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

Chairman Heinrich, 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 2025 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. In a difficult fiscal environment, the Agency greatly appreciates the Committee's sustained commitment to our mission and providing vital resources which have been critical for FDA's protection of the public health, and we look forward to continuing to work with you to further address ongoing and emerging challenges.

During my second tenure at FDA, I have spoken regularly about the need for operational change to address the numerous emerging demands of new technology and the rapid transformation in how the products we regulate are manufactured, distributed, purchased, sold, and used. Looking ahead to FY 2025, we intend to take significant new steps in how we approach these challenges, including by implementing the largest reorganization in FDA's history. Following the independent evaluation by the Reagan-Udall Foundation and FDA's own review of how we addressed the infant formula supply chain response, this reorganization will establish a single, unified Human Foods Program by merging all human foods functions, resources, and personnel from across the Agency. We are also taking this opportunity to further improve other functions of the Agency to create an organization that will break down siloes and fragmentation, leading to enhanced efficiency and collaborative operations to more effectively meet FDA's public health mandate.

The funding requested in the President's FY 2025 Budget builds upon our existing work with additional resources crucial in helping the Agency adapt to a changing landscape. Our FY 2025 program level request totals $7.22 billion, which represents an overall increase of approximately $341 million in annual funding above the FY 2024 Enacted level. Of this total, $3.5 billion is for user fees, which is an increase of approximately $168 million over FY 2024 Enacted levels. As part of the total program level, the Budget also requests $3.7 billion in budget authority, an increase of $173 million. This funding will allow FDA to make significant progress on several important fronts, including (1) food safety and nutrition; (2) medical products; (3) crosscutting issues; (4) modernizing infrastructure, buildings, and facilities; (5) tobacco issues; and (6) strengthening biodefense. Of course, none of the crucial work done at FDA would be possible without our talented and dedicated workforce, which is why we're also requesting an increase of $114.8 million for public health employee pay costs as part of the total request for budget authority.

I. Human Foods Program

FDA has worked in concert with the broad ecosystem of states, territories, local governments, tribes, and the vast array of industry entities to make the American food supply as safe as it's ever been. As our knowledge base expands, we continue to identify areas where improvement would further enhance the safety of our food.

FDA's Budget request includes key investments for the Agency's Human Foods Program with $1.26 billion to support our continued efforts and commitment to strengthening FDA's food safety and nutrition capacity. FDA requests an increase of $15 million, in part to support microbiological methods and sampling improvements, which will enable more rapid and effective mitigation of produce-borne outbreaks in pre-harvest produce production environments. This body of work will strengthen root-cause investigations essential to FDA's outbreak prevention strategy for produce. Such an increase would also help support FDA's food chemical safety programs, including an increased focus on post-market assessments of intentionally added ingredients and authorized substances used in food, food packaging, or color additives for food manufacturing to ensure they meet the safety standard in the Federal Food, Drug, and Cosmetic Act. An increase would also support our work to reduce exposure to contaminants that may enter food through the environment, processing, or other means.

In addition, funding in our request will be used to grow the Agency's nutrition program within the planned Center of Excellence in Nutrition, as envisioned in the Agency's proposed transformation of the Human Foods Program. With an emphasis on early childhood nutrition, this request assists FDA in addressing the enormous public health burden of diet-related chronic diseases. As a cardiologist, I've seen firsthand the results of poor nutrition and diet, often stemming from childhood, and the long-term impacts from diet-related chronic disease that can occur. This is almost certainly one key cause of our recent decline in life expectancy—more than a five-year deficit in life expectancy compared with other high income countries. This request will also assist FDA with its nutrition and labeling work in alignment with the White House's National Strategy for Hunger, Nutrition, and Health.

II. Medical Products

FDA is dedicated to ensuring that safe and effective drugs, biological products, and devices are available to improve the health and quality of life for people in the United States. Without a doubt, responding to the rapid advancements made across regulated industries is one of the most challenging aspects of FDA's work, but one that we are excited about every day. FDA is committed to ensuring that products it regulates meet the requirements for marketing authorization while facilitating innovations in their development. Through effective interactions with private industry, Congress, and the public, we believe that FDA can help harness these groundbreaking advancements, like gene editing and artificial intelligence. Since 2016, FDA has been implementing the 21st Century Cures Act (Cures Act), a law enacted to accelerate medical product development and bring new innovations and advances to patients. The Cures Act authorized $500 million over nine years to help FDA cover the cost of implementing the law. Overall, the enactment of the Cures Act has been associated with a dramatic surge in biomarker-based genetic therapies for rare diseases as one example, but this may be just the front edge of a major surge in highly effective, specific therapies for previously untreatable diseases. FDA requests an increase of $5 million for 21st Century Cures to reflect the last authorized level for Cures in FY 2025, for a total of $55 million.

III. Cosmetics

FDA appreciates the Committee's support for this vital area, and requests $8 million in FY 2025 to support the continued implementation of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). MoCRA provided the most significant expansion of FDA authority to regulate cosmetics since 1938. However, MoCRA did not include any new funding to implement these new authorities. These new resources would allow us to continue building on current efforts to better position the Agency to tackle issues such as asbestos contamination of talc-containing cosmetics, such as tattoo inks and permanent makeup. These requested resources will help bolster our activities in the cosmetics space, such as developing regulations and compliance policies; managing submission platforms associated with MoCRA provisions; reviewing MoCRA-required information submitted to FDA for industry compliance; and hiring additional subject matter experts to manage critical projects, such as the assessments of the use of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products.

IV. Shortages and Supply Chain

Shortages of drugs, devices, and foods that Americans rely on for their everyday needs can occur for many reasons, including market failures, manufacturing and product quality problems, manufacturing delays, and discontinuations. FDA plans to continue to use a proactive approach towards shortages — to the extent possible within its resources and authorities — to make supply chains more resilient, increase regulatory oversight, and when possible, help prevent or mitigate shortages of critical medical and food products that Americans rely on. The FY 2025 budget includes $12.3 million to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are supply- or demand-driven. For example, FDA will use this funding to improve analytics to estimate risk of disruptions in drug manufacturing and identify vulnerabilities so that we can be in a better position to intervene sooner. Further, approximately $3 million of this increase is dedicated to the recruitment of skilled investigators who will conduct inspections. This investment aims to bolster the regulatory oversight of the drugs, devices, and biologics industries, helping FDA to effectively provide inspection coverage to the increasing number of manufacturers within the medical products industry, and enhancing our ability to promote high-level manufacturing quality and a reliable supply chain.

V. Enterprise Transformation

To improve the efficiency of our operations, FDA has proposed targeted investments to support our modernization activities. We request $2 million to support centralization of planning, implementation, and governance of high-priority business process improvement efforts. This funding will also support the work to build a unified data and operational platform to support our inspection work. This comprehensive initiative aims to modernize operational approaches and foster cohesion, with a specific focus to improve how we plan and conduct inspections so that more inspections can be done in the context of better supporting data and more efficient operations.

VI. IT Stabilization and Modernization

FDA requests an increase of $8.3 million to further build FDA's centralized Agency-wide data modernization capabilities and strengthen our common data infrastructure, data exchange, and IT tools. With these additional resources, FDA will continue to improve data exchange and underlying technology platforms in support of the Agency's programs and mission-critical responsibilities to meet future challenges. Specifically, a stronger digital infrastructure better allows us to meet the challenges of emerging threats, support real-time evaluation, and more efficiently analyze information for recalls, adverse events, outbreaks, and biothreats. The rapidly changing capability of the information technology ecosystem demands that our systems evolve to support the rapid adoption of artificial intelligence in the products we regulate, including ensuring the continued success with our intensive cybersecurity program. FDA is requesting two-year budget authority (FY 2025 – FY 2026) for this funding to provide more flexibility and ensure the most effective use of these resources.

VII. Foreign Office Expansion

In addition to assessing the current state of our domestic enterprise, FDA continues to assess the state of our foreign offices and international work including inspections, oversight, and collaboration with foreign food and drug agencies. The dependence of the industries we regulate on increasingly complex and interdigitated global supply chains demands that we apply more resources to assuring the quality and integrity of these dependencies.

To support these efforts, FDA is requesting an increase of $1 million for foreign office expansion. This funding will support the expansion of the Agency's foreign office footprint by increasing our resources to improve oversight of quality management systems and supply chains, facilitate additional FDA foreign inspections, and increase our ability to engage with counterpart regulatory authorities to strengthen public health protections.

VIII. Modernizing Infrastructure, Buildings & Facilities

In addition to necessary investments in our core operations, the FY 2025 budget provides limited funding to support FDA's Infrastructure and Buildings & Facilities. These programs directly support FDA's priorities by providing office and laboratory space for FDA's workforce to perform its critical health work.

IX. Tobacco Regulation

Tobacco product regulation continues to be one of FDA's greatest opportunities to save lives and prevent devastating impairment of quality of life caused by cancer, strokes, and other consequences of tobacco use. FDA regulates the manufacture, marketing, and distribution of all tobacco products. Applications for more than 26 million tobacco products have been submitted over the last three years. FDA has resolved 99% of those submissions, while ensuring decisions are scientifically accurate, legally defensible, and aligned with the authorities granted by Congress. In addition to premarket review, key areas of focus include policy and rulemaking, compliance and enforcement, research support, and public education campaigns. The Budget provides $798.6 million for the Tobacco program, which will further bolster resources to invest in these critical regulatory activities.

Within this request, there is an additional $114.2 million in proposed user fees to ensure that FDA has the resources to effectively address all regulated tobacco products, including e-cigarettes and other novel products, particularly those popular among youth. These products represent an increasing share of FDA's tobacco regulatory activities. The additional funding will bolster compliance and enforcement efforts, enhance premarket application review, and expand tobacco 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 the evolving landscape, the proposal would also index future collections to inflation.

The Agency remains vigilant in overseeing the market and continuing to prioritize the use of our resources to maximize public health impact, including compliance and enforcement efforts to curb the unlawful marketing of all tobacco products, especially those used prominently by youth.

X. Strengthening Biodefense

The COVID-19 pandemic also highlighted the need to proactively plan for the next public health emergency and ensure we have the resources and capacity in place to fully respond. The Agency has a unique and central role in the whole-of-government response to protect public health. The FY 2025 Budget's Strengthening Biodefense request for FDA includes $670 million in new mandatory resources for spending over five years to advance activities to better prepare FDA for the next pandemic. These resources will help ensure an adequate level of regulatory capacity to respond rapidly and effectively to any future pandemic or biological threat by supporting the Agency's biodefense efforts, both domestic and globally, by bolstering FDA's capacity to provide timely recommendations and scientific advice to manufacturers designing and testing vaccines. Additionally, this funding will support increased research and development of diagnostics, next-generation personal protective equipment (PPE), and technology for biosurveillance and early warning. And finally, these resources will further strengthen data exchange and technology platforms to help ensure that FDA is in the position to respond to a public health crisis quickly and effectively.

XI. Conclusion

While we are in the midst of a challenging budget environment, FDA continues to work with the resources at its disposal to serve the Agency's critical public health mission. The additional resources requested in this year's Budget represent the areas of greatest need as we modernize to address evolving consumer and industry needs. Once again, I thank the Subcommittee for your continued support and I look forward to our continued collaboration. I am happy to answer your questions.