Prescription Drug User Fee Act (PDUFA)

Background

The Prescription Drug User Fee Act (PDUFA) was first approved in 1992 in response to prolonged review times for new drug applications at the U.S. Food and Drug Administration (FDA). PDUFA authorized FDA to collect user fees from drug sponsors to support the additional personnel needed to conduct drug reviews. The fees were authorized on a five-year basis. FDA was required to achieve certain performance goals with respect to review times and responsiveness. The program has been reauthorized five times, with the current PDUFA (VI) in place until the end of September 2022. As the major source of funding for drug reviews, this program is critical for ensuring that cancer patients have timely access to the newest therapies.

Over the years, changes were made to the types and amount of certain fees that were required. Currently, sponsors (typically manufacturers) are responsible for paying an application fee (submitted with a new application or biologics license application) and program fee (an annual fee submitted for each approved prescription drug application). The program fees make up 80 percent of the total prescription drug user fee revenue, while the application fees make up 20 percent.[1] PDUFA fees account for 72 percent of the drug review division's operating budget, with federally appropriated funds making up the rest[1], meaning that a lapse of the user fee program would slash the drug review budget. The cost of submitting a PDUFA drug application is approximately 2.4 million dollars.[1]

The terms of each PDUFA agreement is negotiated between industry and FDA, with the final agreement submitted to Congress for approval. Historically, additional scope has been added to each PDUFA agreement. For example, in the last PDUFA reauthorization, funding was included to support the creation of patient-focused drug development guidance documents. While some new responsibilities are sometimes added within each new negotiated PDUFA agreement, the must-pass nature of the reauthorization provides a vehicle for additional FDA-related policy changes to be added alongside the core PDUFA legislation, and this is where advocacy organizations typically try to influence FDA policy.

Other User Fees Programs

There are other user fee programs (all synchronized on the same schedule), which FDA is authorized to undertake including:

- Medical Device User Fee Amendments (MDUFA) include medical devices used to diagnose, treat, monitor, or prevent a disease or condition (e.g. tongue depressors, bedpans, pacemakers, laser surgical devices).
- Generic Drug User Fee Amendments (GDUFA) includes the use of generic drugs.
- Biosimilar User Fee Amendments (BsUFA) includes biologic drugs that are similar to brand-name biologic drugs, but not structurally identical.

ACS CAN Priorities

In past PDUFA cycles ACS CAN's priority was strengthening the patient representative program, and during PDUFA V negotiations ACS CAN led a successful effort to codify the then-optional program. In the current PDUFA VII negotiations ACS CAN has focused on several priority areas.

- Enhancing diversity in cancer clinical trials
- Supporting modernization and harmonization of diagnostic test oversight
- Strengthening the accelerated approval pathway
- Clarifying policies that would allow greater use of decentralized clinical trials

[1] Congressional Research Service. FDA Human Medical Product User Fee Programs: In Brief. Published March 2017.