For release only by the Senate Committee on Appropriations.

Statement by
Robert M. Califf, 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

Chair Baldwin, Ranking Member Hoeven, and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss the President's Fiscal Year 2023 Budget Request for the Food and Drug Administration (FDA or the Agency).

I would like to start by thanking the Subcommittee for your continued support of FDA. The Agency appreciates the funding increases provided by the Subcommittee in the FY 2022 Omnibus and your ongoing partnership is much appreciated as we execute our mission to protect and promote the public health, including our ongoing response work related to the COVID-19 pandemic. As we collectively work together as a nation to try and turn the corner of the COVID-19 pandemic, the Agency is using the lessons learned over the past two years and optimistically looking forward. FDA's talented and dedicated workforce has worked night and day for the past two-plus years to respond to the pandemic and this work has been deeply consequential for strengthening our nation's response and protecting public health. At the same time, one of the biggest lessons learned from our COVID-19 response was the overwhelming need identified by FDA leadership to modernize the Agency, including through improved data processes, IT infrastructure, and facilities, to name just a few priorities. As a private citizen who was involved in the pandemic response alongside many in industry and academia, I can attest to the fact that this sentiment was also observed by many outside the Agency as well. This effort will require significant additional funding and we look forward to providing you with the rationale for our plans to meet these needs, delineating the benefits to the public health that will accrue, and working with you to make sure the FDA remains the gold standard around the world.

FDA's FY 2023 Budget Request builds upon our FY 2022 request while also acknowledging additional future needs and challenges. Our program level request totals $8.4 billion, which represents an overall increase of approximately $2.1 billion above the

FY 2022 Enacted level. Of this total, $3.0 billion is for user fees, which is an increase of approximately $153 million above the FY 2022 Enacted level. Further, the Budget requests a total of $3.7 billion in discretionary budget authority, which is an increase of approximately $356 million above the FY 2022 Enacted level, and $1.63 billion in mandatory funding to support the Administration's plan to transform U.S. capabilities to prepare for and respond rapidly and effectively to future pandemics and other high consequence biological threats. These increases are organized into six critical areas that advance the Agency's critical activities in support of protecting and promoting the public health: (1) enhancing food safety and nutrition; (2) advancing medical product safety; (3) investing in core operations; (4) modernizing infrastructure, buildings and facilities; (5) tobacco user fees; (6) supporting Cancer Moonshot goals; and (7) pandemic preparedness.

I. Enhancing Food Safety and Nutrition

FDA's Budget requests an increase of approximately $76 million above the FY 2022 Enacted level, to support our continuing efforts to enhance human and animal food safety and human nutrition. Every American deserves access to safe and nutritious food, and our foods program staff at FDA work countless hours in partnership with federal, state, local, tribal, and territorial partners to ensure that our nation's food supply is safe. To deliver on this promise, the Budget requests funding to address health equity issues related to access to healthy and safe food. The Budget also seeks to address the rapid changes occurring in the way foods are produced, delivered, and handled. We must have modern tools and technologies to ensure the Agency's capabilities do not lag behind these sweeping changes. As a regulatory agency, if FDA cannot keep up with industry, our oversight will struggle to be effective. Modernization of our systems will enable us to prevent significant harm to the public from unsafe food.

New Era of Smarter Food Safety

The Budget requests approximately $59 million, an increase of $43 million above the FY 2022 Enacted level, for our New Era of Smarter Food Safety initiatives. The goal of these initiatives is to bend the curve of foodborne illness in this country by reducing the number of illnesses attributed to FDA-regulated human and animal foods and to protect consumers from other unsafe foods. This approach builds on the modernized food safety regulatory framework created by the Food Safety Modernization Act (FSMA), including investments in animal food

safety oversight. The requested funding would support the use of new technologies and data analytics to strengthen prevention activities, including the use of artificial intelligence, improve the ability of the Agency to rapidly trace food contamination back to the source and address the cause, and improve the efficiency and effectiveness of FDA's oversight activities.

Healthy and Safe Food for All

As a nation, we continue to need to improve not only the healthfulness of food that we put into our bodies, but also the safety of this food, including steps to reduce the presence of toxic metals and chemicals, especially in the food consumed by our most vulnerable and underserved citizens.

As a cardiologist, I have seen the effect of poor nutrition on the human body, often beginning in childhood. Additionally, I am acutely concerned with the safety and availability of infant formula as a sole source of nutrition for many infants in our country today. To make progress on these issues, the Budget requests an additional $33 million above the FY 2022 Enacted level across several initiatives that would seek to improve health equity through nutrition; to research, detect, and reduce exposure to harmful chemicals and toxins in food; and to complete additional nutrition work specific to infants, toddlers, and pregnant and lactating people.

II. Advancing Medical Product Safety

The increasing sophistication, complexity, and digitization of medical products will benefit the public greatly, but these trends also require more sophisticated regulation to facilitate innovation and prevent unintended harm. In addition to our important work on food safety and nutrition, FDA also continues to face record levels of submissions for new medical products. Despite the pandemic, in the last few years, the Agency has continued to approve a record number of safe, reliable, effective, and innovative products that will improve the length and quality of life of patients and their families. In order to maintain this essential work and uphold the high standards upon which Americans rely when reviewing these products, the Budget requests an increase of approximately $95 million above the FY 2022 Enacted level. These additional funds will help address some of the Agency's highest priorities, including post-market monitoring for the continued performance, safety, and effectiveness of approved products and addressing public health issues such as the opioid epidemic. The U.S. faces significant

challenges, including diseases and conditions, both rare and common, for which there are few or no therapies, current and future medical product shortages, and ongoing efforts to enhance patient safety. Investments in FDA medical product programs will assist on these fronts and ensure that FDA can continue to be an able, dynamic, and trusted partner to patients, physicians, and other health care professionals.

Cancer Moonshot

FDA is committed to supporting efforts to deliver safe and effective new therapies to patients, including through working to advance critical disease research, including on cancer. The Budget requests $20 million for the Oncology Center of Excellence to support the Administration's goal of reducing cancer-based death and illness as part of the Cancer Moonshot initiative. These elements of FDA's contributions to the Cancer Moonshot would include the advancement of research, external collaborations, educational outreach programs, and programs that expedite the development of oncology and malignant hematology products using an integrated clinical evaluation approach. Among other activities, resources will also enable FDA to expand efforts that facilitate approval of important cancer treatments by international regulatory authorities at the time of FDA approval and will foster harmonization of cancer treatments in other countries with the U.S. standard of care.

Supply Chain

By the time a public health emergency is declared, it is often too late to effectively prevent or mitigate shortages, and our goal as an Agency and as a nation should be to proactively intervene to assure patients and our health care providers on the front lines maintain access to the devices they need. That is why I strongly support efforts to fully fund the Budget's approximately $17 million request in additional resources for the Resilient Supply Chain and Shortages Prevention Program. Funding will complement foundational work supported with our COVID-19 supplemental dollars and will continue to build capabilities for a permanent program for U.S. supply chain resilience for medical devices. This program will help ensure that U.S. patients and the clinicians who care for them have access to the critical devices they need and help reduce U.S. dependence on devices from other nations, including masks, gowns, and other forms of PPE. The program will enhance FDA's capacity to rapidly intervene to prevent and mitigate device supply chain interruptions by developing and applying data analytics for predictive modeling, improving early signal detection and monitoring, and investing in

preventive measures to avert shortages. This funding will ultimately promote enhanced resiliency in the medical device supply chain, and in addition to helping FDA be prepared for the next pandemic, it will also allow the U.S. to be better prepared for future events that don't rise to the level of a public health emergency, such as during hurricanes and other natural disasters, as well as during steady state operations.

Complimentary to our initiative on devices, FDA is also seeking over $6 million across both the human and animal drug product areas in order to enhance supply chain surveillance in these industries as well. Investing in these key product areas at FDA will allow us to build both more technologically advanced supply chain surveillance systems beyond just devices and promote a regulatory environment that is more responsive to notifications from stakeholders and health care professionals, allowing for a nimbler and more responsive FDA.

Cybersecurity

Further, the Budget requests approximately $5 million above the FY 2022 Enacted level to address medical device cybersecurity, along with a request for new related authorities, as we continue to see cybersecurity threats to medical devices increase. Cybersecurity exploits are one of the most substantial threats faced by this nation, and the impact could be particularly harmful for our health care system, where vulnerabilities could compromise entire hospital systems or disrupt manufacturing of countless devices. Funds for our device cybersecurity initiative will be used to help address risks associated with legacy devices, such as automated insulin pumps and implantable cardiac pacemakers, and rapidly address new medical device vulnerabilities.

Opioids

I remain deeply concerned about the devastating impact of the opioid crisis on families across our country. FDA's Budget includes a requested increase of $30 million above the FY 2022 Enacted level to support the Administration's Advancing the Goal of Ending the Opioid Crisis. FDA is taking steps to address four priority areas of this epidemic: (1) decreasing exposure and preventing new addiction; (2) supporting the treatment of those with opioid use disorder; (3) fostering the development of novel pain treatment therapies; and (4) improving enforcement and assessing benefit-risk. Among other planned activities, these funds will address these priorities by supporting development of opioid overdose reversal treatments and treatments for opioid use disorder, assessing feasibility to integrate opioid Risk Evaluation and Mitigation Strategies (REMS) education into IT health systems/Electronic Health Records, expand current

initiatives to interdict shipments of opioids, unapproved foreign drugs, counterfeit pharmaceuticals, and fraudulent products, and advance the development, evaluation, and marketing authorization of digital health medical devices that help address opioid use disorder.

III. Investing in Core Operations

The Budget requests an additional $158 million above the FY 2022 Enacted level to support Agency-wide crosscutting initiatives that support both food safety and medical product safety and are complimentary to funding initiatives described earlier in this testimony. While the Agency has a number of critical needs in this area, including the ongoing need to support lab safety, address employee pay costs, and reduce animal testing using alternative methods, I would like to draw your attention to two especially critical topics— data and technology modernization and inspectional activities.

Data Modernization and Enhanced Technologies

To fulfill our ongoing and evolving public health mission, FDA requires the ability to continuously access, aggregate, visualize, and analyze multiple sources of information. Improving FDA's data processes and infrastructure is not only a good investment, but a necessary one in order to keep up with today's modern regulatory landscape. These investments are also important not just for FDA, but for our partners. FDA shares data both internally and externally and requires the ability to quickly and reliably extrapolate information to inform emergency response, as well as for standard oversight activities. FDA is requesting approximately $42 million above the FY 2022 Enacted level for Agency-wide investments in centralized data modernization.

Without additional funds to modernize our data systems, FDA will be forced to continue to use outmoded, legacy systems that do not integrate with more current systems, test reviewers will not be able to reliably keep up with expected growth in product submissions over the upcoming years, and Agency-wide efforts to leverage new data-rich capabilities like machine learning and artificial intelligence will be delayed. This translates into a slower and less effective FDA. We must make these investments now to ensure the Agency remains the gold standard for product standards and reviews.

Optimizing Inspectorial Activities

The Budget also includes a request for an increase of $24 million to optimize our inspections work Agency-wide. As you know, our ability to execute our inspections was disrupted due to the evolving COVID-19 pandemic. The requested funding will help to bring our program back on track and to improve its operational readiness. As we do this, the requested funding would support capacity building to improve data analysis, increase efficiency and productivity, and ultimately streamline and optimize end-to-end inspections across both foods and medical product areas. I am aware of this Subcommittee's interest in our inspectional work and our Budget request will help to ensure the Agency can modernize and execute our inspectional programs effectively.

IV. Modernizing Infrastructure, Buildings & Facilities

FDA's FY 2023 Budget also requests approximately $40 million above the FY 2022 Enacted level, for a total of $353 million, to ensure that FDA's offices and labs across the country are optimally functioning to enable FDA to carry out its mission. This funding is critically needed to complete projects that will improve the condition of FDA's owned buildings and site infrastructure. Of the total $40 million request, $31 million is specifically for Buildings and Facilities, an increase of $18 million above the FY 2022 Enacted level, to improve the condition of FDA's mission-critical, owned site infrastructure and buildings. Currently, the poor overall condition of FDA's owned buildings and facilities, especially its labs, directly affects FDA's ability to foster the scientific innovation necessary to improve health care, expand access to medical products, and advance public health goals.

V. Tobacco User-Fees

Additionally, the Budget request includes $812 million in user fees to support FDA tobacco's program. Included within this total is an additional $100 million in tobacco user fees and updated authorities to include manufacturers and importers of all deemed products (i.e., to include those not already subject to user fees such as e-cigarettes) among the tobacco product classes for which FDA assesses user fees. FDA is also requesting an inflation adjustment for all tobacco user fees to ensure that the resources can keep up with the Agency's public health mandate and with the evolving marketplace of tobacco products. Without additional user fees,

FDA will be forced to continue to spread out the flat budget available for tobacco regulation, which has remained stagnant for the past three years, limiting our ability to protect the over 2 million young people who reported using e-cigarettes and other tobacco products in the last year.

I must also note that in addition to presenting a heavy resource challenge, a lack of new tobacco user fees also represents a fundamental parity issue across tobacco-related industry. Prior to the court-ordered deadline of September 9, 2020, FDA received timely premarket tobacco product applications for approximately 6.7 million products. Thanks to the tireless efforts of the over 1,100 staffers at FDA's Center for Tobacco Products, together with the support of over 200 employees from across other parts of the Agency, we have met this challenge and have acted on over 99% of these applications thus far, and the remaining product reviews will be completed expeditiously. However, I must emphasize that this tremendous effort was undertaken with no additional resources – without e-cigarette manufacturers having to pay a single cent despite their products taking up a significant amount of our tobacco workload. I would strongly urge this Subcommittee to work with authorizers in this fiscal year to provide the requested authority and new resources so that we may more expeditiously and comprehensively take the actions necessary to prevent new youth initiation of tobacco products, and to support those of all ages who are seeking to reduce smoking of tobacco products and quit these products.

VI. Pandemic Preparedness

Finally, the Budget includes a request for $1.63 billion in new mandatory resources over a five-year period to implement the HHS Pandemic Preparedness Plan. Of this total figure, the request includes $1.1 billion to expand and modernize FDA's regulatory capacity, IT, and laboratory infrastructure in order to facilitate development and expedite evaluation of vaccines and therapeutics that target high-profile viral families. The request also includes $355 million to speed development of diagnostics, as well as $175 million to strengthen foreign inspections, harmonize premarket product reviews, and reduce zoonotic pathogen spillover.

The funds would support biodefense preparedness, expediting overall vaccine design, testing, and authorization capacity by bolstering FDA's cadre of reviewers, increasing resources for inspections, and investing in electronic information exchange among stakeholders. It would increase the Agency's readiness to facilitate the development of new vaccines, including those based increasingly on mRNA technology and other rapidly modifiable or novel platforms, and

enhance FDA's active and passive vaccine safety and effectiveness surveillance programs. This request would also support the development of a training center for inspection of advanced medical products.

Along with these initiatives, the pandemic preparedness request would also be used to establish a cross-agency One Health Center of Excellence, allowing FDA to strengthen its interdisciplinary approach to solving multifaceted health challenges, like COVID-19, where the health of humans, animals, and their shared environment are intrinsically linked. This effort will also build internal capacity to address ongoing public health challenges that are exacerbated during pandemics like the COVID-19 public health emergency, such as human and animal food contamination, diabetes, heart disease, and cancer. The resources requested for vaccine activities, One Health, and other integral parts of the broader HHS Pandemic Preparedness Plan, are critical to ensure the United States is properly prepared for the next pandemic and to increasing our chances of preventing future pandemics. As a nation, we cannot afford to play catch up with the next threat to our national wellness and readiness.

VII. Conclusion

I would like to close by thanking the Subcommittee again for your continued support of the Agency, and again thank you for inviting me to testify today. I look forward to working with you and I am happy to answer your questions.