Apr 8, 2025 - Health

FDA cuts threaten medical product review programs

Tina Reed

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.

- The concern is acute because Health Secretary Robert F. Kennedy Jr. has pointed to the user fees as a sign of what he contends is coziness between the agency and the industries it regulates.

"**It would be catastrophic,**" said one former official of the possibility, noting that 83% of the payroll for the FDA's Center for Drug Evaluation and Research (CDER) is covered by user fees.

- "If they go away, 83% of CDER would have to be furloughed, which means that the center is gone."

- Job cuts at Health and Human Services have already led to the termination of product review staff, putting the timelines of some pending evaluations in jeopardy.

Driving the news: The user fee system accounts for nearly half of the FDA's annual budget and aims to ensure there are predictable timelines for reviews of prescription and generic drugs, devices, diagnostics and biologics while keeping decision-making within the agency.

- But under the law, industry payments are contingent on the federal government maintaining its share of program funding, to prevent overreliance on user fees.

- The officials told Axios it's almost certain some, if not all, of the prescription drug and medical device user fee programs will miss

those benchmarks by the end of the fiscal year due to recent contract terminations, layoffs and voluntary departures from the agency.

- That means the money collected from industry can't be used, which could cause reviews to grind to a halt, the officials warn. The stresses on the user fee system were first reported by AgencyIQ by Politico.

Between the lines: Upcoming negotiations between industry and the government on annual revenues companies will pay into the system already are at risk because many of the analysts who did that work across user fee programs were part of the deep staff cuts Kennedy announced last week.

- "I don't know how they'll set the fees for next year. They're typically due on October 1 and that process is usually starting right now," one former official told Axios.

- Beyond that, FDA's five-year authorization from Congress to collect user fees for prescription drug, biosimilar, generic drug and medical device reviews run through fiscal 2027, and negotiations on renewing the programs were due to begin by this summer.

- The program for over-the-counter drugs is up for reauthorization this September.

"**They need to stop** all of the slash and burn spending cuts and reinstitute a bunch of the staff that were let go who manage all these processes. That's the only way this is going to be resolved," the former official said.

HHS said the recent cuts and restructuring are meant to streamline operations and improve efficiency.

- "While we understand the concerns regarding the user fee programs, the agency is focused on mitigating risks and ensuring continued collaboration with industry stakeholders," an agency spokesperson said in a statement. "The FDA remains committed to maintaining the integrity of its programs and protecting public health."

The former officials say the most threatened user fee-funded work surrounds reviews of new biosimilars, which are seen as a way to increase lower-cost competition to branded biological drugs.

- While the biosimilar user fee program cleared the spending trigger of $25.9 million in fiscal 2024 by more than $10 million, it has been very close to missing that threshold the previous four years, said one former FDA official familiar with the program, who spoke on the condition he not be identified.

- It's not just cuts to jobs, but to outside contractors that will make it nearly impossible to meet the spending trigger, the official said. The administration called for a 40% cut in contracts last week in addition to contracts already terminated in recent months.

- "I don't see how it can make the trigger unless there's some extraordinary measures or numbers are made up," the official said.

The officials said it's not clear what happens when the spending trigger isn't met, but that they were advised by FDA lawyers that

continuing the work would be unlawful. It would also make it illegal to use any leftover industry fees or to collect more, effectively bringing an end to the program, they said.

- "The biosimilar industry is going to be hit because their work will probably be deprioritized. ... And consumers will lose out because of lack of cheaper biologic products given delays on the agency side," the official said.

The bottom line: If these user fee programs collapse, officials warn, it wouldn't just slow the drug review process. It could erode FDA's status as the gold standard regulator and drive companies to seek approvals elsewhere.

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Tina Reed
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Drug industry worries about FDA delays

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.

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Victoria Knight
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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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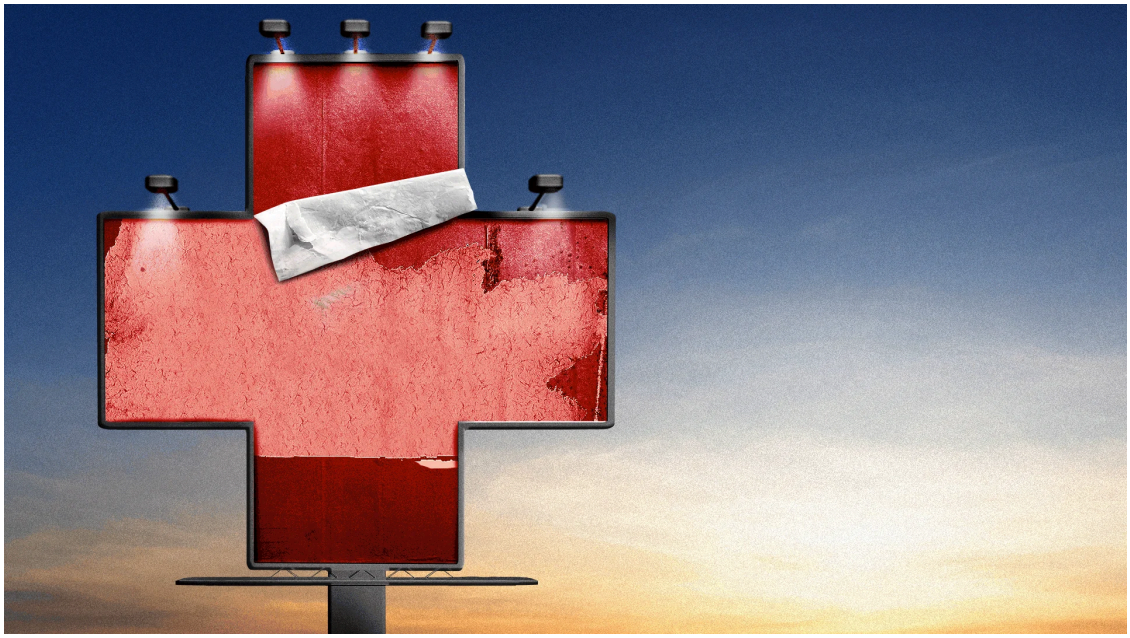

Illustration: Lindsey Bailey/Axios

Food and Drug Administration databases that physicians and public health experts rely on for key drug safety and manufacturing information have been neglected due to DOGE-directed layoffs, leaving health professionals flying blind on basic questions about certain drugs they're prescribing, current and former FDA officials tell Axios.

Why it matters: Information gaps that have become a hallmark of the workforce reductions and the sweeping reorganization of federal health agencies under Health Secretary Robert F. Kennedy Jr. are putting patient safety at risk, according to agency employees.

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