FDA User Fee Talks Offer Clues On Upcoming Reforms

By **Jordan Brossi, Michael Werner and Parker Reynolds** (March 24, 2026)

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The Prescription Drug User Fee Program, passed by the U.S. Congress in 1992 — was the first piece of major legislation to give the U.S. Food and Drug Administration the authority to collect fees from applicants seeking product approval of drugs and biologics.

The fees were intended to bolster the FDA's resources by supplementing — not supplanting — congressionally appropriated funds, allowing the FDA to hire additional review staff to speed application reviews. In return for collecting the fees, the FDA agreed to meet certain performance goals and maintain specific staffing levels.

Since passage of the original PDUFA, the collection and use of user fees by the FDA has largely been viewed as a success, with increased staffing helping to reduce review times and streamline patient access to newly approved products.

As the FDA's oversight and regulatory activities have grown in scope over the past several decades, so have the allowable uses of user fees. Today, user fees have been expanded to additional product categories regulated by the FDA and support both pre- and postmarket regulatory activities.

The User Fee Act reauthorization process — which happens every five years — has become a critical avenue for the FDA and stakeholders to address regulatory issues that arise between reauthorization cycles. The user fee agreements themselves are negotiated between the FDA and regulated industry and ensure the FDA has sufficient resources to conduct review activities.

The agreements also contain performance goals to make sure the FDA uses those resources to reduce review time and regulate in a more transparent way. Once the industry-FDA negotiations conclude, the agreement is published in the Federal Register, with all companies and stakeholders having the opportunity to submit comments.

Congress enacts legislation coincidental with the FDA-industry agreement to effectuate its terms. Because that legislation ensures critical funding for the FDA, it is considered "must pass" by Congress and all stakeholders. Consequently, the UFA legislation becomes an opportunity for the FDA, Congress and stakeholders to achieve reforms in the product evaluation and review process.

Where User Fee Acts Are Today

The UFA activities focus on four human medical product programs that were last reauthorized in 2022 and are currently set to expire on Sept. 30, 2027: PDUFA, the Medical Device User Fee Program, Generic Prescription Drug User Fee Program and Biosimilar User Fee Program.

Consultation meetings between the FDA and three of the regulated industries will continue through spring 2026, after which the final negotiated agreement can be expected. After publication of the agreement, the FDA will begin providing briefings to Congress, starting with committees with jurisdiction over the FDA.

The U.S. Department of Health and Human Services secretary will formally submit the agreements to Congress no later than Jan. 15, 2027. Congressional debate will continue throughout the year, with passage expected before Sept. 30, 2027.

The Four UFA Programs Under Discussion

A key theme across all discussions has been the FDA's support for advancing principles related to the "America First," policy approach, emphasizing that the Trump administration will continue to apply pressure on manufacturers of not just prescription drugs, but also medical devices and other regulated products to bring manufacturing and other technological components of human product development back to the U.S.

The FDA is expected to continue utilizing all levers of the UFA process to offer changes to FDA operations in line with the Trump administration's priorities. This message will find support in Congress, but it is not a given that representatives from the regulated industries will agree to advance the proposals as part of the final, negotiated agreement.

Below is an overview of key specific issues related to each of the four packages based off of public meeting minutes and the status of discussions released to date.

PDUFA

On July 14, 2025, the FDA hosted a public meeting to initiate PDUFA reauthorization. The meeting was attended by FDA Commissioner Dr. Martin Makary, representatives from the Center for Drug Evaluation and Research, trade associations representing pharmaceutical manufacturers and biotechnology companies, and drug and rare disease stakeholders.

During the meeting, the FDA shared its progress on initiatives from the previous user fee agreement and described its focuses for reauthorization. Representatives of trade associations shared their priorities and objectives for the reauthorization, including predictability and greater efficiency of FDA review processes, as well as improved communication between the FDA and sponsors.

Meetings between the FDA and industry representatives commenced on Sept. 11, 2025, with discussions held through February. Recent meetings have centered upon ways to make the review process more efficient, the approval process for rare disease products, FDA workload and staffing, and the amount of the user fee needed to fund review activities.

MDFUA

On Aug. 4, 2025, the FDA hosted a public meeting to initiate MDUFA VI reauthorization. Stakeholder consultation meetings and industry discussions commenced on Oct. 27 and 29, 2025, respectively.

During recent consultation meetings, discussion focused on post-market surveillance resources, the need to balance authorization speed without compromising safety or effectiveness, and key aspects of the Total Product Life Cycle Advisory 2.0 program.

Notably, the FDA and medical device industry will look to finalize MDUFA VI negotiations and begin writing the agreement this month.

GDUFA

On July 11, 2025, the FDA hosted a public meeting to kick off the GDUFA process and formally initiated consultation with industry, patient and consumer advocates, clinicians and other stakeholders on Oct. 22, 2025.

Improvements to generic drug programs have been discussed, including revising the

GDUFA fee structure to ensure long-term financial stability of the program, improving abbreviated new drug application review cycles, and onshoring and enhancing domestic production of generic drugs and active pharmaceutical ingredients.

During meetings in the last couple months, the FDA presented and industry responded to a proposal that would infuse "America First" principles into onshoring efforts. Specifically, the FDA proposed waiving for three years the annual facility fees for companies that break ground on facilities in the U.S. to manufacture one or more finished generic drug or active pharmaceutical ingredient.

This proposal builds on the FDA's efforts outside of UFA reauthorization processes to create a precheck process for certain manufacturers and seek to streamline permitting processes for new manufacturing facilities.

In response, industry representatives shared concerns regarding whether fees on other facilities may be raised as a way to offset lost revenue and urged the FDA to review other potential incentives to enhance domestic manufacturing. This is anticipated to be an issue of continued focus through spring 2026, as the FDA and industry seek to arrive at an agreement.

BsUFA

BsUFA is the newest UFA program, with Congress authorizing the FDA to collect user fees from biosimilar manufacturers in 2012. The FDA held a public meeting on Dec. 3 to begin the process, and stakeholder discussions and meetings between the FDA and industry will follow.

When discussions and consultations do begin, it is anticipated that the FDA will include in a list of proposals additional clarification on interchangeability with FDA-licensed reference products, especially following the release of draft guidance on Oct. 29, 2025, to reduce clinical testing requirements for biosimilars.

What Congress Is Doing

Until a final agreement between the FDA and industry is formally transmitted to Congress, much of the work done by members of Congress, committees of jurisdiction and congressional staff will be a mix of priority planning — through introduction of legislation on issues of concern — and convening industry stakeholders and patient advocates to

inform Congress of key priorities, such as what was seen with a report released last month by Bill Cassidy, R-La., chair of the U.S. Senate Committee on Health, Education, Labor and Pensions, on the future of the FDA.

Committees of jurisdiction are also working with the potential lead sponsors of the UFA bills, with chairs and ranking members of relevant committees and subcommittees most likely to fill those roles.

The HELP Committee and U.S. House of Representatives Committee on Energy and Commerce will be the focal points of these efforts, though virtually all members of Congress will engage.

Congress may also use the UFA package as a vehicle for broader FDA reforms, potentially including clinical trial modernization, artificial intelligence regulatory authorities and manufacturing incentives, which could significantly reshape compliance and development strategies beyond user fee negotiations.

There is likely to be sustained attention throughout 2026 and into 2027 on improving approval pathways, especially for rare and ultra-rare diseases, following the recent release of the FDA's draft guidance on plausible mechanisms, improving the FDA inspection process domestically and internationally, addressing FDA regulation of AI products, and speeding clinical trial timelines without compromising quality or safety.

For example, many of the recommendations outlined by Cassidy's report echo sentiments offered by stakeholders in previous meetings with the FDA — namely that the FDA's review processes must be more consistent and predictable, clinical trials made less burdensome and inexpensive without compromising safety, and the study of rare and hard-to-treat disease and conditions accelerated.

What Sponsors and Stakeholders Can Do Now

The FDA is expected to release the agreements negotiated with industry — known as commitment letters or goals letters — within the next several months.

Stakeholders should prepare to submit written comments for the agency's consideration when commitment letters are published for comment in the Federal Register. This is an important opportunity for input.

Stakeholders should also plan to advocate for their priorities through participation in congressional hearings or briefings, preparing statements or questions for the record, or working with policymakers to advance legislation.

Stakeholders should also be mindful that UFA action will continue after Congress passes UFA reauthorization legislation, as it will be critical to track the FDA's implementation of any changes — large or small — to its regulatory activities.

User fees have continued to grow in costs since Congress authorized them in 1992, and this is a pivotal opportunity for sponsors and industry to ensure the costs associated with these user fees ensure the FDA has the proper resources, staffing and skill to adequately and timely review — and ultimately approve — the sponsor's product.

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