Health Policy and Legislation Alert

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It's UFA Time Again Reauthorization of the FDA User Fee Acts Takes Center Stage in Congress

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[Video]

This week, the House Energy and Commerce Committee will hold the first hearing as part of the process to reauthorize the Food and Drug Administration's (FDA) user fee programs for human prescription drugs and biologics, medical devices, generic drugs and biosimilars. The reauthorization of these user fee programs has historically been considered to be "must pass" given the significant portion of the premarket review budget that is funded through user fees. The current five-year authorization is set to expire on September 30, 2022. As in previous reauthorization cycles, lawmakers will likely seek to advance other FDA-related policy priorities on this legislative vehicle, and the legislative process will be closely watched given the significance of the timely reauthorization of these programs for patients, the agency and industry.

Background

This year marks the 30th anniversary of the enactment of the Prescription Drug User Fee Act (PDUFA). Enacted in 1992, PDUFA authorized FDA to collect various user fees from companies that submit applications for certain human drug products. In the years that followed, PDUFA resources enabled a more modern and efficient approach to FDA's review of new drug applications. The time it took for FDA to review and approve new drug applications significantly decreased—from an average of more than 31 months in the years before PDUFA passage to an average of less than 18 months in the fifth year of the first PDUFA cycle. As a point of comparison, in the PDUFA VII commitment letter, the goal for FDA to review and act on new drug applications is six months for priority drugs and 10 months for standard drugs. PDUFA, then, was a pivotal development in enabling new medicines to become available to Americans sooner in those early years. It established the model that appropriate resources being dedicated to the review of medical products could result in a much more efficient and timely decision-making process by FDA with significant public health benefits as new, safe and effective therapies were approved.

Following the initial passage of PDUFA and initial reauthorization of that user fee program, Congress subsequently enacted three additional user fee programs that are also up for reauthorization this year. The same year Congress reauthorized PDUFA for

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the second time, it also gave FDA the authority to collect user fees from medical device companies in the Medical Device User Fee and Modernization Act of 2002 (P.L. 107-250), and that user fee program is commonly referred to as “MDUFA.” Ten years later, in 2012, Congress enacted the Biosimilar User Fee Act (BsUFA) and the Generic Drug User Fee Act (GDUFA) as part of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144).

Since the passage of PDUFA and the other three user fee packages spanning human drug and devices, the user fees and related performance goals have become an integral and enduring part of modernizing the medical product review and approval processes. This paradigm has also fostered resource alignment and enhanced regulatory certainty for developers, the agency and stakeholders, with the shared goal of advancing safe and effective medical products in as timely a manner as possible. It has also fostered increased transparency as the agency regularly publishes user fee performance reports.

Each user fee program reauthorization is also a reflection of the interest among Congress, the agency, patients, industry and a wide range of stakeholders that FDA keeps pace with advancements in science and technology as part of their public health charge and commitment to patients and consumers, and in a manner consistent with the agency’s gold standards. Over the years, Congress has enhanced the transparency and opportunity for public input in the reauthorization process. Today, the reauthorization process includes the posting of information from meetings between the FDA and industry negotiators, a public meeting and docket for feedback and comments from stakeholders on the proposed recommendations for the reauthorization, and consultation with the House Energy and Commerce Committee and the Senate Health, Education, Labor and Pensions (HELP) Committee, in addition to enhanced agency reporting requirements, including an annual report on user fee performance.

Today, FDA relies on user fees paid by regulated industry to supplement general appropriations and to fund premarket and postmarket regulatory activities. The user fee programs for prescription drugs, medical devices, generic drugs and biosimilars have consistently been reauthorized together on a five-year cycle; authorizing legislation typically sets a total amount of fee revenue for the first year of the program, specifies the fees that FDA can collect, and outlines the parameters and expectations with respect to the agency’s use of the user fees. More details relating to performance goals and initiatives to be funded with user fees are laid out in commitment letters agreed to between FDA and the applicable industry groups. While the user fees support activities related to the premarket review of a drug or device under consideration by the agency, it does not predetermine the regulatory decision by the agency. FDA bases its regulatory decision making on whether a product meets the requisite regulatory standards for premarket clearance or approval.

By law, the reauthorization process is kicked off with FDA holding initial public meetings on the user fee programs. These meetings are followed by negotiations with industry stakeholders to develop recommendations and performance goals, such as certain timeframes for completing reviews of premarket applications. For PDUFA, GDUFA and BsUFA reauthorizations, the industry meets primarily with representatives from FDA’s Center for Drug Evaluation and Research (CDER), while the MDUFA reauthorization is negotiated by representatives from the Center for Devices and

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Radiological Health (CDRH). The Center for Biologics Evaluation and Research (CBER) also participates in these negotiations, as regulators of biologics and certain devices. The proposed agreements with industry are finalized in written commitment letters, which FDA releases for public comment before the ratified agreements between the agency and industry negotiators are submitted to Congress for further action. FDA is also required to meet with stakeholders during the period of time the agency is conducting negotiations with each set of industry participants.

The five-year reauthorization cycles present an important opportunity to consider FDA-related policies in Congress in addition to the overall performance of the agency and resource alignment for medical product regulatory activities. Given the rapid pace of scientific advancements and innovation, and the potential these innovations hold for patients, there is public health value in the regular cadence by which the agency, industry, patient and stakeholder groups come together with Congress to consider how best to enhance the regulatory pathways and processes for developing and reviewing safe and effective medical products for patients, and is part of FDA's mission to protect and promote public health.

In addition to outlining the user fee and performance goals for the agency, each of the previous user fee reauthorizations have included significant FDA-related policy riders. For example, in 1997, Congress reauthorized PDUFA for the first time and codified the fast track designation. In 2002, the Public Health Security and Bioterrorism Preparedness and Response Act (P.L.107-188) reauthorized PDUFA and created new offices at FDA, including the Office of Drug Safety and the Office of Generic Drugs. Ten years later in 2007, the Food and Drug Administration Amendments Act (FDAAA) reauthorized PDUFA for the third time, MDUFA for the first time, and established FDA's risk evaluation and mitigation strategies (REMS) authority. In 2012, in addition to authorizing GDUFA and BsUFA, the FDA Safety and Innovation Act created the breakthrough drug therapy designation, included numerous supply chain provisions (including requiring risk-based inspections for domestic and foreign drug facilities), updated drug shortage authorities and reformed the de novo review pathway for novel devices.

The most recent reauthorization package, the FDA Reauthorization Act of 2017 (FDARA; P.L. 115-52), was enacted in August 2017 and reauthorized PDUFA, MDUFA, GDUFA and BsUFA through Fiscal Year (FY) 2022. FDARA also included a number of non-user fee provisions, including policies related to pediatric drugs and devices; device inspections, generic drug access and other reforms.

Although the current legislative authority for the user fee programs expires at the end of FY 2022 on September 30, 2022, Congress often passes reauthorization legislation the summer before the September 30 deadline, in order to avoid disruptions to agency operations with respect to user fee funded activities, including the review of drugs and devices.

User Fee Reauthorization for FY 2023-2027

The reauthorization process for the next iterations of the user fee programs—the Prescription Drug User Fee Act (PDUFA VII), Generic Drug User Fee Amendments (GDUFA III), Biosimilar User Fee Act (BsUFA III) and the Medical Device User Fee

Amendments (MDUFA V)—began in 2020 and will continue this year as Congress takes up reauthorization legislation.

PDUFA VII

The PDUFA VII reauthorization process kicked off with a public meeting on July 23, 2020, followed by extensive negotiations and industry discussions throughout 2020 and 2021. The PDUFA VII commitment letter was released on August 23, 2021, and a public meeting on the agreement was held September 28, 2021. FDA submitted the commitment letter to Congress before the January 15, 2022 statutory deadline.

GDUFA III

FDA held an initial public meeting on the GDUFA III reauthorization on July 21, 2020. Following industry negotiations in 2020 and 2021, FDA published the commitment letter on October 29, 2021. A reauthorization public meeting was held November 16, 2021, and the agreement was submitted to Congress by January 15, 2022.

BsUFA III

The kickoff public meeting for BsUFA III was held on November 19, 2020. Negotiations with industry took place throughout 2021 and the BsUFA III commitment letter was released on September 21, 2021. Following a November 2, 2021 public meeting, the agreement was submitted to Congress by January 15, 2022.

MDUFA V

FDA held an initial public meeting on MDUFA V on October 27, 2020. FDA-industry negotiations are ongoing, and the agency has yet to publish a commitment letter for MDUFA V. FDA has not submitted an agreement to the Hill, though a delay is not unprecedented; the commitment letter for MDUFA III, which was reauthorized in 2012, was not released until March of that year.

Congressional Outlook and Next Steps

With three of the four commitment letters having been ratified by negotiators and transmitted by the Department of Health and Human Services to Congress, the Senate HELP Committee and House Energy and Commerce Committee will soon hold hearings to discuss the user fee agreements and legislation to reauthorize the programs. As with prior reauthorizations, Congress is likely to use this must-pass vehicle to advance a number of other priorities related to FDA regulation of medical products. Congress may focus on the following areas as the legislative process for user fee reauthorization gets underway.

- Members may seek to include some of the policies from the “Cures 2.0” legislation released last year by Reps. Diana DeGette (D-CO) and Fred Upton (R-MI). Cures 2.0 includes a number of provisions affecting FDA, including proposals related to clinical trial diversity, the collection of patient experience data and grants for novel clinical trial designs, among others.
- Congress may also choose to use this vehicle to advance bipartisan, bicameral in vitro diagnostics reform (the VALID Act).

- There is general interest in applying the learnings of the agency's COVID-19 experiences to inform ongoing efforts by FDA to be as modern and efficient as possible in fulfilling its public health mission. These interests may take the form of "riders" related to the use of real world evidence and modernizing risk-based inspection practices more broadly.
- Expediting the development, review and approval of safe and effective medical products to meet unmet medical needs has been an enduring area of focus since prescription drug user fees were first established in 1992. Congress may use the reauthorization as an opportunity to consider how the agency's tools in this space may be further modernized over the next five years, in areas such as the accelerated approval pathway, the use of real world evidence, clinical trial modernization and the development of surrogate endpoints.
- Members may seek to build on the previous provisions enacted in response to the opioid epidemic.
- Congress may look to include FDA-related provisions unrelated to medical products covered by the user fee programs, such as dietary supplements and cosmetics reforms.
- There is interest in a variety of reforms to drug and device regulation, including medical device software.

As the previous reauthorizations have shown over the past three decades, there's a lot at stake with the reauthorization of the user fee programs. This process provides an important opportunity for FDA, the industry, patients, stakeholders and Congress to come together on behalf of patients and public health—the full extent of which will be revealed in the coming weeks and months as the legislative process to reauthorize the UFAs plays out.

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