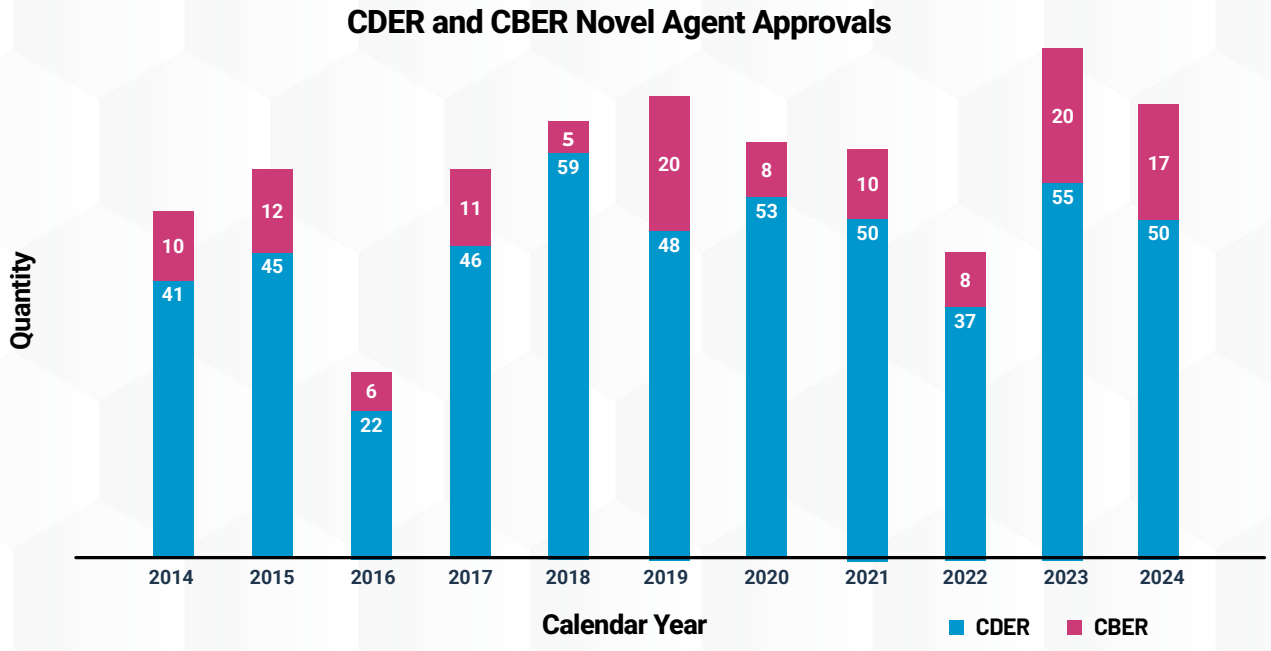
The Prescription Drug User Fee Act:
Ensuring the Timely Availability of Safe and Effective Medicines for Patients

The Prescription Drug User Fee Act (PDUFA) was first enacted by Congress in 1992 as a bipartisan solution to provide resources to speed the FDA's review of drug applications. The HIV/AIDS epidemic of the1980s and 1990s made clear the challenges with timely FDA review of drug applications. At the time, it took the under-staffed and under-funded FDA more than two years to review new medicines, which sparked patient activists to call for an end to these delays so that all Americans could receive timely access to safe and effective medicines.

Before PDUFA, more than 70% of medicines were first approved outside of the United States. Currently most new medicines are approved first in the U.S. including 68% in 2024 alone.[i]

Today, PDUFA supports the timely availability of treatments and cures for patients and plays an important part in positioning the United States as a global leader in biopharmaceutical innovation.

By the Numbers: PDUFA Helps Ensure Patient Access to Safe and Effective New Medicines



In 2024, FDA's Center for Drug Evaluation and Research (CDER) approved 50 novel drugs.[i]

In 2024, FDA's Center for Biologics Evaluation and Research (CBER) approved 17 novel biologic license applications (BLAs).[ii]

Source: FDA, Novel Drug Approvals at FDA, https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda; FDA, Biological Approvals by Year, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biological-approvals-year.

Learn more at PhRMA.org/PDUFA

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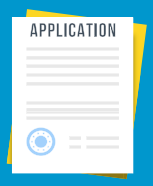
User Fees Provide Resources for Efficient Drug Review

PDUFA authorizes the FDA to collect user fees from biopharmaceutical companies to help provide the agency with resources to increase capacity to review new medicines. There are two types of user fees: an application fee, that companies pay when they submit a drug or biologic product application to the FDA for review; and a program fee that companies pay annually for eligible approved drugs.

These user fees are intended to enhance FDA performance and provide supplemental resources to specific regulatory functions for the review of new drug applications. These user fees supplement the funding that the U.S. Congress otherwise provides to the FDA through non-user fee appropriations. This gives the agency additional resources for the independent review of new drugs and helps ensure that safe and effective new cures and therapies reach patients.

The PDUFA program also supports advancements in regulatory science such as novel drug development approaches, as well as post-market safety monitoring activities. The program supports transparency through FDA's commitments to publish performance goals and performance reports, hold stakeholder meetings and engagements, and more. Also, the FDA publicly discloses detailed financial information in annual PDUFA financial reports.



Critically, there is no connection between a fee paid to submit an application and the independent review outcome for that application by the experts at the FDA.

PDUFA must be reauthorized every five years. The latest PDUFA (PDUFA VII) was signed into law on September 30, 2022, and runs through September 30, 2027.

How PDUFA Benefits Patients

America's patients have benefited from PDUFA with:

- **Reduced approval timelines:** Since PDUFA's implementation, the average drug approval time has dropped from more than two years to 10 months for standard applications and 6 months for priority applications. Faster approval times mean patients with conditions like cancer, rare diseases and chronic illnesses gain earlier access to innovative treatments.
- **Increased treatment access:** PDUFA has helped enable timely access to more than 1,700 new drugs and biologics, including treatments for conditions like cardiovascular, neurological and rare diseases and cancer. This helps improve the quality of life and health outcomes for patients all over the country.

Between 2015 and 2024, the FDA approved

23

cell and gene therapy products,

83%

of which were first approved in the U.S.[iii]

Learn more at PhRMA.org/PDUFA

PDUFA and the Future of Patient Access and American Innovation

Today, the U.S. leads the world in the introduction of new medicines. In fact, from 2013 to 2022, the number of medicines approved in the U.S. before other countries was 308, or 72%.

The FDA's human drug review program is the global gold standard for regulatory review. This is, in large part, because of PDUFA and its role in modernizing the FDA's independent review and approval process. By helping support efficiency, accountability, and scientific rigor in regulatory review, PDUFA has enabled the FDA to keep pace with the rapid increase in number and complexity of applications, as well as the rapid scientific advances within the U.S. biomedical enterprise.

Without PDUFA in place, patients could face years of delays in critical treatments due to the FDA having limited resources and diminished capacity, and the U.S. could cede its leadership position in the industry to other nations.

For over 30 years, PDUFA has played an important role in maintaining a predictable and efficient U.S. regulatory review process that can address the evolving needs of patients. The program has helped increase timely access to new medicines for patients and helped industry bring innovative treatments such as cell and gene therapies to the market.

Moving into the future, PDUFA should continue to enhance the FDA's ability to keep pace with the volume and complexity of innovative medicines entering the review pipeline by being efficient, pro-innovation, patient-centric and helping ensure that the FDA is accountable for metrics-based performance. It is crucial that PDUFA is reauthorized before the current program expires on September 30, 2027, to ensure the U.S. continues supporting a robust, biopharmaceutical ecosystem and remains competitive in biopharmaceutical innovation.

In 2024, the FDA approved the highest number of new drugs, followed by the regulatory bodies from Japan, Switzerland, the European Union, Australia and Canada.[iv]

i FDA, "Novel Drug Approvals for 2024," https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2024.
ii FDA, "2024 Biological Approvals," https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/2024-biological-approvals.
iii FDA, "Approved Cellular and Gene Therapy Products," https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.
iv CIRS, "New drug approvals by six major authorities 2015-2024: Trends in an evolving regulatory landscape," https://cirsci.org/wp-content/uploads/dlm_uploads/2025/08/CIRS-RD-Briefing-101-v1.1.pdf.

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