

Committee on Energy and Commerce

**Opening Statement as Prepared for Delivery
of
Subcommittee on Health Chairwoman Anna G. Eshoo**

***Hearing on “FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and
Biologics”***

February 3, 2022

Today, our Health Subcommittee is holding its first hearing on the FDA Medical Product User Fee Programs, each of which must be reauthorized every five years. The current user fee programs need to be reauthorized by September 30, 2022, and the focus of today’s hearing will center on reauthorizing three of the four user fee programs for Fiscal Years 2023 through 2027: prescription drugs, generic drugs, and biosimilars.

The creation of the Prescription Drug User Fee Act, or PDUFA, in 1992 came at a time in our country when HIV/AIDs had reached epidemic proportions. In the late 1980s, Americans with HIV, AIDS and cancer had to wait years for lifesaving medicines to work their way through notoriously backlogged approval process at the FDA. Thousands of patients were dying yearly because the agency simply did not have the resources nor the staff to review human drug applications. PDUFA introduced a new opportunity for the FDA to take a transformative approach and vastly expedite its drug review process.

By authorizing the collection of user fees from industry, PDUFA provided the FDA with an additional revenue source to hire more staff and meet ambitious review deadlines for new medicines to treat the deadliest of diseases. Prior to PDUFA, the average review time for standard New Drug Applications and Biologics License Applications was 29 months. Today, PDUFA’s timeline for standard review is ten months, and the timeline for priority review is only six months.

Following the success of the PDUFA program, Congress enacted the Generic Drug User Fee Act, or GDUFA, and the Biosimilar User Fee Act, or BsUFA, in 2012 to clear additional backlogs and ensure patients have timely access to safe and effective generic drugs and biosimilars. These user fee agreements have successfully led to the development of more life-saving products at reduced costs for the American public. The user fees of each these programs are strictly used to accelerate the FDA’s drug and biologics review processes. They supplement and do not supplant congressional appropriations to the FDA.

Every five years, Congress reassesses the user fee programs to ensure each program has a fresh chance to improve its goals of getting critical medicines to patients who need them. Improvements to these programs are made with input from industry, regulators, and patient advocates, while working in agreement with the FDA to ensure the agency is appropriately equipped to assess the next wave of diagnostics, vaccines, and therapeutics.

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Today, we will hear from representatives from the FDA, industry, and public health who have worked diligently together on negotiations for the user fees programs. I'm pleased that the parties have reached an agreement on PDUFA, GDUFA, and BsUFA. The negotiated recommendations for each of these programs build upon successes of the existing programs and refine elements in light of the recent pandemic.

With these new programs, the FDA estimates that user fees for PDUFA will average \$1.4 billion per year; the user fees for GDUFA will average over \$600 million per year; and the user fees for BsUFA will average \$51 million per year.

As we discuss the sixth reauthorization of PDUFA and the second reauthorizations of GDUFA and BsUFA, it is my hope that Congress will act quickly to reauthorize these user fee programs to ensure that companies can continue to innovate and the FDA can quickly assess the next wave of life-saving medications.