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Statement by
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Food and Drug Administration, and Related Agencies
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Chairman Harris, Ranking Member Bishop, and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss the President's Fiscal Year 2024 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 greatly appreciates the funding increases provided by the Subcommittee in the FY 2023 omnibus, as well as the expanded and new regulatory authorities included in the legislation to address cosmetics and medical device cybersecurity. Your continued partnership is critical as we further our mission to protect and promote the public health. FDA's talented and dedicated workforce has worked around the clock for the past three-plus years to respond to the COVID-19 pandemic, confront related challenges, and ultimately strengthen our nation's response to future outbreaks. We appreciate your ongoing support on a variety of programs and initiatives, including the dedicated resources in several critical areas that support our personnel and efforts, including employee pay costs, infrastructure, and data-modernization to ensure continuity of our vital work.

The COVID-19 pandemic has underscored the need for a swift, unified governmental response with collaboration across federal agencies, state, local, tribal, and territorial governments, industry, and the private sector. As we collectively work together as a nation to turn the corner on COVID, the Agency is using the lessons learned to continue our core mission while we pursue new ways to better prepare for future threats and confront new challenges posed from an ever-expanding marketplace of food, tobacco products, and medical products.

For example, in the foods area, the Agency has remained laser-focused on a variety of critical efforts, including stabilizing the supply chain for critical products such as infant formula,

mitigating the risk of potential exposure to certain chemicals, toxic elements, and allergens, and facilitating consumer education regarding healthy foods through the development of updated and more accessible food labeling. Furthermore, with a Human Foods Program that regulates approximately 80% of foods consumed by Americans, including those bought in grocery stores, restaurants, and cafeterias, we are actively working towards a new, transformative vision for the program that is forward-thinking, proactive, and adaptive to an ever-changing and evolving landscape. FDA is taking steps, in line with the recommendations of the external evaluation conducted by the Reagan-Udall Foundation, to ensure that our customers, the American public, can remain as fully confident in the food they eat as they are in the medical products they rely on to support their health; our FY 2024 Budget places us firmly on the steps towards this path.

The funding requested in the President's FY 2024 Budget request builds upon funding provided in the FY 2023 omnibus for foods and other product areas, while also acknowledging additional future needs and challenges. Our FY 2024 program level request totals $7.2 billion, which represents an overall increase of approximately $521.4 million in annual funding above the FY 2023 Enacted level. Of this total, $3.3 billion is for user fees, which is an increase of approximately $149.5 million above the FY 2023 Enacted level. As part of the total program level, the Budget also requests $3.96 billion in budget authority, which is an increase of approximately $372 million above the FY 2023 Enacted level. These increases are organized into five critical areas that advance the Agency's activities in support of protecting and promoting human and animal health: (1) enhancing food safety, nutrition, and cosmetics oversight; (2) advancing medical product safety; (3) investing in core operations; (4) modernizing infrastructure, buildings and facilities; and (5) tobacco user fees. The Budget also provides $670 million of mandatory funding to advance the goals of HHS's Pandemic Preparedness Plan.

I. Enhancing Food Safety, Nutrition, and Cosmetics Oversight

FDA's Budget request provides a historic investment in FDA's Foods Program with $1.7 billion for food safety, nutrition, and cosmetics, an increase of $210.6 million above FY 2023 levels, to support our continual efforts and commitment to strengthening FDA's food safety and nutrition capacity. This funding will help to ensure our human and animal food supply is safe, sanitary, wholesome, and accurately labeled, as well as ensure that FDA can start

to implement new authorities given by Congress to provide oversight of the safety and proper labeling of cosmetic products. Additionally, this Budget will increase FDA's inspectional capabilities, which include the risk-based oversight of food facilities subject to FDA's food safety regulations and help ensure a reliable and safe food supply chain.

New Era of Smarter Food Safety

As a nation, our food supply is the safest it has ever been—but that does not mean we can't improve upon it. Specifically, as part of the total $1.7 billion request for FDA's Foods Program, the FY 2024 Budget includes an increase of $37 million for our New Era of Smarter Food Safety initiative. This approach aims to bend the curve of foodborne illness by strengthening data access and analysis capabilities, as well as bolstering capacity and food safety inspectional efforts.

Healthy and Safe Food for All

Within these requested Foods Program investments, FDA is also seeking resources for our ongoing efforts to provide safe food to the American public, with a renewed emphasis on the availability of healthy food options. The infant formula shortage from the last year serves as a stark example of the need for continued attention to the critical issues of food safety and security, the importance of quality nutrition, and the need for a safe and accessible supply of food products. To meet this goal, FDA is requesting an increase of $64 million to modernize oversight of infant formula, empower consumers to make healthier food choices, and reduce exposure to toxic elements in the food supply. We are further requesting an increase of $5 million in order to improve FDA's ability to assess and track certain elements of the food supply chain and industry capacity in order to help minimize supply chain disruptions and enable a more resilient food system.

White House Commitment to Nutrition and Food Labeling

Finally, I would note that as a cardiologist, I've seen firsthand the result of poor nutrition and diet, often stemming from childhood, and the long-term impacts from diet-related chronic disease that can occur. One of the first steps to addressing this often-neglected issue is to ensure consumers have adequate and necessary information on the food they eat. To advance these efforts, our budget also requests an increase of $12 million to strengthen nutrition and labeling work in alignment with the White House's National Strategy on Hunger, Nutrition, and Health.

II. Advancing Medical Product Safety

In addition to ensuring a safe and healthy food supply, FDA's FY 2024 Budget request includes $4.6 billion for strengthening human and animal health efforts across FDA's medical product centers, an increase of $199.9 million above the FY 2023 Enacted level.

Device Shortages and Supply Chain

For example, as part of FDA's total medical product safety investments, this budget requests an increase of $11.6 million, for a total of $21.6 million, to continue building capabilities for FDA's Resilient Supply Chain and Shortages Program for medical devices, and for recruiting data science, supply chain, and medical device experts to properly staff the program. These resources support our efforts to help prevent and mitigate shortages of critical medical devices, improve our ability to work proactively with medical device stakeholders to assess vulnerabilities and enhance resiliency, and ultimately safeguard the availability of life-saving technologies that are most often needed by vulnerable populations.

ALS (ACT for ALS)

In addition to maintaining access to current devices and other existing medical products, FDA also continues its focus on promoting the innovation and scientific advancement of new medical products, including products to address critical and rare diseases. Our medical products request therefore includes an increase of $2.5 million for staffing to implement the ACT for ALS Act and to help facilitate access to therapies for neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS). Additionally, this funding will help to expand the related development of new scientific approaches and tools that are available for the development of effective new medical products to prevent, diagnose, mitigate, and treat rare neurodegenerative diseases.

Combating the Overdose Crisis

Finally, in addition to the ongoing efforts at the Agency to promote medical product access and innovation, I also remain deeply involved in efforts to address an issue that has devastated countless families across our country, the overdose crisis. FDA's Budget request includes a proposed increase of $23 million, for a total of $102.5 million, to support the continued development of overdose reversal treatments, as well as treatments for Opioid Use Disorder (OUD). This funding will also support preventative methods and tools which involve establishing satellite labs at International Mail Facilities with permanent staffing of scientists and investigators, along with expanding FDA's use of analytical tools for screening entries of

potentially illicit products before they can enter our country. In addition, this funding will help advance the development, evaluation, and market authorization of digital health medical devices for further monitoring and addressing OUD inclusive of the patient perspective. Addressing this crisis is largely dependent on collaboration across the country, and utilizing real-time data to take effective and evidence-based approaches on this issue remains crucial to our next steps to turning the corner on this epidemic.

Cancer Moonshot

Further, FDA's Budget provides $50 million for FDA to advance the President's Cancer Moonshot goals. These funds will enhance Agency-wide efforts to improve evidence generation for underrepresented subgroups in oncology clinical trials, as well as to support pragmatic, decentralized trials and the development of sources of evidence that incorporate patient-generated data and real-world evidence. Additionally, these resources will assist in the expansion of FDA's efforts to facilitate the approvals of innovative and new cancer treatments by international regulatory authorities at the time of FDA approval and will foster collaboration on cancer treatments with other countries with standards comparable to the U.S. standard of care.

III. Investing in Core Operations

As highlighted in earlier portions of this testimony, our nation relies on FDA to provide rigorous and transparent scientific review, a predictable and responsive regulatory structure, a strong inspectorate, and expert staff to provide support for these activities. To meet these needs, as part of our total program level, our FY 2024 Budget requests $131.1 million above FY 2023 levels to continue to strengthen and support FDA's core operations and pursue new areas of improvement and innovation. In order to support further efforts, the Agency needs a strong framework for our programs, and for us that begins with data. Core operations also include initiatives such as advancing lab safety, information technology, and support services to help ensure FDA's ability to carry out its programmatic responsibilities.

Data Modernization and Enhanced Technologies

FDA's core operations request includes an increase of $10 million for Data and IT Modernization to build new tools and greater capacity to analyze real-time information. To meet the challenges of emerging threats and the need for real-time evaluation, FDA relies on the ability to rapidly and continuously access, analyze, and aggregate multiple sources of

information. From the COVID-19 pandemic to import alerts and domestic recalls, continual modernization of FDA's IT infrastructure has become increasingly more vital in order to keep pace with the evolution of outbreaks and disease. With these resources, FDA will continue to further build our centralized enterprise data modernization capabilities and strengthen the Agency's common data infrastructure, data exchange, and IT analytic services, talent, and tools. Investments in these critical areas will enable FDA to directly meet the challenges of our modern data-driven world, and continue to operate as the gold standard for product regulation and oversight.

IV. Modernizing Infrastructure, Buildings & Facilities

In addition to necessary investments in our core operations, including digital infrastructure, the continuity of the Agency's critical work also requires funding to complete projects that will improve the condition of FDA's owned buildings and physical site infrastructure. As part of our overarching FY 2024 Budget, FDA's request provides a total of $395.9 million for infrastructure, buildings, and facilities. This funding will help to ensure that FDA's offices and labs across the country are optimally functioning. This funding will also directly support the Agency's priorities across the country by providing secure, modern, reliable, and cost-effective office and laboratory space that empowers FDA's workforce to protect and promote the safety and health of American families. By investing resources in FDA's facilities, the Agency will be able to continue to provide the high-quality infrastructure and facilities needed for FDA employees to work to ensure FDA can achieve its strategic priorities across the country and the world.

V. Tobacco Regulation

As one of these strategic priorities, tobacco product regulation represents one of FDA's greatest opportunities to save lives. The Tobacco Control Act gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. FDA finalized the Deeming rule in 2016, which extended FDA's tobacco authorities to all tobacco products, including cigars, hookah (waterpipe) tobacco, pipe tobacco, nicotine gels, and electronic nicotine delivery systems (ENDS) such as e-cigarettes. In 2022, a new federal law went into effect clarifying FDA's authority to regulate tobacco products containing nicotine from

any source, including synthetic or non-tobacco nicotine (NTN). FDA regulates the manufacture, marketing, and distribution of tobacco products. Key areas of focus include policy and rulemaking, compliance and enforcement, premarket review, research support, and public education campaigns.

In addition to the priorities mentioned earlier across foods, medical products, core operations, and infrastructure, the Budget also requests an additional $100 million in user fees and requests authority to include manufacturers and importers of all deemed products – including ENDS - among the tobacco product classes for which FDA assesses tobacco user fees. These products represent an increasing share of FDA's tobacco regulatory activities. The additional funding will support hiring more staff, help FDA bolster compliance and enforcement efforts for all tobacco products, and expand public education campaigns and science and research programs, as we work to mitigate harms and to protect consumers from the dangers of tobacco use. To ensure that resources keep up with new tobacco products, the proposal would also index future collections to inflation. This proposal would ensure that FDA has the resources to address all regulated tobacco products, including ENDS, which currently have high rates of youth use, as well as future novel products.

VI. Pandemic Preparedness

Finally, as we advance towards regular operations across our product centers, FDA remains aware that there is work yet to be done in our response to COVID-19, and it is critical that we learn from both our successes and the challenges we experienced to best improve our operations moving forward. Lessons learned from the COVID-19 pandemic have reiterated the need to proactively plan for the next public health emergency by ensuring FDA has the resources and capacity in place to fully respond. FDA plays a unique and central role to the whole-of-government response to protect and promote the public health, and in turn, we are requesting funding to improve FDA's core capabilities to help ensure there is the appropriate level of regulatory capacity to respond rapidly and effectively to any future pandemic or high consequence biological threat.

Separate from our aforementioned requests for discretionary budget authority, FDA's Budget includes a request for $670 million in new mandatory resources available over five years to advance activities to better prepare FDA for the next pandemic. These funds would support

the Agency's biodefense efforts, domestic and globally, by bolstering FDA's cadre of medical product reviewers and strengthening foundational processes. It would also increase FDA's capacity to leverage a One Health approach to respond to emerging threats. And lastly, these resources would help strengthen underlying technology platforms to improve electronic information exchange among stakeholders and bolster central coordinating capacity within the Office of the Commissioner. With these resources, FDA will have the opportunity now to build on lessons learned from previous responses and provide transformational investments to help ensure that FDA can respond quickly and effectively in times of a public health crisis.

VII. Conclusion

This last year has presented some defining moments for the Agency and ample opportunities to bring the Agency into a new chapter. This Budget will help FDA maintain and expand on our current efforts, pursue new innovative strategies and methods, and provide a renewed focus on, and investment in, a variety of endeavors in the interest of public health for both humans and animals. I would like to close by thanking the Subcommittee again for your continued support of the Agency. I look forward to answering your questions today, and FDA looks forward to our collaboration and work together.