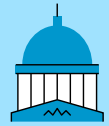




The Prescription Drug User Fee Act (PDUFA) VIII

OCTOBER 2026

PDUFA is a bipartisan solution to strengthen the FDA's efficiency to review new medicines



Congress has reauthorized PDUFA six times since 1992 with consistent bipartisan support

WHY

The onset of the AIDS epidemic in the 1980s prompted calls for faster drug review times

AIDS activist group ACT UP! staged a shutdown of the FDA to protest the slow pace of drug reviews and approvals

WHO

The FDA, Congress and the biopharmaceutical industry work together to reauthorize PDUFA every five years

The FDA also meets with the patient advocacy communities to understand their priorities for the PDUFA agreement

HOW

PDUFA supplements Congressional funding for review of new drugs by increasing FDA resources through user fees collected from the biopharmaceutical industry

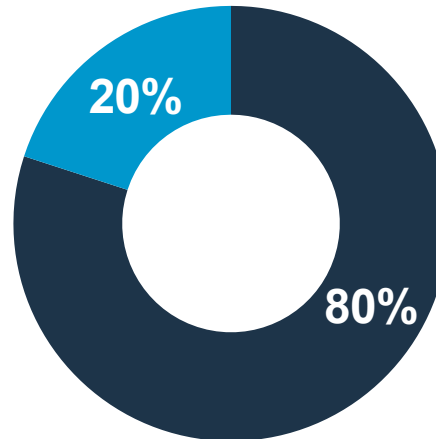
PDUFA includes negotiated FDA performance goals and commitments to help facilitate timely access to safe and effective new medicines for patients

Biopharmaceutical companies currently pay two distinct user fees

PDUFA user fees supplement funding from Congressional budgetary authority

Application Fee - Fee due when a sponsor submits a New Drug Application (NDA) or Biologics License Application (BLA)

20% of the total prescription drug user fee revenue comes from application fees.

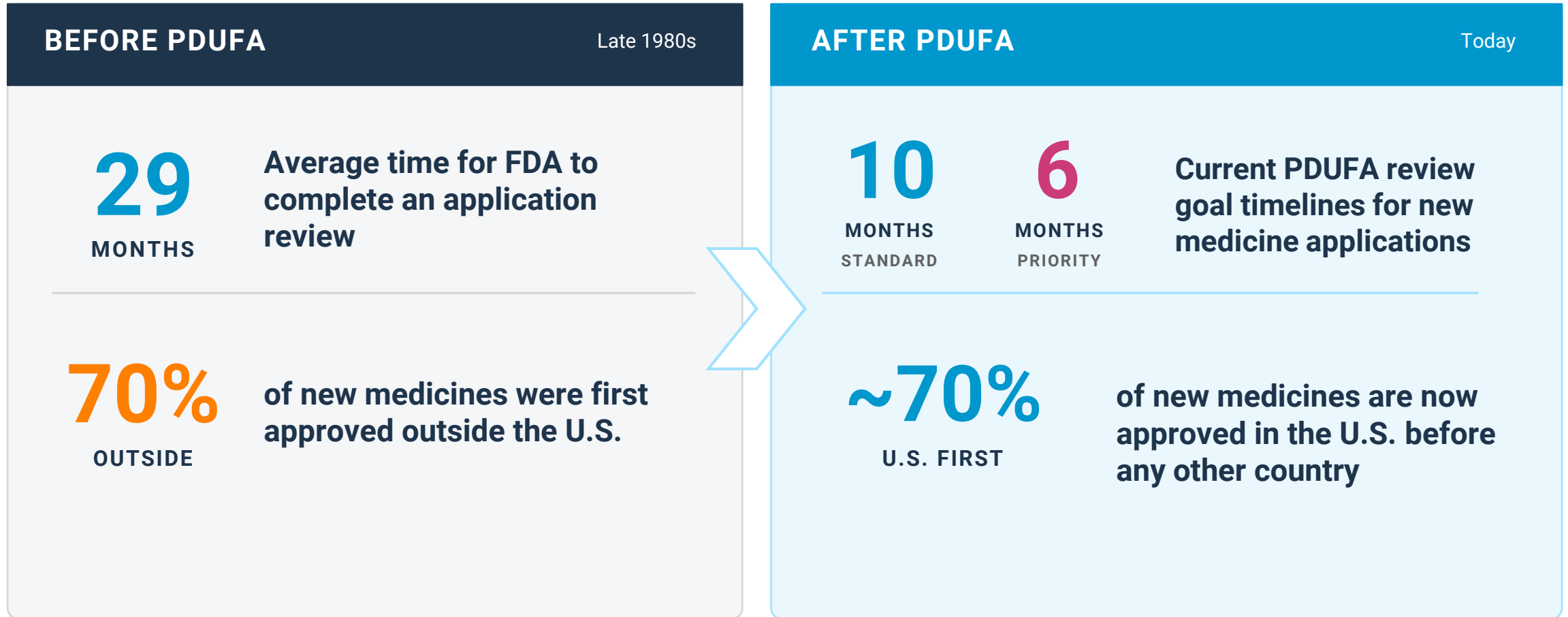


Program Fee - Annual fee for most approved prescription drug products without an approved generic

80% of the total prescription drug user fee revenue comes from program fees, intended to support a stable funding source for the FDA.

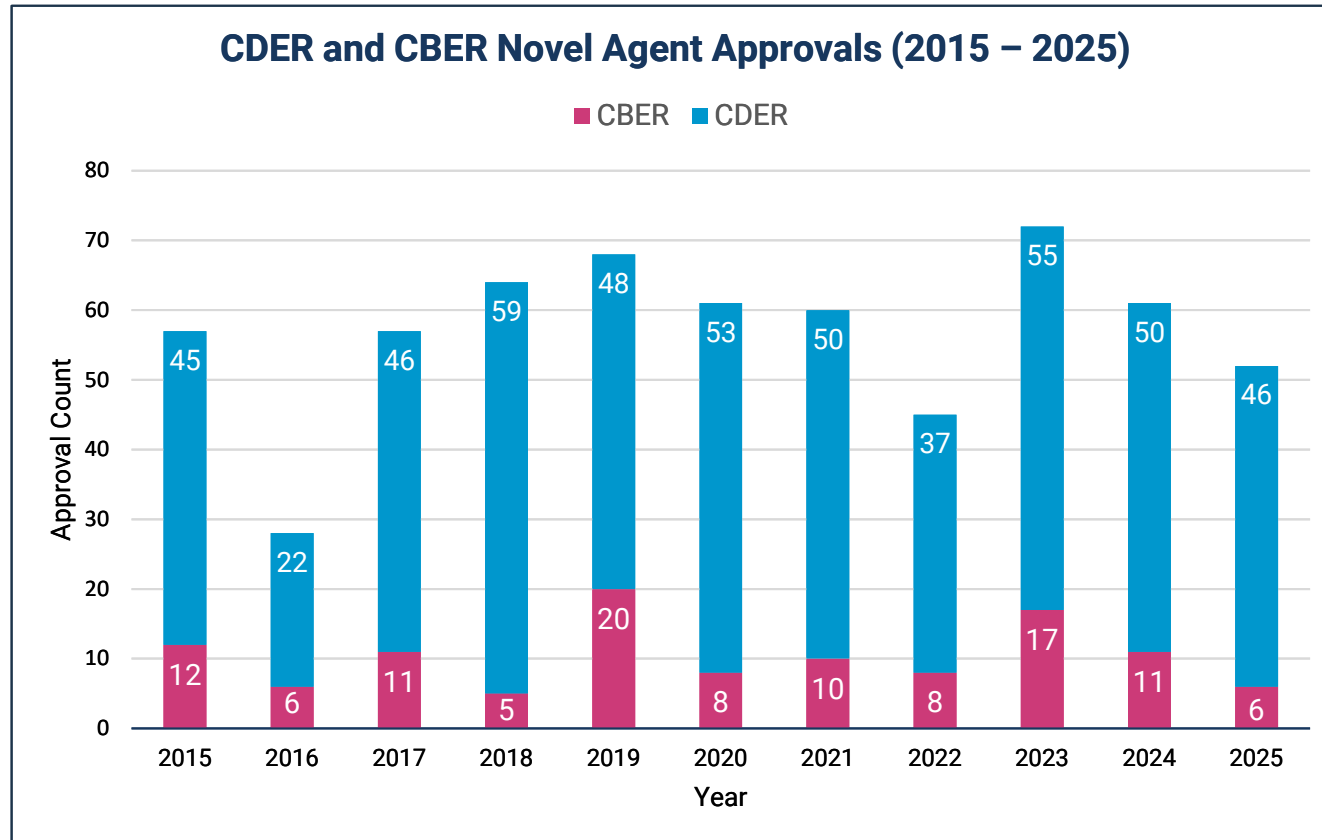
PDUFA transformed U.S. drug review

Since enactment in 1992, review timelines shortened significantly and the U.S. moved from lagging other countries to leading many new medicine approvals.



PDUFA helped turn the “drug lag” into U.S. leadership in timely review and first approvals.

PDUFA helped make the U.S. the global leader in new medicine approvals and patient access to innovative treatments



Note: CBER approval numbers do not include reagents, cord blood, or immunoassays.

Source: CDER: New Drug Therapy Approvals 2025; CBER 2025 Biological License Application Approvals.

In 2025, CDER approved 46 novel drugs:

- 85% were approved on the first cycle of review
- 70% were approved in the US before any other country
- 50% were for rare or orphan diseases
- 43% were first- in-class

In 2025, CBER approved 6 novel biologics:

- 67% were approved in the US before any other country

PDUFA brings innovation to patients

PDUFA has helped enable timely access for patients to more than 1,700 innovative new drugs and biologics across a wide range of diseases and conditions.

Chronic Diseases



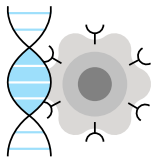
PDUFA has supported the timely review of new medicines seeking to prevent and treat a host of chronic conditions, including anti-obesity treatments like GLP-1s.

Neurological Conditions



PDUFA supports the timely review of new treatments for neurological conditions, including innovative treatments for Alzheimer's disease.

Rare Diseases



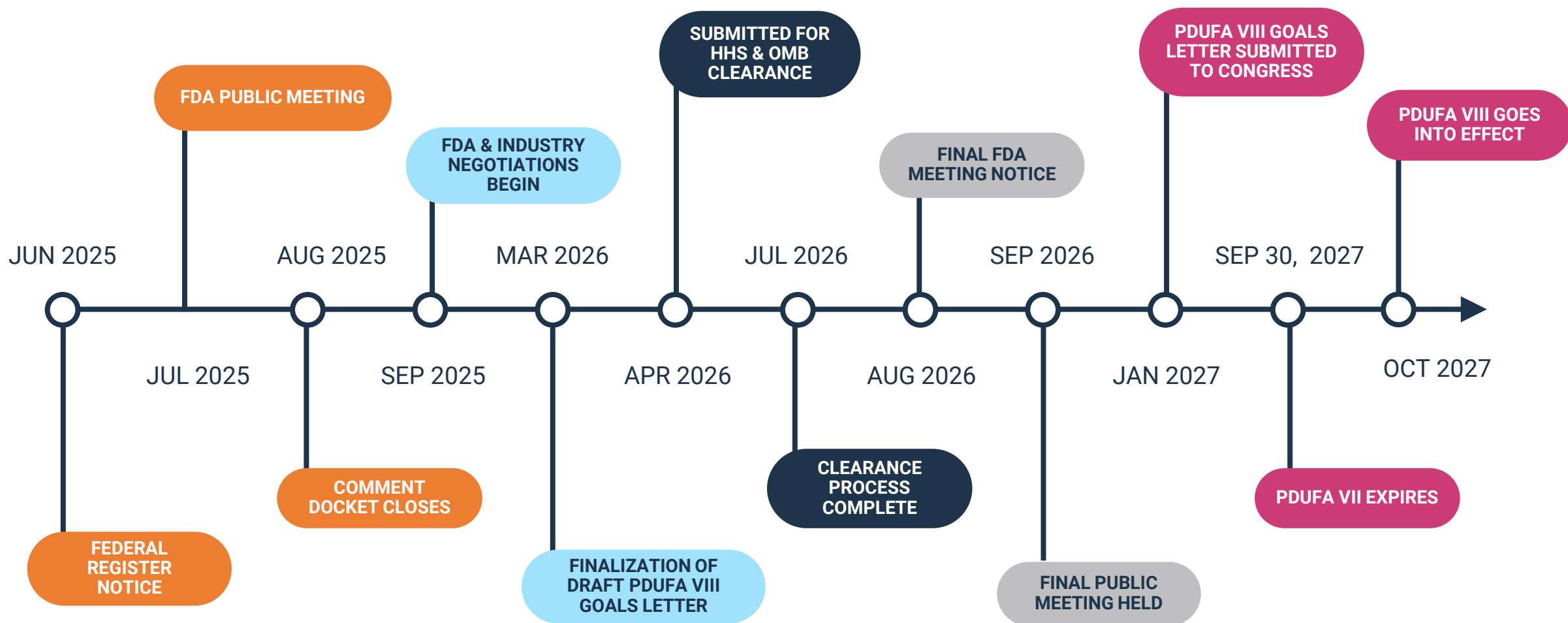
PDUFA supports the timely review of rare disease treatments, including new medicines for sickle cell disease and hemophilia.

Immunology



PDUFA's expedited reviews help bring groundbreaking treatments to patients faster, including a new medicine for myasthenia gravis, a severe neuromuscular autoimmune disease.

PDUFA's reauthorization includes several phases



PDUFA VIII Commitment Letter

PDUFA VIII will strengthen America's competitive edge in biopharmaceutical innovation

The PDUFA VIII commitments will help modernize the development and ensure efficient review of innovative medicines, advance domestic manufacturing and strengthen America's regulatory ecosystem to keep pace with scientific advances

Reduce delays in the drug regulatory review process

Allow the FDA to keep pace with scientific innovation

Strengthen public trust by improving transparency and accountability

1 Reduce delays in the drug regulatory review process

- **Introduces a new mechanism for timely feedback during drug review through enhanced FDA-company interactions, helping identify and resolve issues before they cause delays**
 - Includes timely labeling feedback 1-2 months prior to PDUFA date; enhanced transparency on Information Requests received late in the review cycle
- **Establishes a program to address manufacturing and facility issues earlier, reducing the risk of late-stage setbacks**
 - Includes two new meetings to address facility-related issues: (1) A pre-submission meeting to facilitate applicant and facility readiness and (2) a post-inspection meeting to ensure transparency and enable resolution of any identified facility issues by original action date
- **Further enhances efficiency by ensuring predictable reviews of pivotal clinical trial protocols, and streamlining the review of products with multiple indications with new multi-divisional meeting**

2 Allow the FDA to keep pace with scientific innovation

- **Makes successful pilot programs a standard part of FDA review**
 - Patient Focused Drug Development, Complex Innovative Trial Designs, Model Informed Drug Development and Real-World Evidence transitioned to regular review practice
- **Advances rare disease drug development, including for pediatric patients, through a mechanism for collaboration on the development of novel efficacy endpoints, and by supporting a series of FDA's Rare Disease Innovation, Science, and Exploration (RISE) workshops**
- **Enhances FDA surveillance and capabilities, including through improving existing tools for monitoring post-marketing safety data, with the aim of reducing the need for additional studies after approval**
 - Includes maintaining the high-quality and large quantity of data available to support the FDA's needs, advancing implementation of Sentinel 3.0 safety monitoring system and sustaining the processes and tools required to ensure appropriate use of these data

3 Strengthen public trust by improving transparency and accountability around PDUFA performance and user fee spending

- **Evaluates FDA performance against agreed-upon goals and identifies actionable recommendations for improvement through an independent, third-party analysis**
 - Includes assessing trends in review outcomes and timelines and review practices and communications
 - Actionable recommendations will aim to help the FDA and sponsors limit first cycle complete responses (for approvable applications), missed goal dates and review clock extension
 - Includes a public workshop and report on findings
- **Dedicates user fee funding to support the FDA's restaffing of drug review personnel**
- **Evaluates the new manufacturing facilities program through a third-party assessment to ensure it's effective in timely addressing any manufacturing facility issues**
 - Includes a public workshop and report on findings

**Learn more at
PhRMA.org/PDUFA**