DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

**STATEMENT**

**OF**

**ROBERT CALIFF, M.D.**

**COMMISSIONER OF FOOD AND DRUGS**

**FOOD AND DRUG ADMINISTRATION**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE**

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

**UNITED STATES SENTATE**

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## I. Introduction

Good afternoon Chairman Moran, Ranking Member Merkley, and Members of the Subcommittee, I am Dr. Robert Califf, 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) 2017 Budget Request for FDA. I would like to thank the Subcommittee for its past investments in FDA, most recently for FY 2016 funding, which have helped us meet the demands of our increasingly complex and diverse mission at home and abroad. For FY 2017, FDA is requesting $5.1 billion to support our essential functions and priority needs.

I am honored to have been chosen by the President and confirmed by Congress to lead the FDA. Thank you all for your willingness to share with me and my predecessor, Dr. Ostroff, your perspectives on ways the FDA can better serve the American people. My first priority as Commissioner is to strengthen and better support the FDA's talented and dedicated workforce. I will focus on the need to carry our critical priorities over the finish line. FDA's ambitious agenda currently includes implementation of the Food Safety Modernization Act, finalizing the Tobacco Deeming Rule, facilitating the development of medical counter measures, and making progress on the Combating Antibiotic Resistant Bacteria (CARB) initiative, and the Precision Medicine Initiative. I also want to further development of the FDA's science base that informs decision-making across drugs, medical devices, food safety, and more. FDA's work on the groundbreaking Sentinel system, supported by your mandate, demonstrates the power of the use of our new national digital infrastructure. We are increasingly able to rapidly develop evidence to inform FDA's decision-making, and giving us the ability to act quickly on safety issues, rather than having to wait for a new study every time a safety issue arises. I look forward to continued dialogue with you to gain support for FDA's important public health mission.

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

FDA is a science-based regulatory agency charged with an enormous and significant responsibility: to promote and protect public health. Our goal in carrying out our mission is to ensure the safety, effectiveness, and quality of human and veterinary

drugs, biological products and medical devices; the safety of dietary supplements; as well as the safety and security of the vast majority of our nation's food supply. Additionally, the Agency regulates the manufacturing, marketing, and distribution of tobacco products, and seeks to reduce the use of tobacco products by minors and the detrimental effects of tobacco on the general population. FDA's relatively new authority to oversee tobacco products, as well as the Agency's heightened role in the food supply, has tremendously increased FDA's responsibilities and opportunities to promote and protect public health.

FDA plays a unique and vital role in facilitating the availability of safe and effective products and treatments, while also protecting people from products that are promoted using false claims or may cause harm. FDA works with a broad array of stakeholders including industry, other government agencies, and the public, in order to achieve the best possible outcomes.

Congress has recognized the dynamic role that FDA plays and the increasingly complex and inter-connected 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 (TCA). While FDA has stepped up to meet these essential public health responsibilities under current funding levels, successful implementation of these new authorities requires 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, given the importance of our work, FDA's budget is a bargain for American taxpayers. The products regulated by FDA account for more than 20 percent of every consumer dollar spent on products in the U.S.; individual Americans only pay about 2 cents per day to support oversight to help ensure that those products are safe and

effective. This is a small price for life-saving medicines and treatments approved as fast as 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 Innovations Improve and Protect America's Food Supply**

Food Safety Modernization. Congress enacted FSMA in response to dramatic changes over the last 25 years in the global food system and in our understanding of foodborne illness and its consequences, including the realization that foodborne illness is a significant public health problem, is preventable, and is costly. FDA is modernizing our food-safety system, using quality systems and analytics to prevent foodborne illness before it occurs. These food system changes and the new FSMA mandates require transformative change in how FDA does its work.

FDA published seven major proposed rules in 2013 and, after much stakeholder input, five of those became final in 2015: the preventive controls rules for human and animal food, the produce safety rule, the foreign supplier verification program rule and the third-party accreditation rule. These groundbreaking final rules will help food manufacturers, produce farmers, and food importers take steps to prevent food safety problems. The produce safety and foreign supplier verification rules, for the first time, establish enforceable science-based safety standards for the growing and harvesting of produce and make importers accountable for conducting risk-based verification to determine that imported food meets U.S. safety standards. In addition, as part of these rulemakings we are establishing a program for the accreditation of third-party certification bodies to conduct food safety audits of foreign food facilities.

Nutrition. Americans eat and drink about one-third of their calories away from home. To this end, on December 1, 2014, FDA carried out a congressional mandate to publish 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. In 2015, FDA issued two guidances to help affected industries implement the menu labeling rule, one aimed at small businesses, and the second providing more detailed advice on how the rule works in the context of a diverse industry. FDA also listened to stakeholders and extended the compliance date for menu labeling.

**V. Promoting Innovative Medical Product Development**

Medical Product Application Review. This year, through application of our efficient and flexible approval process, we again were able to approve a broad range of innovative medical products and treatments with the potential to make a positive difference in the lives of patients. These products included a new generation of targeted therapies that will be used to treat or prevent diseases that affect only a few individuals and additional products that will be used to treat diseases that affect large portions of the population. They involve novel approaches to therapy developed from the rapidly accelerating science of genomics and even new product categories, such as our approval of the first biosimilar biological product.

We also enhanced engagement of patients in the development, approval and evaluation process. And we continued to make progress in our application of some of the most cutting edge areas of science and technology, such as precision medicine, which is helping us to advance biomedical understanding and provide targeted therapies that will allow us to better treat individual patients and diseases.

FDA's rapid drug reviews and use of expedited programs for certain categories of drugs haves helped provide meaningful new products to U.S. patients quickly without compromising our safety and efficacy standards. In 2015, FDA approved 56 novel new drugs. These approvals included four new treatments for patients with multiple myeloma, two new drugs for patients with heart failure, and another robust year of approvals of drugs for rare or "orphan" diseases.

In 2015, we also approved several important vaccines, including one for serogroup B meningococcal disease, the first seasonal influenza vaccine to contain an adjuvant (intended for people 65 years and older), and a new indication for anthrax vaccine to prevent disease following exposure to anthrax – the first vaccine to receive an approved indication based on the Animal Rule, which allows efficacy data generated in animal models to serve as the basis for the approval of medical countermeasures against chemical, biological, radiological or nuclear threats when human efficacy studies aren't ethical or feasible. We also saw the approval of several innovative devices that will make a positive difference in the lives of patients, including a device that extends the survival

time of patients with brain cancer, and a transcatheter pulmonary valve that can be placed in certain patients with congenital heart disease, without requiring open heart surgery.

We have also seen important progress in our device review program. Our average time to reach decisions on premarket approvals (PMAs) has dropped 36 percent since 2009. And in 2015, FDA approved 79 novel devices, the most since the start of the Medical Device User Fee Program. Most importantly, enhanced flexibility and an efficient approval process have come without lowering our standards for safety and efficacy.

An important component of all of the medical product reviews is the use of interaction between product developers and our expert staff at FDA at critical points in product development. Our expert review teams "see it all" and therefore play an important role in providing guidance and feedback to companies that is enabling more effective product development. The enhanced communication and growing expertise within FDA promotes earlier exit of products that will not pass muster and a much higher rate of approval on first review for products that do meet our rigorous criteria for safety and efficacy. The success of this approach highlights the need for talented people at the FDA—as medical products become more sophisticated the need for talented reviewers at FDA will grow.

Opioid Medications. Prescription opioid analgesics are an important part of modern pain management; however, misuse and abuse of these products contribute to a serious and growing public health epidemic. After extensive internal review, the Agency has issued a detailed action plan that includes a new framework for considering the consequences of addiction, abuse and misuse not only on the individuals for whom the treatment is intended, but also upon the larger society that is affected by abuse and misuse. Additional post-market requirements for studies have been added. FDA continues to support development of antidotes to treat overdose, abuse deterrent formulations, non-addictive pain relievers, and medication-assisted treatments for dependence.

Biosimilars. FDA has been developing its biosimilar program, an effort which led to the approval of the first biosimilar biological product in March 2015. And there are more applications in the pipeline. To prepare, FDA has produced a variety of guidances

in this area. FDA remains committed to strengthening the biosimilars pathway by continuing to work diligently to provide development phase advice to sponsors and evaluate applications submitted under this abbreviated pathway, and issue additional guidance as needed to provide clarity to stakeholders.

Next Generation Sequencing and Precision Medicine. Our strengthened focus on regulatory science is helping to drive innovation. One illuminating example is our growing ability to apply the sophisticated technologies of next generation sequencing and precision medicine. FDA today is better prepared for and more engaged than ever in facilitating the development of these new technologies (as well as new uses for older technologies), with reasonable assurance of safety and effectiveness. These efforts help to achieve more precise diagnosis or treatment, through the development and review of state of the art diagnostics and drugs that are targeted to an individual's genetic blueprint. We continue to move forward on the White House's Precision Medicine Initiative to advance biomedical understanding by leveraging genomic advances, health information technologies, and new methods of analyzing large volumes of data. Recently, we launched FDA's precisionFDA web platform, a cloud-based portal that has already succeeded in enabling scientists from industry, academia, government and other partners to come together to foster innovation and develop the science behind next-generation sequencing. PrecisionFDA provides a clear example of regulatory science stimulating innovation.

We are also working to refine clinical trial design and statistical methods of analysis to create more efficient studies that take advantage of advances in genomics and information technology to provide more rapid, less expensive and more reliable answers about medical products. For instance, we continue to support collaborative efforts in clinical trials, such as the NIH's Lung-MAP protocol for lung cancer.

Drug Quality and Security Act. FDA is implementing the DQSA and working diligently to reduce the risks of compounded drug products in the U.S. Since enactment of the DQSA, FDA has conducted over 230 inspections of compounders, many in response to reports of serious adverse events, product quality problems, or other complaints. FDA continues to identify serious problems during these inspections, including contamination in purportedly sterile drugs and in the sterile compounding

environment, and other insanitary conditions that put patients at risk. FDA has also investigated serious adverse events associated with non-sterile drugs that were superpotent, as much as 1000 times the labeled strength. As a result of these inspections, FDA has taken aggressive action to protect the American public from compounded drugs that could cause harm. Since enactment of the DQSA, FDA has issued over 75 warning letters to compounders and has worked closely with the Department of Justice on civil and criminal enforcement actions. Many compounders have recalled all of their sterile drugs and ceased sterile operations at FDA's recommendation. FDA has also been working diligently to implement sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (as added by DQSA) by publishing draft and final policy documents while taking into consideration stakeholder input. FDA has issued 12 draft guidance documents, five of which were finalized, a proposed rule, and a draft memorandum of understanding related to interstate distribution of drugs compounded by state-licensed pharmacies and federal facilities. FDA has consulted with the Pharmacy Compounding Advisory Committee, convened three intergovernmental working meetings with state representatives, and has actively engaged with more than 50 stakeholder groups during listening sessions. FDA will continue to work diligently on draft and final policy documents to implement the DQSA, and to engage with stakeholders on our proposed policies. We have also put out a draft guidance on the appropriate use of compounded products for animals. Even though not specifically included in the legislation, stakeholders have asked us to clarify our policy on animal drug compounding for years, which we are now doing.

## VI. FDA Works to Reduce the Impact of Tobacco on the Public Health

Family Smoking Prevention and Tobacco Control Act.

FDA closely monitors retailers' compliance with restrictions on tobacco product marketing and sales to youth – and takes strong corrective action when violations occur. In late 2015, FDA issued its first ever no-tobacco-sale-orders to retailers who continually violate the law. In addition, the Agency launched a second major public education campaign, "Fresh Empire," targeting multicultural youth with powerful messaging about

the dangers of tobacco products, all as part of the effort to reduce the number of young people who use tobacco products.

Also for the first time, in 2015, FDA authorized the marketing of eight new tobacco products under the premarket tobacco application pathway. We have made significant progress and have taken many steps to improve timeframes in reviewing marketing applications. Our actions include increasing scientific staffing; providing feedback to industry; issuing multiple guidance documents; holding meetings with industry; hosting webinars; sending letters and other communications to clarify expectations for industry; and, finally, establishing performance goals that include timeframes for review of Substantial Equivalence (SE) reports for products that are not on the market.

**VII. FDA Tackles Emerging, Unique, and Complex Challenges**

Combating Antibiotic-Resistant Bacteria (CARB). FDA has made progress on each of the five goals of the President's National Action Plan for CARB. These goals are to slow the emergence of resistant bacteria and prevent the spread of infections caused by resistant bacteria; strengthen national one-health surveillance efforts to combat resistance; advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria; accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines; and improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control and antibiotic research and development.

On June 2, 2015, both human and animal health stakeholders came together in support of a one-health antibiotic stewardship forum hosted by the White House. Additionally, CDC and FDA launched the antimicrobial-resistant isolate bank of over 160 isolates composed of collections of carbapenem-resistant Enterobacteriaceae and other multi-drug resistant bacteria of antibiotics that are approved for use in food-producing animals. FDA also is working closely with CDC and USDA on a data collection plan to verify the changes in on-farm antibiotic use that are expected to result from FDA's initiative to eliminate animal production uses (e.g., growth promotion) of medically important antibiotics in food-producing animals and to require veterinary

oversight for therapeutic uses of these drugs for the treatment, control or prevention of a specifically-identified disease. In support of this effort, FDA finalized changes to the Veterinary Feed Directive (VFD) regulation in June 2015 which took effect in October 2015. FDA also published a proposed rule in May 2015 that includes additional reporting requirements regarding the sale and distribution of antibiotics that are approved for use in food-producing animals.

Responding to Ebola. In a world where disease knows no borders, FDA's response to the Ebola outbreak in West Africa demonstrated how we used our scientific expertise and regulatory authorities to the fullest extent possible to address a tragic public health crisis of global impact. Our response involved collaborating with partners across government, pharmaceutical and diagnostic companies, international organizations like the World Health Organization, and our international regulatory counterparts. We played a key role in encouraging the appropriate study of and expediting the availability of diagnostic tests, investigational therapeutics, and vaccines, as well as investigating fraudulent products marketed to diagnose, prevent and treat Ebola. And many FDA commissioned corps officers of the U.S. Public Health Service served on the front lines, deployed in a humanitarian mission to provide care to patients at the Monrovia Medical Unit in Liberia, one of the West African nations that were hard hit by the outbreak.

Medical Countermeasures. FDA's Medical Countermeasures mission is to promote national health and security by facilitating the development and availability of medical countermeasures (MCMs) such as drugs, biologics, vaccines, devices, and diagnostic tests. These products are used to diagnose, prevent, or treat conditions stemming from an attack with a chemical, biological, radiological, or nuclear material, or a naturally occurring emerging infectious disease, such as Ebola or the most recent outbreak of Zika virus in the Americas. Sixteen diagnostic tests have been authorized under FDA's Emergency Use Authorization authority in response to emerging infectious disease threats. MCMs have been approved for anthrax, plague, botulism, Acute Radiation Syndrome, and pandemic influenza, and several others are on an accelerated development track. FDA finalized the guidance "Product Development Under the Animal Rule"; to date, eleven drug and biologic products have been approved under this

regulation. We also established a publicly available microbial DNA reference database to help advance diagnostic test development.

## VIII. FDA's FY 2017 President's Budget Request

The FY 2017 Budget Request for FDA is $5.1 billion, an increase of eight percent or $358.3 million compared to the FY 2016 enacted level. The budget includes $2.7 billion for budget authority – an increase of one-half of one percent or $14.6 million compared to FY 2016; $2.3 billion for user fees[1] – an increase of twelve percent or $268.7 million compared to FY 2016. Mindful of the larger pressures on the federal budget, we have focused our request on the most urgent needs for FY 2017.

Food Safety. The FY 2017 Budget provides $1.5 billion for food safety, an increase of $211.6 million above the FY 2016 level. The budget includes $1.3 billion for budget authority – an increase of one percent or $18.4 million compared to the FY 2016 Enacted budget – and $209.8 million for user fees – an increase of $193.2 million compared to the FY 2016 Enacted budget. The budget includes an increase of $25.3 million to improve food and feed safety through continued FSMA implementation.

FDA's FY 2017 budget will build on the FY 2016 investments and focus on two strategic areas of investment that are essential to the success of FSMA: state capacity to partner with FDA and the safety of imported food. The FY 2017 budget request for state capacity building will be used primarily to fund state cooperative agreements and grants that support the essential state role in implementing FSMA's new produce safety rule requirements.

Additionally, the FY 2017 request will enable FDA to continue progress toward implementing the multifaceted new import safety system mandated by Congress, including the Foreign Supplier Verification Program (FSVP) rule, foreign food facility and produce inspections, and partnerships with foreign governments. Under the FSVP rule, importers must verify that imported food has been produced in a manner consistent with FSMA's new standards for produce safety and preventive controls.

[1] Includes proposed Food Facility Registration and Inspection, Food Import, International Courier, Cosmetics, and Food Contact Substance Notification fees and proposed increase to the Export Certification fee.

The user fee request for food safety includes $105.3 million in new resources to support the new import safety system and $61.3 million in new resources to further modernize the FDA inspection program.

Medical Product Safety and Innovation. The FY 2017 Budget request for FDA for Medical Product Safety and Availability is $2.8 billion, an increase of $116.2 million above the FY 2016 Enacted level. The request includes $1.3 billion for budget authority – an increase of 0.2 percent or $3.2 million compared to the FY 2016 Enacted level, $1.4 billion for user fees – an increase of three percent or $38.0 million compared to the FY 2016 Enacted level, and $75.0 million in new mandatory funding for the Vice President's Cancer Moonshot. With this request, FDA will improve medical product safety and innovation in five key areas: evaluating Precision Medicine-based diagnostics, improving the safety of compounded drugs, combating antibiotic resistant bacteria, supporting animal drug and medical device review, and improving cancer diagnostics and treatments.

FDA requests $4 million in FY 2017, an increase of $2.0 million above FY 2016 for Precision Medicine. With the majority of the increase, FDA will help advance Precision Medicine by establishing the National Medical Device Evaluation System (NMDES) to identify patients who benefit most or do not benefit from specific types of devices. FDA will also continue to invest in precisionFDA, which provides a crowd-sourced, cloud-based platform to advance regulatory science around NGS-based analytical tools and datasets.

FDA requests $18 million, an increase of $1 million above FY 2016, to enhance oversight of human drug compounding through increased inspection and enforcement activities, policy development and implementation, and state collaboration and coordination.

For CARB, FDA requests $42 million to support continued work to address public health concerns associated with antimicrobial drug use in animals and to better protect antibiotic effectiveness for both human and animal populations. FDA will work in collaboration with USDA to support efforts to monitor antimicrobial drug use in food-producing animals.

FDA requests an additional $2.9 million to support ongoing activities within the

Animal Drugs Review Program and the Devices Program to achieve enhanced and predictable review performance that meets industry, congressional, and public expectations. The increased funding requested will enable FDA to continue to meet premarket animal drug review requirements by having the necessary review staff to carry out these activities. The request will also support ongoing review activities in the Devices Program to meet statutory requirements for the review of medical device applications.

In FY 2017, FDA requests $75.0 million in mandatory resources as part of the Vice President's Cancer Moonshot in order to accelerate progress in cancer – to reduce the number of people who develop cancer and to improve the outcome for those who do. In order to support the dramatic increase in the number, complexity, and strength of cancer diagnostics and therapeutics, FDA will establish an Oncology Center of Excellence to streamline collaboration across FDA's Human Drugs, Biologics, and Devices and Radiological Health Programs and to interface more effectively with the NIH and the clinical environment. A highly effective interface will be needed to deal with the proliferation of highly effective but complex combinations of targeted drug and biological therapies and immunotherapy, driven by sophisticated diagnostic testing and monitoring devices. There is hope that many forms of cancer will be cured or changed to chronic diseases.

Infrastructure, Rent and Facilities. The FY 2017 Budget Request provides an increase of $3 million over the FY 2016 Enacted level, for a total of $12 million, for urgent facility investments that will provide functioning offices and labs across the country to ensure FDA can execute its Food Safety and Medical Product Safety mission. This $3.0 million increase will be used to address repairs, improvements and mission support needs at FDA's owned laboratories and other critical owned facilities across the U.S.

## IX. Conclusion

FDA's public-health mission is indispensable to the health and well-being of every American. We carry out our broad and expanding 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. The FY 2017 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.