

**Statement by
Stephen Hahn, 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. House of Representatives**

Chairman Bishop, Ranking Member Fortenberry, and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss the President's Fiscal Year (FY) 2021 Budget (Budget) request for the Food and Drug Administration (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 2020 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 staff of FDA is grateful for your support of their work and the funding increases the Subcommittee provided FDA in FY 2020.

Last year, FDA accomplished a broad array of scientific advances and regulatory actions across our extensive portfolio, helping to improve the daily lives of Americans. Our work included continuing efforts to combat both the opioid crisis and youth-use of tobacco products, expanding efforts on medical device safety, approving a record number of generic drugs, and addressing human food and animal food safety challenges. With the Subcommittee's continued support, we will have more opportunities to deliver on the promises of promoting the health of the public we serve.

Overall, the Budget requests \$6 billion in total resources for FDA—an increase of 4.5 percent or \$265 million compared to the FY 2020 Enacted Level. This total includes \$3.3 billion in discretionary budget authority and \$2.9 billion in user fees. The funding requested in the Budget will allow the Agency to sustain its current work—protecting the safety of the food and medical products consumers use every day—and continue to build on these efforts with additional investments. Some of the additional investments include: fostering innovation, choice and competition to bring better and more affordable products to market; unleashing the power of data to strengthen science and efficient risk-based decision making; empowering consumers to make informed choices about the products they use; advancing tools for smarter food safety, and strengthening foodborne illness response; implementing tobacco regulations that protect the

American public, and making key investments in the Agency’s infrastructure. As the regulatory Agency responsible for ensuring the safety and effectiveness of more than \$2.5 trillion worth of products used by consumers, I assure you that the funds requested are critical investments.

I. Advancing Access to Safe and Effective Medical Products

The Budget request for medical product safety is \$3.8 billion, an increase of \$140 million above the FY 2020 Enacted Level, which includes increases of \$29 million in budget authority and \$112 million in user fees. The following section outlines a few examples of the medical product initiatives requested in the Budget.

A. Modernizing Influenza Vaccines

The Budget requests an increase of \$5 million across FDA for influenza preparedness activities. This initiative supports the implementation of Executive Order 13887, “Modernizing Influenza Vaccines in the U.S. to Promote National Security and Public Health,” to help make the U.S. influenza vaccine supply more robust, secure, and nimble to combat seasonal influenza and potential influenza pandemics. The increased funding will advance key FDA activities including providing scientific and technical support to advance new influenza vaccine manufacturing technologies, expanding the domestic vaccine manufacturing capacity and supporting the development and availability of other medical countermeasures (MCMs) – including antiviral drugs, therapeutics, and diagnostic tests.

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

The Budget requests an increase of \$18 million to continue building an integrated knowledge management system and portal for medical devices using modern, agile information technology systems with secure data storage. This continued investment would allow FDA to transform the Agency’s pre-market review and post-market surveillance programs, which could allow FDA to more quickly identify and address safety signals and cyber vulnerabilities. A new platform also will enable FDA to be more transparent by making additional information on medical device adverse event and malfunction reports available to the public. This system and portal will enable safety issues to be monitored along the total product life cycle of a device. Improved capability to better leverage pre-existing and new data in near-real-time is essential for

implementing FDA's new approaches for digital health technologies, breakthrough devices, use of real-world evidence, and cybersecurity. The system also has the potential to reduce review cycles which is critical to ensuring patients have timely access to innovative, safer and more effective devices. These platforms also will foster interactions between FDA and its customers, provide industry with the ability to send and track premarket submissions electronically, and give patients clearer information about the benefits and risks of medical devices.

C. Compounding

The Budget requests an additional \$4.5 million for FDA oversight of human drug compounding. FDA's compounding program aims to address the potential risks associated with compounded drugs, while preserving access to compounded drugs for patients with a medical need. To achieve sustainable success in the regulation and oversight of drug compounding, it is essential that FDA continues to establish a robust compounding program with increased capacity. The additional resources will help FDA to continue to, among other activities, strengthen the scientific framework, develop lists of bulk drug substances that may be used for compounding, bolster regulatory compliance, and expand policy development.

II. Strengthening Food Safety

The Budget request for food safety is \$1.5 billion, an increase of \$33 million above the FY 2020 Enacted Level, which includes increases of \$5 million in budget authority and \$28 million in user fees. The following section outlines a few examples of the food safety initiatives requested in the Budget.

A. Smarter Food Safety

The Budget requests an increase of \$2 million for emerging technologies related to food safety. Recognizing the rapidly changing landscape of technologies available and the growing need for FDA's engagement on how these technologies can be used to address some of our biggest food safety challenges, FDA plans to launch an initiative called the New Era of Smarter Food Safety. At the heart of this initiative is a focus on efforts to modernize track and trace capabilities that better enable FDA to track products throughout the supply chain – from the time that they are grown or manufactured, until purchased by a consumer, and back through the

supply chain – in the event of an outbreak or recall. In addition, the New Era of Smarter Food Safety initiative recognizes that as more data is captured than ever before, advanced analytical tools such as machine learning and AI could strengthen FDA’s predictive capabilities, thereby enhancing our ability to detect potential safety issues with food products and more effectively prioritize inspections and work based on modern risk prioritization techniques.

The Budget also requests an increase of \$1.2 million for continued strengthening of FDA’s response capabilities for foodborne outbreaks, building on funding increases received in FY 2019 and FY 2020. The increased number of detected outbreaks and subsequent investigations resulting from the success of Whole Genome Sequencing (WGS) of foodborne pathogens has greatly increased FDA’s workload to identify and mitigate potential food safety concerns, and we expect this trend to continue. Through additional resources, FDA is building capacity to investigate outbreaks and to prevent future contamination, which helps protect public health.

B. Proposed User Fee Program: Innovative Human Food Products User Fee

The Budget proposes a new user fee program to modernize FDA’s regulatory oversight of innovative biotechnology products and emerging human food production technologies. The proposed user fee program will authorize additional resources of \$28 million to support increased expertise and scientific review capacity for novel emerging products, including new proteins, new ingredients, and innovative new technology-driven approaches to produce cell-cultured foods. Investments in the program will also allow the Agency to better assist industry as it develops and implements new technologies in food, including biotechnology products through increased transparency, coordination, and predictability of the system.

C. Cannabis and Cannabis Derivatives

The Budget requests a total of \$5 million across FDA to support regulatory activities for cannabis and cannabis-derived substances, such as cannabidiol (CBD). FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. FDA is aware that companies market products containing cannabis and cannabis-derived compounds in ways that violate the law and may put human and animal health and safety at risk. Questions remain about the safety of these

compounds. FDA is committed to protecting the human and animal health and improving regulatory pathways for the lawful marketing of cannabis and cannabis-derived products within the Agency's jurisdiction. The additional funding requested will continue to build upon the \$2 million funding increase FDA received in FY 2020 by supporting regulatory activities, including policy development, and continued performance of existing regulatory responsibilities including review of product applications, inspections, enforcement, and targeted research.

III. Artificial Intelligence

Research and development of artificial intelligence (AI) has produced transformative technologies that have improved lives and grown innovative industries. The FY 2021 Budget requests \$10 million to increase FDA's ability to leverage new AI technologies and to build on expertise and capabilities across the Agency, including the \$2 million discussed as part of food safety for tech-enabled traceability. Further employing AI at FDA will transform device and food safety by using the vast data generated on these products.

AI in medical devices promises to drive growth of the U.S. economy and improve patient safety and quality of life. For FDA to keep pace with the innovation in these smart, new medical devices—our regulatory framework must evolve. The additional resources requested in the Budget will allow FDA to lead in the development of appropriate, consensus-based international standards to bring safe, innovative products to market in a predictable, efficient, transparent, and consistent manner. The request will also allow FDA to take steps to ensure products are designed to be customer-friendly.

Expanding the use of AI to food safety, particularly in relation to post-market surveillance and signal detection, will enhance FDA's ability to detect potential problems associated with foods, dietary supplements, and cosmetics. AI will allow the Agency to better leverage data to investigate outbreaks and potential issues with chronic, long-term consumption of food constituents/contaminants or long-term use of cosmetics and will ideally allow FDA to intervene earlier to help remove unsafe products from the market. The Agency ultimately plans to utilize this information to enhance the science that supports protecting public health.

IV. Tobacco Regulation

The Budget includes \$812 million in user fees, including a legislative proposal to increase user fee collections in support of the tobacco program by \$100 million and make Electronic Nicotine Delivery Systems (ENDS) manufacturers and importers subject to user fees. Preventing youth access to and use of ENDS remains one of the Agency's top priorities and these additional funds will help the Agency complete this work.

The Budget also proposes to reform tobacco regulation by moving the Center for Tobacco Products (CTP) out of FDA and creating a new agency within HHS to focus on tobacco regulation. This reorganization will also allow the FDA Commissioner to focus on its traditional mission of ensuring the safety of our nation's drug, food and medical products supply.

On January 7, 2020, FDA took further steps to curb youth-use of ENDS and issued a final guidance for industry prioritizing enforcement of premarket authorization requirements for flavored, cartridge-based e-cigarettes—products that we know are appealing to youth. Under this policy, companies that do not cease manufacture, distribution and sale of unauthorized flavored, cartridge-based e-cigarettes (other than tobacco or menthol) risk FDA enforcement actions. In addition, FDA intends to prioritize enforcement for all other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access, and for any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors. FDA began implementing the policy on February 6, 2020, and the Agency looks forward to continuing to work with Congress on this extremely important public health issue.

V. FDA Buildings, Facilities and Infrastructure

The Budget includes an increase of \$30 million for FDA infrastructure, which will support rent, utilities, maintenance and infrastructure improvements. The increase includes \$14 million in buildings and facilities (B&F) funding, a \$2 million increase over the FY 2020 Enacted Level. B&F funding for FDA facilities directly supports FDA's strategic policy areas by ensuring that FDA's owned offices and labs across the country function optimally and empower the FDA's workforce to carry out its public health mission. Improving the condition of site infrastructure and modernizing buildings at FDA owned locations, is essential to strengthening FDA's workforce. In FY 2021, FDA plans to use B&F funding to initiate a variety of projects

that include critical improvements and repairs, reducing maintenance backlogs, and implementing the sustainability goals established in the HHS Sustainability Implementation Plan.

VI. Combatting the Opioid Crisis

Continuing to address the opioid crisis remains one of FDA's highest priorities. FDA regulates the drugs and devices used in the treatment of pain, as well as opioid addiction and overdose, to ensure that the actions taken are in the best interest of public health. FDA is working to improve the transparency of our benefit-risk paradigm for opioids, ensuring that we continue to consider appropriately the wider public health effects of prescription opioids. FDA is taking immediate steps to reduce the scope of the opioid addiction epidemic. We continuously examine our role and policies in the regulation of opioids, drugs and devices used in pain treatment, and in opioid addiction and overdose. FDA continues to accomplish goals laid out under the HHS Opioid Strategy — the comprehensive, evidence-based plan that provides the overarching framework to strategically leverage HHS resources and expertise. As part of the HHS Opioid Strategy, FDA is committed to examining all facets of the epidemic in the United States, including opioid abuse, misuse, addiction, overdose, and death. The issue of opioid misuse and abuse remains one of our highest priorities, and we believe it is going to take carefully developed, sustained, and coordinated action by everyone involved to reduce the tide of opioid addiction and death afflicting our communities; while maintaining appropriate prescribing for patients in medical need. To assist in these efforts the Consolidated Appropriations Act, 2019 (Public Law 116-6) allocated \$47 million to support FDA's work on opioids. These funds were directed to support opioid system modeling efforts, conduct studies to improve our understanding of the opioid crisis as well as to create an Opioid Data Warehouse to facilitate large scale data integration and analysis. In addition, the Further Consolidated Appropriations Act, 2020 (Public Law 116-94) provided an additional \$8 million that will enable the Agency to continue building out the IMF facilities, develop surveillance programs, improve product targeting, increase staff, and enhance regulatory oversight. The Agency thanks the Committee for supporting our ongoing work to stem the opioid epidemic.

VII. Conclusion

The Budget request will allow FDA to sustain and build upon our current efforts to fulfill our mission to protect the public and provide a crucial investment toward America's most urgent public health priorities. I would like to thank you again for your continued support of the Agency and for the opportunity to appear before you today. I look forward to answering your questions.