ALLIANCE FOR HEALTH POLICY

BACKGROUND ON

FDA USER FEE PROGRAMS

ADAPTED FROM:

Part IV of the Alliance for Health Policy's Health Policy Roundup and 2022 Forecast series, February 4, 2022.

BACKGROUND

The Food and Drug Administration (FDA) was first authorized to collect user fees in 1992 under The Prescription Drug User Fee Act (PDUFA, said as puh-doo-fuh) to provide funding to the agency during a period of federal budget cuts. Over the past 30 years, user fee programs have helped finance the FDA's review of human medical products such as drugs and medical devices. About 54 percent, or $3.3 billion, of the FDA's budget is provided by federal budget through the congressional appropriations process. The remaining 46 percent, or $2.8 billion, is paid for by industry user fees.

User fees, alongside a baseline of funding from the congressional appropriations process, finance the FDA's regulation of medical products. User fees are aggregated into pots of money for their respective category such as medical devices, drugs, or generic medications, and are used to fund staff, IT essentials, and other supporting resources. The expenditure of the user fee funds is not specific to a manufacturer's application, nor tied to a specific industry company or drug. User fees are also collected regardless of whether the application is approved or not.

Health care professionals and patients depend on the FDA to evaluate important medical devices and treatments, and user fees aim to expedite this process. By authorizing the collection of user fees from biopharmaceutical companies, the FDA can support increased staffing and resource capacity building, as well as generate regulatory predictability. This predictability, in turn, is meant to help incentivize industry investment in clinical research and development. Before PDUFA, the median drug approval time was 22.2 months. Now, the median review time for new prescription drugs is about 10 months. Similar in practice to PDUFA, the Medical Device User Fee Amendments (MDUFA), the Biosimilar User Fee Act (BsUFA), and Generic Drug User Fee Act (GDUFA) also enacted user fees, with the goal to improve patients' timely access to medical products.

During the pandemic, user fees have also helped enable the FDA to provide prompt recommendations and regulatory guidance for COVID-19 vaccines and therapeutic development.

Over the years, the FDA has enhanced the transparency around user fee program reauthorization in response to the high-level interest from patients, industry, and other stakeholders. This public, private, and governmental collaboration is a defining feature of this program that is not seen with other public health program reauthorizations. The fact that Congress continues to support this mechanism 30 years later is a testament to the integral role of user fee programs and their public health benefits.

CONGRESSIONAL REAUTHORIZATION

The User Fee reauthorization process begins about two years prior to its submission to Congress. The FDA first consults with the industry and other stakeholders, sorting through priorities, expansions, and improvements of the program. Next, the FDA hosts public meetings and congressional briefings to receive input from various players on program priorities. Lastly, private negotiation meetings between the industry and FDA occur, but meeting minutes are published shortly after for the public. The resulting commitment letter is cleared and published for comment by HHS (U.S. Department of Health and Human Services), FDA, and OMB (U.S. Office of Management and Budget) and then submitted to Congress in January.

The commitment letters and proposed legislative language to amend the statute are received by the **FDA authorizing congressional committees**, the House Committee on Energy and Commerce and the Senate HELP Committee. PDUFA, GDUFA, BsUFA, and MDUFA become the first four titles of a legislative package that must be signed into law by September 30. Both chambers will hold hearings and markups.

Because the **user fees reauthorization package is considered a "must-pass" bill**, members of Congress can use it as an opportunity for policy riders, or the practice of attaching other bills (related or not) as amendments. Common policy riders for user fee reauthorization legislation include recall authority and expeditated approvals, or reform around how diagnostic tests, cosmetics, or dietary supplements are regulated.

FY 2023-2027

User Fee programs are renegotiated every five years and involve careful negotiation among manufacturers, the FDA, and Congress. The current legislative authority previously reauthorized in 2017 for PDUFA VI, MDUFA IV, GDUFA II, and BsUFA II expires in September 2022. The latest reauthorization (PDUFA VII, MDUFA V, GDUFA III, BsUFA III) is a must-pass piece of legislation for Congress in 2022 in order for the FDA to continue collecting prescription drug user fees for the next five years.

RESOURCES

Health Policy Handbook: Chapter 4
Foundation information on the U.S. FDA

FDA Human Medical Product User Fee Programs
Additional background on user fees

Subject Matter Experts
Download a list of contact info

Background on FDA User Fee Programs Webinar
Review additional resources & recording

"Transparency and public engagement are important aspects of the user fee negotiation process. Our success, both in the past and the future depends upon collaboration and communication with stakeholders, policy makers, and industry."

Andi Lipstein Fristedt, MPP
Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. FDA

"Patients are highly vested in the time it takes for safe and effective therapy to be developed, reviewed, and made available. PDUFA was a direct response to the concerns from patients about potentially promising drugs being stuck in the agency. The experience of the AIDS crisis was a turning point in catalyzing reform to address these concerns."

Anna Abram
Senior Advisor, Akin Gump Strauss Hauer & Feld, LLP

Cover Photo: National Cancer Intitute via Unsplash. | Page 3: Prescription drugs. Sezeryadigar via Getty Images.