Biotechnology Innovation Organization

PDUFA At-a-Glance

WHAT IS PDUFA?

The Prescription Drug User Fee Act (PDUFA) is a law that helps the Food and Drug Administration (FDA) review new medicines more quickly while still holding every drug to the same strict safety and effectiveness standards. Through PDUFA, drug companies pay fees that give the FDA additional resources to carry out its work, including hiring more scientific experts, improving the technology used in drug reviews, and strengthening the systems that monitor medicine safety after a drug reaches the market. These fees supplement the taxpayer funding FDA receives from Congress and help ensure American patients have the earliest possible access to safe and effective medicines.

WHY DID CONGRESS CREATE PDUFA?

The FDA is responsible for making sure medicines are safe and work as intended before they can be prescribed to patients in the United States. Over time, this responsibility has grown much larger and more complex as medical science has advanced and the number of marketing applications has increased. Before PDUFA was passed in 1992, the FDA simply did not have enough staff to keep up with this growing workload. Patients sometimes waited years for potentially life-saving therapies (median review time of 29 months), and many new medicines reached patients in other countries first. PDUFA was created to solve this problem by giving the FDA the resources it needed to review drugs in a timely and predictable way. PDUFA fees support the FDA review process – not drug approval. Companies must pay the same application fees regardless of outcome of the review process.

HOW DOES PDUFA ADVANCE INNOVATION FOR PATIENTS?

Since PDUFA began, FDA review times have improved significantly (to less than one year, and often much quicker) without degrading the assessment of safety and efficacy. The United States is now often among the first countries to approve new medicines, and the FDA has expanded its ability to monitor drug safety throughout the entire life cycle of a medicine. As a result, patients gain access to new treatments more quickly while still benefiting from strong oversight.

PDUFA operates on a five-year cycle. Each renewal includes updated goals for how quickly the FDA should review new drugs, commitments to improve the review process, and new tools to strengthen drug safety. The current version, PDUFA VII, covers 2023 through 2027.

WHY DOES PDUFA MATTER TODAY?

For patients, PDUFA supports faster access to new treatments, more predictable review timelines, and better communication between the FDA, patients, and drug developers. These improvements can make a meaningful difference for individuals and families waiting for new therapies.

For biotechnology companies, the PDUFA framework supports the U.S. regulatory framework to ensure predictability and efficiency, which enables investment in biotechnology research and development and allows the U.S. to maintain global biotech leadership by efficiently providing promising treatments to patients.

For FDA, PDUFA provides needed resources that supplement taxpayer funding and ensures that FDA staff, FDA resources, and FDA regulatory science are all world-class.

Key Takeaways

- PDUFA helps FDA review new medicines **faster** without lowering safety standards.
- It was created to eliminate long delays that once kept new treatments from reaching U.S. patients.
- It must be renewed every five years to keep the review system running smoothly.
- PDUFA supports regulatory **speed** without compromising regulatory independence — helping patients get timely access to safe and effective new therapies.