



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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**STATEMENT
OF
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**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 SENATE

June 20, 2017

Good morning Chairman Hoeven, Ranking Member Merkley, and Members of the Subcommittee, I am Dr. Scott Gottlieb, 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) 2018 Budget request for FDA.

First of all, I would like to thank you all for your continued support of FDA. FDA has received strong bipartisan support throughout the appropriations process in recent years. This funding is critical to the agency fulfilling its mission. Without your support, we could not meet the critical public health challenges confronting the nation.

I am honored to have been chosen by the President and confirmed by Congress to lead FDA. As a physician, an entrepreneur, a cancer survivor, and a father, I know personally the importance of FDA's role in improving and protecting the lives of all Americans. Every person in this country is affected in one way or another by the decisions made by FDA. For this reason, I am honored and humbled to serve as FDA's Commissioner.

FDA's FY 2018 Budget requests \$5.1 billion—a nearly 10 percent (\$456 million) increase over the FY 2017 Continuing Resolution (CR) funding level. Mindful of the larger pressures on the federal budget, FDA has focused our request on the most urgent needs. The FY 2018 Budget aims to protect the public health by wisely investing taxpayer dollars, requiring industries that benefit from the FDA's review process to pay their share, and advancing regulatory and administrative efficiencies.

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

As a science-based regulatory agency, FDA's broad mission is to promote and protect the nation's public health and touches the lives of all Americans. Over \$2.4 trillion annually, roughly 20 cents of every dollar, is spent by consumers on a product that FDA regulates. These products include human and animal drugs, medical devices, biologics, such as vaccines and blood, dietary supplements, and cosmetics. Tobacco is another product within FDA's purview—the agency protects the public health of future generations by reducing tobacco use by America's children.

FDA's regulation of food is another critical part of FDA's mission. FDA works to assure that the nation's food supply is safe, sanitary, wholesome, and appropriately labeled. FDA has made great strides in promoting the safety of the foods we eat as envisioned by Congress in the FDA Food Safety Modernization Act (FSMA). Thanks to the support of this Committee and your colleagues in the House, we have been working closely with our state partners, to educate and assist industry during the implementation of FSMA's provisions. These include preventive controls for manufactured human and animal foods, sanitary transportation of our food, and as of May 30, verification that our high food safety standards have been met by foreign suppliers. FDA remains committed to working with industry to facilitate innovation to make safe and healthy food choices available to consumers.

II. FDA Has a Proven Track Record of Success, But There's More Work to Do

In the last year, FDA has helped bring new treatments, including several life-saving cures, onto the market. FDA's Center for Drug Evaluation and Research approved 22 novel drugs in 2016; approvals included the first treatment for patients with spinal muscular atrophy, a new drug to treat patients with a rare chronic liver disease known as primary biliary cirrhosis, and two new treatments for patients with hepatitis C. Additionally, 2016 marked the highest number of generic drug approvals and tentative approvals in the history of the FDA's generic drug program – more than 800 in total. In September 2016, FDA approved the first “artificial pancreas,” a medical device that automatically monitors blood sugar and provides insulin doses when needed. This device has the potential to improve the lives of roughly 1.5 million Americans living with Type-1 diabetes.

As highlighted by the above examples, FDA's collaboration with innovators brings products to the market that make a difference in the lives of all Americans. Since the creation of the first user fees in 1992, user fees have been instrumental in allowing FDA to build capacity and improve the timeliness of the medical product review process without compromising the agency's high standards. The user fee programs provide FDA with the critical and stable funding we need to hire and train the highly-qualified reviewers needed to keep pace with innovation.

However, the medical products field is ever-changing and advancing, and to ensure the agency has the critical resources needed to keep pace with this field, the FY 2018 Budget recalibrates how the agency finances our medical product review work. Calling for an increase of \$1.2 billion in user fees, the FY 2018 Budget includes a total

program level of \$3.2 billion for medical product safety investments, which is \$505 million above the FY 2017 CR level. The Budget finances the full cost of FDA pre-market review through user fees. These resources will dramatically increase the agency's capacity for pre-market review, and bring more new products to market faster than ever before.

III. Cures Implementation

The FY 2018 Budget's focus on medical products complements Congress' direction last December in passing the 21st Century Cures Act (Cures). Cures provided a dual directive to FDA—to support innovation while maintaining the evidentiary standards that provide assurance to the American public about the safety and efficacy of medical products. This includes advancing patient-focused drug development and using real-world evidence in modern clinical trial design. As a result, Cures will help FDA facilitate more patient-centered, efficient, and less costly medical product development, ultimately leading to more timely patient access to important medical products. The FY 2018 Budget requests a total of \$60 million to support this critical work, and we look forward to working with Congress, and this Committee, as FDA continues its work on implementing Cures.

IV. Promoting Innovation by Prioritizing Regulatory Efficiency

As FDA's Commissioner, part of my job is to ensure the Agency has the policies and processes in place needed to address the important public health issues of our day, as well as emerging threats of tomorrow. We must hold true to our consumer protection mission, while not hampering innovation.

The Administration is committed to the goal of reducing barriers to innovation and spurring innovation on behalf of patients. At FDA, we understand the impact our regulations have on industry and the public – which is why we have, and will continue to engage in robust dialogue with outside stakeholders to ensure our actions strike the right regulatory balance while maintaining our gold standard.

The FY 2018 Budget includes proposals designed to make sure we are taking a risk-based approach to our work and make the process for developing safe and effective medical products more efficient. By leveraging FDA’s statutory mandates, including recent enhancements made by Cures, the agency is working to reduce review times by improving processes and gaining efficiencies to the greatest extent possible. These proposals will help reduce uncertainty in medical product development by increasing engagement and early interactions with manufacturers. Improved regulatory science and policies will not only lead to more efficient approvals and increased competition that can help reduce costs to consumers, but more importantly, they will improve patient-outcomes. By streamlining clinical trials, integrating patient voice throughout the regulatory process, and promoting greater preparedness for novel and emerging public health threats, Americans will get better products, faster.

V. Prioritizing Administrative Efficiencies

In addition to regulatory efficiencies, FDA is taking a close look at all of our programs, policies, and procedures to ensure that every dollar dedicated to administrative costs is spent wisely. The FY 2018 Budget proposes the establishment of a Working Capital Fund (WCF) to support agency-wide business services. A WCF will allow FDA to operate in a more efficient and transparent business environment. Over time, this

WCF will also allow FDA to recapitalize resources to support IT infrastructure, reduce cost redundancy and improve service delivery for mission critical needs.

Dollar for dollar, FDA remains one of the smartest investments made by the American taxpayer. The FY 2018 Budget also identifies targeted reductions and program changes totaling \$127 million in budget authority while preserving core mission activities. These reductions in budget authority are targeted to certain areas where better tools and policies will allow us to do more with less, and will be coupled with policy efforts to improve the efficiency of the programs that see reductions, to make sure that we are improving our effectiveness and taking a risk-based approach to our consumer protection mission.

VI. Conclusion

Today, we are at an inflection point in public health. Cures for diseases we once believed were incurable are now within our reach. The FY 2018 Budget will protect and advance the health and well-being of every American, while providing American taxpayers the assurance that we are requiring industries that benefit from the FDA's review process to pay their share. I look forward to answering your questions today and to working with all of you going forward.