization authority. We have collaborated extensively with the World Health Organization, NGOs and several international regulatory counterparts to support international response efforts. FDA has also monitored for fraudulent products that claim to prevent, treat, or diagnose Ebola and took action, as warranted, to protect public health.

IV. FDA's FY 2016 President's Budget Request

The FY 2016 President's Budget Request for FDA is $4.9 billion for the total program level, which is $425 million above the FY 2015 Enacted Level. Of the total funding, $2.7 billion is budget authority and $2.2 billion is user fees. The FY 2016 increase consists of $148 million in budget authority and $277 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. Mindful of the larger pressures on the federal budget, we have focused our request on the most urgent needs for FY 2016.

Food Safety

The FY 2016 Budget provides a total program level of $1.5 billion for food safety, which is $301 million above the FY 2015 Enacted level. This total includes a $109.5 million increase in budget authority and a $191.8 million increase in user fees. The proposed budget authority increase will be almost exclusively dedicated to implementation of FSMA.

FDA's successful implementation of FSMA is essential to reducing foodborne illness, bolstering public confidence in the food supply, and maintaining U.S. leadership on food safety internationally. With FDA under court order to issue many key FSMA regulations in 2015, FY 2016 is an absolutely crucial year for the investments needed to ensure timely, effective, and non-disruptive implementation. FDA's collaborative implementation strategy requires a modernized approach to inspection and enforcement, focusing on food safety outcomes and encouraging voluntary compliance. To be successful, this strategy requires retraining and retooling of FDA and state inspectors. In keeping with FSMA's theme of collaboration and partnerships, the largest single portion of the budget authority will go to the states to better integrate, coordinate, and leverage federal and state food safety efforts.

FDA's FSMA philosophy of "educate before and while we regulate" also requires investing in guidance, education, and technical assistance for industry to support their compliance efforts, especially among smaller scale farmers and manufacturers. FDA will deliver this assistance through collaborative alliances and training partnerships.

Finally, FDA must make crucial investments in FY 2016 to implement the new import safety system mandated by Congress. This includes FSMA's Foreign Supplier

Verification Program requirements, which are the foundation for FSMA's new import safety system and key to helping assure a level playing field of food safety standards and oversight for U.S. consumers and industry.

The investments FDA can make with the FY 2016 budget authority request will enable the agency to maintain momentum toward timely and successful implementation of FSMA. Without these investments, implementation will be disrupted and delayed.

Medical Product Safety and Innovation

The FY 2016 Budget provides a program level of $2.7 billion, which is $84.8 million above the FY 2015 Enacted Level, to continue core medical product safety activities across FDA programs.

With part of this increase, FDA will support implementation of three initiatives of FDASIA: the Unique Facility Identifier; Unique Device Identifier; and Electronic Biological Product Application Submission programs. FDA will also continue contributing to the National Strategy for Combating Antibiotic-Resistant Bacteria (CARB) to help ensure the judicious use of medically-important antimicrobials in food-producing animals; to evaluate new antibacterial drugs for patient treatments; to streamline clinical trials; and to develop better vaccines for antibiotic resistant organisms. An increase of approximately $1 million will support continued implementation of new compounding oversight authorities and the evaluation of sunscreen ingredients. Finally, $10 million of the increase will help FDA adapt its regulatory process to developments in "precision medicine." Funding this initiative will permit FDA to keep pace with scientific advancements and help speed the development of promising new diagnostics and treatments that will enable precision medicine to be successful.

Rent and Facilities

Within the Budget Request, FDA requests a program level increase of $38.9 million for infrastructure. FDA has a growing workforce of 16,000 FTEs, resulting in rising operational rent costs. Without the requested funding, FDA cannot simultaneously support this expanded workforce, critical facility needs, and its increasing programmatic responsibilities. The request also includes funding for a feasibility study to address FDA's expanded workforce and facility needs on the White Oak campus.

Current Law User Fees

A $78.5 million increase is requested for current law user fees, which will help FDA fulfill its mission of protecting the public health by assuring the safety and efficacy of human and veterinary drugs, biological products, and medical devices, assuring the safety of our nation's food supply, and advancing the public health by helping to speed innovations that will offer safer, more effective and higher quality medical products.

V. Conclusion

FDA's public-health mission is indispensable to the health and well-being of every American. We carry out our broad public health responsibilities effectively and with relatively few taxpayer dollars, despite dramatic expansions in our responsibilities as a result of new legislation, scientific and technological advances, and a globalized marketplace. Our budget request plans for efficient spending on programs that are essential to providing Americans with the safe foods and safe and effective medical products they expect. We look forward to answering your questions today and to working with you in the coming year.