Apr 3, 2025 - Health

# Drug industry worries about FDA delays

Tina Reed


Illustration: Gabriella Turrisi/Axios

Pharmaceutical companies are growing increasingly concerned widespread cuts at the Food and Drug Administration could set the

agency back as crucial review deadlines loom.

**Why it matters:** Health industries pay billions developing and shepherding drugs through the regulatory process, including user fees that help ensure there are enough staff to evaluate products on a predictable timeline.

- There are dozens of expected approval dates scheduled for drugs and biologics in the next three months. They include a monoclonal antibody for RSV from Merck, as well as expanded uses for a GlaxoSmithKline drug for COPD and a Gilead drug for HIV prevention.

- As yet, there have been no delays to drug approvals, but industry watchers worry that may not last in light of the agency job cuts. On Wednesday, CBS News reported the FDA is planning fewer food and drug inspections as a result of reductions in the FDA's Office of Inspections and Investigations.

**Potential delays would not only be costly** to drug makers, particularly smaller manufacturers, but can drive up prices for patients waiting for innovative treatments, experts say.

- HHS did not immediately respond to a request for comment.

**The big picture:** By the time companies file new drug applications, they typically are far enough along in the review process that there is an expected timetable for how long it will take to get their products evaluated.

- When those dates are delayed, it can make the investment community jittery and can be destabilizing from a business perspective, said Epstein Becker Green partner James Boiani. "If you're talking about a brand innovator product, you're losing patent life each day. If it's not approved, the asset's really depreciating," Boiani said.

- And, he said: "If you have a drug that's safe and effective, but it's kind of sitting on the shelf because someone doesn't have time to review it, that's a public health detriment as well."

**State of play:** There have not been any delayed approval dates tied to the cuts so far, but the loss of key FDA officials and career staffers could put that at risk, industry leaders warn.

- "The cumulative barrage on that drug-discovery enterprise, threatens to swiftly bring back those frustrating delays for American consumers, particularly affecting rare diseases and areas of significant unmet medical need," former FDA commissioner Scott Gottlieb wrote on X this week.

**Zoom in:** Before deep staffing cuts took place this week, the FDA's Center for Drug Evaluation and Research (CDER) communications team was already preparing talking points in the event of a delay, said a communications staffer who was laid off from the team this week.

- That was because there were so many disruptions from DOGE, as well as the departure of a large number of staffers who took buyouts or early retirements or simply quit when told they could no longer work remotely, said the staffer, who was granted anonymity out of fear they might lose their severance for speaking to the media.

- Multiple cuts — such as the elimination of the FDA's library staff who offer critical research assistance to drug reviewers or deep reductions among the lawyers in the Office of Regulatory Policy who write draft guidances and Federal Register notices — could slow work even more, the staffer said.

- "I'm sure [industry is] upset about these layoffs. They've paid 60% of our salaries at CDER through user fees. So they're probably like: 'We paid to have these people on staff. How dare you cut them?'"

*Editor's note: This story has been updated to correct the name of Epstein Becker Green partner James Boiani.*



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### FDA cuts threaten medical product review programs

Illustration: Allie Carl/Axios

The upheaval at the Food and Drug Administration is threatening to cripple the user fee system that funds reviews of new drugs, devices and diagnostic tests, with the most immediate threat to look-alike biological drugs, according to four recently dismissed agency officials familiar with the process.

**Why it matters:** Drug and device manufacturers pump billions of dollars into the system to ensure their products get timely evaluations. The collapse of that process could return the FDA to the early 1990s, when patients faced long waits before they could access promising treatments and devices.

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# User fee hearing becomes referendum on HHS cuts


Illustration: Aïda Amer/Axios

The future of FDA user fees collided with DOGE-directed layoffs at a fiery House Energy and Commerce hearing Tuesday during which Democrats accused GOP colleagues of whitewashing a dismantlement of federal health agencies.

**Why it matters:** The user fees levied on industry to fund product evaluations could change under HHS Secretary Robert F. Kennedy Jr., who's been vocal about what he contends is FDA coziness with the industries it regulates.

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# HHS sees day of chaos as layoffs hit scientists, policy experts

Illustration: Allie Carl/Axios

Veterinarians, population researchers, records officers and neuroscientists were all swept up in a chaotic series of layoffs Tuesday that effectively ended the government's health establishment as we know it.

**The big picture:** The sheer breadth of the cuts and reshuffling may not be apparent for weeks. But in the immediate aftermath, health care industry players and former federal workers say the workforce reductions will almost certainly affect drug approvals, low-income assistance, disease tracking and biomedical research once held up as the gold standard.

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