

**Statement by
Scott Gottlieb, M.D.
Commissioner of Food and Drugs, Food and Drug Administration
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. Senate**

Good morning Chairman Hoeven, Ranking Member Merkley, and Members of the Subcommittee. Thank you for the opportunity to appear before you today to discuss the President's Fiscal Year (FY) 2020 Budget request for FDA.

First, I would like to thank the Subcommittee for your continued support of the Agency. FDA has received strong bipartisan support throughout the appropriations process in recent years and FY 2019 was no different. I believe this support reflects our shared commitment to the vital role FDA has protecting and promoting the public health. The funding this Subcommittee provides is essential to the Agency fulfilling its mission. The professional staff of FDA is grateful for your support of their work and the funding increases the Subcommittee provided FDA in FY 2019.

Last year, FDA accomplished a broad array of scientific advances and regulatory actions across our broad portfolio. Our work included promoting generic drug entry as a way to foster drug competition and lower drug prices through the implementation of the Drug Competition Action Plan, a record-setting year for approvals of novel medical devices and advanced several meaningful initiatives to continue enhancing the safety of medical devices. The Agency also continued advancing food safety and nutrition, launching our Nutrition Innovation Strategy to leverage nutrition as a tool to reduce the burden of chronic disease, and we took steps to empower consumers with nutrition information by supporting retail food establishments in meeting menu labeling requirements. We also furthered implementation of the Food Safety Modernization Act (FSMA) which builds proactive safety approaches into the production of human and animal foods. With your continued support, we have more opportunity to deliver on the promises of promoting the health of the public we serve.

The funding requested in the President's FY 2020 Budget will allow the Agency to sustain its current work—protecting the safety of the food and medical products consumers use every day—and build on these efforts by requesting additional resources to make significant

progress on several important fronts; including fostering innovation and competition to bring better and more affordable products to market, promoting the development of innovative medical products, combatting the opioid epidemic, modernizing food safety and strengthening foodborne illness response, and implementing the 21st Century Cures Act (Cures).

Overall, the Budget requests \$6.1 billion in total resources for FDA—which is an increase of \$643 million or 12 percent above the FY 2019 Annualized Continuing Resolution (CR). At this total level, the Budget includes an increase of \$362 million in budget authority and an increase of \$281 million in user fees. The Budget requests considerable new resources for FDA and makes significant new investments in advancing critical areas of science, technology, and public health.

As the regulatory Agency responsible for ensuring the safety and effectiveness of more than \$2.5 trillion worth of products used by consumers, I remain steadfast that these funds are critical investments in our public health agency.

I. Efforts to Advance Safe and Effective Medical Products

The FY 2020 Budget request for medical product safety is \$3.8 billion, an increase of \$428 million above the FY 2019 Annualized CR, which includes increases of \$316 million in budget authority and \$112 million in user fees. A few examples of the new medical product initiatives this Budget request supports are described below.

A. Transform Medical Device Safety, Cybersecurity, Review, and Innovation

FDA has been improving policies and processes to address scientific advances and enhance the safety of medical devices. These improvements are critical to protect patients and foster innovation. FDA's fragmented information technology systems are not well-suited to support these activities. The Budget requests \$55 million for an initiative to build an integrated knowledge management system and portal for medical devices to enable safety issues to be monitored, and effectiveness to be evaluated, across the total life cycle of the device and to build out our digital health program. These capabilities will better leverage pre-existing and new data in near real time. This modernization effort is essential for implementing FDA's new approaches for digital health technologies, breakthrough devices, use of real-world evidence and medical device cybersecurity.

B. Medical Countermeasures

FDA works with partners at all levels of government—local, state, territorial, tribal, federal, and international—to support medical-countermeasure-related public health preparedness and response efforts. This includes working closely with federal partners through the Public Health Emergency Medical Countermeasures Enterprise to build and sustain the medical countermeasures programs necessary to respond effectively to chemical, biological, radiological, and nuclear (CBRN) threats and emerging public health threats, such as pandemic influenza, as well as with the Department of Defense to support the development of medical products needed to protect American military personnel. In FY 2018, FDA approved 28 medical countermeasures, including the first drug with an indication for treatment of smallpox.

The Budget includes \$128 million for medical countermeasure activities, of which \$31.5 million is for the Medical Countermeasure Initiative, an increase of \$7 million above the FY 2019 Annualized CR level. This investment will increase FDA capacity to facilitate the development and availability of medical countermeasures to respond to CBRN and emerging infectious disease threats by furthering the establishment of clear, scientifically supported regulatory pathways for medical countermeasures, filling critical scientific gaps, and advancing platform and manufacturing technologies for medical countermeasures.

C. Integrated Pathogen Reduction of the Blood Supply

Advancing the continued safety of U.S. blood supply through new safety innovations is a critical public health priority for FDA. The Agency currently works to prevent transmitted infections through a combination of blood donor screening and laboratory testing methods. Pathogen reduction technologies, however, are a potentially more efficient method of decreasing the risks posed by viral and other pathogens that may be found in blood. These technologies are currently available for platelets and plasma, but with this new funding, FDA would work to promote innovation and expand their use to improve the protection of our blood supply.

The Budget requests \$20 million to pilot this technology as a tool that could help reduce the risk of transmission of contaminating viruses and other microorganisms from Whole Blood and still allow its subsequent separation into various blood components. This pathogen reduction technology could eventually help protect the blood supply from existing and emerging pathogens and, if successful, could potentially reduce or eliminate certain existing blood donor screening and testing requirements. It is possible that if this technology were incorporated broadly, it could

enhance national security by enabling a blood supply that would be safe in the face of a wide variety of emerging pathogens. It may also deliver these protections for a potentially lower cost than those associated with current screening and testing methods.

D. Compounding

FDA's compounding program—including implementation of the Drug Quality and Security Act—is a priority for the Agency. We understand that compounded products serve a critical role for many patients across the country and we are committed to develop new policies for outsourcing facilities, including policies to improve the quality of outsourcing facilities' compounded products. We are also helping address providers' needs for supplies of non-patient-specific compounded medications (office stock). For example, with the new resources provided by Congress in FY 2019, we plan to establish a Compounding Center of Excellence to provide training on good manufacturing practices for outsourcing facilities and develop a specialized group of investigators who would focus on outsourcing facility inspectional activities. By engaging with outsourcing facilities and states, we can help the domestic outsourcing facility adhere to the quality standards needed to protect patient health and support sector growth.

The Budget builds on our efforts and requests \$76 million to support compounding activities. Of this total, \$14 million will be used to catalyze the development of policies and regulations for the outsourcing facilities, including advancement of the list of bulk drug substances that outsourcing facilities may use in compounding and current good manufacturing practice guidance and regulation specific to outsourcing facilities. The activities supported by this funding would give outsourcing facilities tools to better meet healthcare providers' and patients' needs for compounded drugs.

II. Efforts to Advance Food Safety

The FY 2020 Budget request for food safety is \$1.4 billion, an increase of \$67 million above the FY 2019 Annualized CR, which includes an increase of \$38 million in budget authority and \$29 million in user fees. A few highlights of the Budget request are described below.

A. Advancing FSMA

As part of our ongoing implementation efforts related to FSMA, the Budget proposes allocating an increase of \$16 million above the FY 2019 Annualized CR level to provide inspections through the state cooperative agreement programs. These additional resources are

essential to the successful implementation of FSMA and are key to protecting public health by ensuring that manufacturing and processing facilities comply with the new FSMA requirements.

B. Strengthening Response Capabilities for Foodborne Outbreaks

Efficient global markets for food production and distribution allow American families access to a wide range of wholesome and affordable food choices that can improve their health. We want to provide Americans the benefits from access to a highly diverse food supply, while reducing risks from foodborne illnesses.

In order to strengthen our response capabilities to foodborne disease outbreaks by improving our capacity to detect early signals associated with foodborne illness and shortening response timelines once human or animal food contamination is detected, the Budget requests an increase of \$16 million above the FY 2019 Annualized CR level. In FY 2017 and FY 2018, FDA's Coordinated Outbreak Response and Evaluation network evaluated nearly 120 potential human food safety outbreak incidents per year. That is nearly double what was reviewed in FY 2015 and FY 2016. The increase requested in the Budget will allow the Agency to add new staff and resources to enhance signal detection, response to outbreaks, and post-response evaluations. FDA will also add staff to oversee its recall process and make the recall process timelier.

C. Promoting Innovation and Emerging Technology While Maintaining Product Safety

Innovations in plant and animal biotechnology offer tremendous opportunities for advancing public health. Promising new technologies have the potential to improve human and animal health, animal well-being, food productivity and food security. FDA will continue to facilitate the safe development of these emerging technologies by investing in continued enhancements to our review capabilities for biotechnology products and other novel products, assessing these products in a risk-based manner to provide predictable commercialization pathways that can foster product innovation and market access in a safe and timely way, and improve consumer nutrition. To these ends, the Budget proposes a new \$28 million user fee for Innovative Food Products, which FDA intends to develop in collaboration with industry and other stakeholders. The Budget also requests an additional \$8 million in budget authority to improve review times and eliminate unnecessary burdens to industry related to the premarket safety reviews of animal food ingredients.

III. Tobacco

The Budget requests \$100 million in new tobacco fees, and includes manufacturers and importers of deemed tobacco products, including electronic nicotine delivery systems, and certain other products within the FDA's tobacco user fee assessments. E-cigarettes, in particular, represent an increasing share of the tobacco marketplace. The new resources will support the FDA in its continued efforts to create a modern regulatory framework for the appropriate oversight of e-cigarettes and in taking continued steps to reduce youth use of all tobacco products. One of our most important public health efforts is to continue standing up a framework to make sure we can put e-cigarettes through an appropriate series of regulatory gates, and aggressively confront youth use of these products to make sure children do not become addicted to nicotine.

IV. Opioids

One of my highest priorities as FDA Commissioner is combatting the ongoing crisis of opioid addiction. The FDA has changed its approach to the opioids crisis and is taking a much more aggressive approach to regulatory action. At the FDA, we've committed to taking more rapid action in the face of new threats, like the growing prevalence of illicit fentanyl that's contributing to overdose deaths, or the continued prevalence of prescriptions being written for durations of use that are too long for the clinical circumstances for which they're intended. We've changed the way we're tackling these issues and stepped up our intervention when it comes to opioids. Going forward, we're going to be looking at the potential for evaluating the comparative benefits and risks of new opioids relative to other opioids already on the market. We've raised the question of whether there should be such a standard for new opioid approvals to offer some advantage over the existing armamentarium. We plan continue to evaluate this concept as we work to modernize the FDA's framework for assessing the risks and benefits of opioid drugs. FDA is focusing its efforts in the following four priorities:

- Decreasing exposure and preventing new addiction,
- Supporting the treatment of those with opioid use disorder,
- Fostering the development of novel pain treatment therapies, and
- Increasing enforcement and assessing benefit-risk.

The Budget requests an additional \$55 million above the FY 2019 Annualized CR level to continue supporting the four main areas of the Agency's work. These funds will continue to

build on the tremendous financial investments this Subcommittee has provided to the Agency for our opioids work over the last two fiscal years.

V. 21st Century Cures Act

Implementation of the 21st Century Cures Act (Cures) continues to be a top priority for the Agency. Cures includes provisions that have the potential to impart far-reaching effects on scientific advancements in medical product development. The law complements many efforts underway at FDA. All of these efforts are aimed at transforming the way we support product development and maintaining FDA's gold standard for safety and effectiveness. Toward these efforts, the Budget requests a total of \$75 million to support our implementation work.

VI. Conclusion

The last year was historic for the Agency. We are diligently working on a number of fronts and the vital work we do provides Americans with better ways to improve their health and welfare, empowering consumers to make informed choices about the products they use and the foods they feed to their families. This Budget will help FDA maintain and complement our current efforts, as well as provide a renewed focus and investment in some of the Agency's and the nation's top public health priorities. I look forward to answering your questions today and the Agency looks forward to working with all of you going forward.