Steven A. Grossman

Executive Director

Alliance for a Stronger FDA

Before the

Subcommittee on Agriculture, Rural Development,

Food and Drug Administration and Related Agencies

Senate Committee on Appropriations

May 6, 2022

The Alliance for a Stronger FDA thanks the Subcommittee for its continuing support of the Food and Drug Administration (FDA). Because of the resources that you have provided, the agency has been able to serve the American people and assure a safe food supply and safe and effective medical products. We can all be proud of FDA and its many accomplishments. We believe that the primary beneficiary of FDA's activities is the American public. Accordingly, it is critical that the public remains the largest source of FDA funding.

The Alliance for a Stronger FDA is composed of 150 stakeholder organizations that advocate for FDA to have resources commensurate with its growing responsibilities. Our members are consumer and patient groups, research advocates, health professional societies, trade groups, companies, and individuals. Because FDA's mission continues to grow and its vital activities have become more sophisticated and complex, the Alliance supports further funding increases for the agency.

The Alliance strongly supports the Administration's budget authority (BA) request of $3.653 billion for fiscal year (FY) 2023. This provides for an increase of $318 million in BA salary and expenses (S&E) and an increase of $18 million in BA buildings and facilities (B&F). We also support the proposed no-year money requests for pandemic response ($1.6 billion) and the Cancer Moonshot ($20 million). We urge Congress to adopt these proposed funding levels.

Our request for FY 23 funding focuses exclusively on appropriations that come from monies paid by taxpayers (BA) and intentionally does not include user fees and mandated funding (e.g., *Cures* monies transferred from National Institutes of Health). However, we urge Congress to fully fund those programs, as well.

FDA's jurisdiction includes responsibility for 70% of the food supply and all drugs, medical devices, biologics, vaccines, veterinary food/medicine, dietary supplements, and cosmetics. Altogether, the agency oversees products that represent 20% of all consumer spending ($2.8

trillion) and touch the American public multiple times each day. FDA's mission continues to grow, and its vital activities have become more complex and require greater sophistication and expertise to complete.

Background

The funding provided in the FY 2022 Consolidated Appropriations Act is an essential down payment on important FDA priorities that are continued in the FY 2023 request. Completing the job of making FDA into a modern 21st Century regulatory agency will require substantial new investments. The agency needs an increased budget, more scientific and technical staff, and better analytical tools that support science-based decision-making and keep up with innovation in both food and medical products.

The growing complexity of science, interwoven with new innovative technology is a challenge across the agency. In food safety, this means the use of artificial intelligence, whole genome sequencing, and enhanced electronic recordkeeping that will contribute to a safer food supply. In medical products, this means new tools to evaluate medical products that incorporate cell and gene therapy, digital health, artificial intelligence, and real-world evidence and other new technologies.

FDA has released a Technology Modernization Action Plan and a Data Modernization Action Plan, both in need of substantial new funding. Investment in technology and data modernization is a pressing agency need that affects both food and medical products.

FDA needs to attract and retain specialized personnel that are experts in increasingly complex fields such as artificial intelligence, genomics, diagnostics, digital technology, cybersecurity, block chain, advanced manufacturing, robotics, and whole genome sequencing. It is essential for FDA to have personnel capable of conducting FDA's ongoing responsibilities while looking for innovative ways to conduct FDA's work. The need exists in both food safety and medical products.

The Administration identified four priorities in its Budget Request, which the Alliance supports:

- **Investing in Core Operations** The budget supports cross-cutting agency-wide efforts that provide resources, technology, capacity, and infrastructure to address public health needs and tackle complex challenges due to advances in the global food and medical product technology and supply chains.
- **Enhancing Food Safety and Nutrition** FDA's budget supports new funding towards ensuring healthy and safe food for every American.
- **Advancing Medical Product Safety** The budget provides monies to a $95 million increase for FDA's medical product safety work.
- **Modernizing Infrastructure, Buildings and Facilities** FDA's facilities budget includes an increase of $40 million for the upkeep and rental of FDA's laboratories and buildings.

Areas of Need and Opportunity

We see specific programs and initiatives where additional investment in FDA would add to the value of the agency's activities on behalf of the American public:

Food Safety – For FY 23, we urge Congress to consider:

- More robust and rapid Food Safety Modernization Act (FSMA) implementation, including increased cooperation with states, finalization of guidances, and a focus on produce safety, import safety, and training/education;
- Enhanced funding of systems for surveillance of foodborne illnesses and outbreak response;
- Upgrades to the public health laboratories network;
- Strengthening the scientific capabilities of the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the National Center for Toxicological Research (NCTR); and
- Starting the development and implementation of initiatives contained in the agency's New Era of Smarter Food Safety.

Funding should also be considered for: FDA's recall initiatives, nutrition education, safety of cosmetics and dietary supplements, antimicrobial resistance, CBD, and standards of identity/food labeling and product claims.

Medical Products – For FY 23, we urge Congress to consider:

- Addressing the shortage of agency staff and expertise in 1) new high-growth scientific areas, notably the dramatic increase in products being developed with gene and cell therapy and 2) new technology-driven challenges, such as cybersecurity, artificial intelligence, digital health, and blockchain;
- Expanding FDA's ability to respond to public health emergencies, including coordinated efforts to speed development of diagnostics, therapeutics, and vaccines for viral and other emerging threats to public health;
- Strengthening FDA ability to address the safety of imported medical products and API's;
- Renewing and expanding initiatives first funded in prior years, including innovative initiatives in advanced manufacturing, outsourcing, real-world evidence, compounding, generics, and rare diseases; and
- Strengthening the scientific capabilities of the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), CVM, and NCTR.

Funding should also be considered for integrated knowledge management systems to support medical devices and biologics, and efforts to develop and integrate interoperable data systems.

Conclusion

Additional monies in FY 23 are needed to support the entire range of FDA responsibilities, in addition to investments in increased readiness. While we appreciate that important FDA user fees are before Congress this year, we urge you to keep in mind that those fees are dedicated to specific activities and are not available for the broad range of FDA's obligations. The agency and the American public counts on your provision of budget authority for FDA's complete role.

We urge Congress to recognize the multiple opportunities for FDA to be a more effective protector of the public health, as well as a fair and efficient regulator. We are at a point where additional investment in FDA will result in substantial added value to the American public.

The Alliance again thanks the Subcommittee for its support of the agency and looks forward to working with Members of Congress and staff on FY 2023 appropriations for FDA.