



ALLIANCE FOR A STRONGER **FDA**

All FDA Stakeholders United in Supporting the Agency's Resource Needs

How FDA Is Funded

March 24, 2022

For more information about FDA funding or to learn about the benefits of being an Alliance member, please contact Steven Grossman, Executive Director, at sgrossman@strengthenfda.org.

FDA Stakeholders Support a Strong, Well-funded FDA

- Across the breadth of FDA responsibilities, the agency's stakeholders support a strong and well-funded FDA
- Reflecting this, the Alliance for a Stronger FDA has 150 members and is devoted to:
 - advocacy for increased BA appropriations for FDA and
 - education about the FDA's mission and responsibilities
- The Alliance's unique coalition of patient and consumer groups and industry reflects FDA's unique role in public health, safety and commerce

For more information about FDA funding or to learn about the benefits of being an Alliance member, please contact Steven Grossman, Executive Director, at sgrossman@strengthenfda.org.

Presentation Overview

FDA Overview

- Why does it matter how FDA is funded?
- FDA's unique public health mission
- Review of FY22 funding

Sources of agency funding

- Budget authority (taxpayer paid) appropriations (BA)
- Medical product user fees
- Tobacco user fees
- 21st Century Cures
- No-year supplemental funding

Funding by mission

- Food safety funding
- Medical products funding
- Rental costs and buildings and facilities

Conclusions

Why Does It Matter How FDA Is Funded?

- The breadth and depth of FDA's mission touches every American multiple times each day
- Congressional and Administration support has assured growth in FDA funding, providing needed resources to respond to acceleration of medical progress and the potential for a dramatically safer food supply
- More change is coming: no federal agency's mission and responsibilities are more affected by advances in science, technology, innovation, and social trends than the FDA
- Promising scientific advances, such as gene therapy, drive up the number/complexity of sponsor submissions and the need for more well-qualified FDA staff. CBER projects the need for a 50% increase in CBER staff over current levels
- FDA revenue and expenditures are complex compared to most federal agencies. Notably:
 - Budget Authority (BA) funding is paid by taxpayers and provides FDA with the broadest and most flexible means of responding to all its responsibilities; all other funding comes with restrictions
 - User fees are very important, but always must be spent within specified parameters. They do not support the entire agency or the full range of FDA responsibilities

FDA's Unique Public Health Mission

- Strong FDA essential to America's public health and safety, economy, balance of trade, and homeland security
- FDA supported by \$3.304 billion in appropriated (taxpayer) funds plus industry user fees plus other funding. The FDA is responsible for reviewing:
 - 100% of drugs, biologics, medical devices, diagnostics, vaccines, cosmetics, and veterinary products (“bench to bedside”)
 - 75% of our nation's food supply (“farm to retail”)
 - 20% of all consumer spending (\geq \$2.6 trillion)
 - Critical role in preventing future pandemics, setting global standards, facilitating commerce/trade
- Taxpayer (BA) funding: ~\$10.00 per American per year
- User fees supplement BA appropriations/pay for specific functions. Unavailable for general agency needs.

Status of FDA In The FY 22 Budget Cycles

- FY22 funding enacted through omnibus
 - Administration proposed a \$343 million increase in BA funding for FDA
 - House passed an Ag/FDA funding bill: \$257 million increase in BA funding for FDA
 - The Senate Appropriations Committee approved an Ag/FDA funding bill: \$200 million increase in BA funding for FDA
 - All were consistent with Alliance’s FY 22 “ask” for “no less than a \$200 million increase”
- Final omnibus provided an increase of \$102 million, reflecting topline constraints

FDA Funding Streams: Budget Authority Appropriations (FY22)

- **Budget Authority (BA) funding (\$3.04 billion)—appropriated annually from the Treasury’s General Fund (taxpayer funding). Most federal agencies are funded solely from BA.**
- Funds available for any FDA activity, as specified in:
 - laws and regulations
 - the President’s Budget Request*
 - enacted appropriations bills and their committee and conference reports
- Plus any activity required/necessary for FDA to carry out its public health and safety responsibilities
- **These are all-purpose funds**—BA funding pays for broad array of programs, coordinating public health initiatives, and preparing for emerging needs and threats

* The President’s request sometimes includes monies for proposed programs not yet authorized under law.

FDA Funding Streams: Medical Product User Fees

(all numbers are for FY 22)

- **Medical product user fees (\$2.08 billion)—provided annually; limited to amounts in UF agreements**
- User fees are intended to supplement, not replace BA funding
- Separate programs for different medical products.
 - Rx drugs (PDUFA) generic drugs (GDUFA)
 - biosimilars (BsUFA) medical devices (MDUFA)
 - over-the-counter drug (OMUFA) Rx animal drugs (ADUFA)/generic animal drugs (AGDUFA)
- **Only available for purposes specified in law and in 5-year negotiated agreements.**
- FDA uses both BA and user fees to fund ongoing medical product programs and new initiatives. FDA tracks and audits to assure user fee funds are only allocated to permitted purposes
- Most of the user fee programs will be renewed next year. FDA must send the negotiated agreements and legislative language to Congress by January 2022

FDA Funding Streams: Tobacco User Fees

- **Tobacco User Fees (\$712 million)—appropriated annually, based on section 919 of the FDCA**
- Entire tobacco control program funded by user fees (no BA/taxpayer monies appropriated for tobacco)
- **A self-contained regulatory program that is not negotiated with industry**
 - Tobacco user fees are essentially different from other user fees and should be counted separately
 - The Alliance's funding requests are for BA only, so tobacco is never included.
- If the question is: how much of FDA's traditional food and drug responsibilities are paid for by user fees?
 - With tobacco included, FDA is approximately 52% BA to 48% user fees
 - With tobacco excluded FDA is approximately 60% BA to 40% user fees

FDA Funding Streams: 21st Century Cures; No-Year Funding

21st Century Cures funding (\$50 million)—appropriated annually for 9-years, ends 2025

- Funds available for activities specified in the Cures Act (medical product development programs)
- Per-year monies peaked in FY 20 at \$75m and decline each year; program expires in 2025
- Monies derived from CHIMPS (Changes In Mandatory Programs; not traditional BA, not user fees)

One-time, no-year funding (appropriated but not counted against annual spending limits)

- More than \$500 million for COVID-19 emergency activities
- In past years (some still carried over): medical countermeasures, opioids, seafood safety

Food Safety Funding

(all numbers are for FY 21)

- \$1.421 billion in BA and \$16.4 million in user fees support food safety across human and animal products
- User fee funds derived from several certification and inspection fee programs
- Food safety funding includes nutrition programs, dietary supplements, and cosmetics
- BA includes:
 - CFSAN (\$1.099 billion)
 - animal food portion of CVM (\$140 million)
 - food projects at NCTR (\$5 million)
 - food programs in the Office of Commissioner (\$56 million)
- The BA food safety funds also contribute about \$120 million to rent payments and other overhead

Medical Product Funding

(all numbers are for FY 21)

- \$1.716 billion in BA and \$2.027 billion in user fees to support FDA priorities for medical product safety
- BA includes:
 - CDER (\$689 million)
 - CBER (\$254 million)
 - animal drug portion of CVM (\$52 million)
 - CDRH (\$408 million)
 - medical product projects at NCTR (\$62 million)
 - medical product programs in the Office of the Commissioner (\$120 million)

The BA medical product funds contribute about \$130 million to rent payments and other overhead. Medical product user fees contribute about \$130 million for the same purposes.

Rental Costs and Buildings and Facilities

(all numbers are for FY 21)

- **Rental costs (\$425 million)** = improvements to the White Oak Complex + Other Rent and Rent Related items + GSA rental payments:
 - **BA.** Food = \$120 million + Medical Products = \$ 130 million + WO complex (not allocated) = \$ 46 million. Total: \$296 million
 - **UF.** Medical Products (\$115 million) + Tobacco (\$13 million). Total: \$128 million
- **Buildings and Facilities (B&F) (\$13 million)**
- Building and facilities improvements has stayed at about the same level (\$12-13 million of BA) for years
- President's proposal included a \$19 million increase in B&F
- Omnibus provided \$12.788 million in total B&F BA funding

Conclusions

- Congressional and Administration support has assured growth in FDA funding, providing needed resources to respond to acceleration of medical progress and the potential for a dramatically safer food supply
- More change is coming: no federal agency's mission and responsibilities are more affected by advances in science, technology, innovation, and social trends than the FDA
- BA funding provides FDA with the broadest and most flexible means of responding to all its responsibilities; all other funding comes with restrictions
- User fees are very important, but always must be spent within specified parameters. They do not support the entire agency or the full range of FDA responsibilities
- Across the breadth of FDA responsibilities, the Alliance and its members support a strong and well-funded FDA



All FDA Stakeholders United in Supporting the Agency's Resource Needs

For more information about FDA funding or to learn about the benefits of being an Alliance member, please contact Steven Grossman, Executive Director, sgrossman@strengthenfda.org.