Press Release

Primer: Prescription Drug User Fee Agreement

ALLIE WATSON | NOVEMBER 17, 2025

The Food and Drug Administration (FDA)'s Prescription Drug User Fee Act (PDUFA) authorizes the agency to collect fees from pharmaceutical sponsors in exchange for the agency meeting drug-review performance goals. In a new primer, Director of Health Care Policy Michael Baker explains the history of PDUFA, what the latest agreement funds and expects, where the benefits are most tangible, and which policy choices will shape the next reauthorization.

Key points:

- *The FDA's user fee programs – including PDUFA – are five-year, negotiated agreements that pair industry fees with performance goals and public reporting, and collectively form the backbone of modern review capacity.*
- *Across successive program cycles, the user fee agreements have shortened and stabilized review timelines, expanded early sponsor–FDA engagement, and funded critical capacity to support earlier approval and access to many innovations while strengthening postmarket signal detection and labeling updates.*
- *The FDA and affected industries have begun negotiating a reauthorization that may set clearer frameworks for artificial intelligence/machine learning and digital endpoints, stronger tools for initiating and enforcing confirmatory studies, continued workforce and IT modernization, smarter workload and fee calibrations, and greater transparency and global harmonization.*

Read the analysis.