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ONE HUNDRED NINETEENTH CONGRESS

Congress of the United States
House of Representatives

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July 14, 2026

The Honorable Orice Williams Brown
Acting Comptroller General
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Acting Comptroller General Williams Brown:

I write to request the Government Accountability Office (GAO) conduct a study on the funding sources used to pay for the 2025 Reductions in Force (RIFs) at the Food and Drug Administration (FDA) initiated by Department of Government Efficiency (DOGE) or otherwise.

FDA is authorized to collect user fees from manufacturers and other regulated entities to supplement its budgetary authority to ensure medical product applications for prescription, generic and over-the-counter drugs, biologics, and medical devices that are submitted to the agency are reviewed in a timely manner. FDA and industry engage in negotiations to determine appropriate amounts of user fees to support the agency's function to enable those reviews and, in exchange for these user fees from industry, FDA agrees to meet certain performance metrics, such as timelines for review and to maintain certain hiring levels so those reviews can occur on that timeline.

As FDA itself explains, the agency "is required by law to spend user fee funds only on specified activities."[1] The activities that FDA can use these dollars to fund are specified in statute and are intended to support the goal of timely review to bring safe and effective medical products to Americans. For example, under the most recent reauthorization of the Prescription Drug User Fee Act (PDUFA), this includes support for regulatory review activities, such as reviewing applications, conducting inspections, monitoring of research, conducting post-market safety activities, and resources needed in connection with those activities.[2] As such, FDA has used these resources for staffing and resource capacity building to engage in those activities.

[1] Food and Drug Administration, *FDA: User Fees Explained* (https://www.fda.gov/industry/fda-user-fee-programs/fda-user-fees-explained) (accessed July 13, 2026).

[2] Pub. L. No. 117-180; 21 U.S. § 379g(6).

As part of the negotiation process, FDA and industry agree to performance measures that are ratified in a commitment letter, intended to provide industry with certain assurances. For example, in the most recent PDUFA letter, there are solidified plans to "set clear goals for human drug review program hiring."[3] Specifically, FDA agreed to targeted hiring numbers across each fiscal year (FY) of the program's implementation between FY 2023 through FY 2027. This included 210 hires for FY 2023, 79 for FY 2024, 44 for FY 2025, 15 for FY 2026, and 4 for FY 2027.[4] In the most recent Medical Device User Fee Amendments (MDUFA) commitment letter, the "minimum hiring goals FY 2023 through FY 2025 are listed as 144, 42, and 24, respectively. The MDUFA commitment letter specifically states that the planned enhancements that were agreed to "require that FDA recruit, hire *and retain* sufficient numbers and types of technical, scientific, and other program experts" for which the MDUFA agreement provides "significant new resources" to support the application review process.[5]

The user fee statutes for each of the programs, which codify the fees and are reauthorized every five years, and the commitment letters, ratified by FDA and industry, clarify the intended purpose for use of the funds. Nowhere in the statute or commitment letters is there a stated or implied allowance for fees to pay for loss of staff that were spurred by actions of the federal government.

In February 2025, FDA terminated approximately 700 employees categorized as "provisional," which included medical device reviewers. Many of these staff needed to be rehired to fulfill critical functions at the agency.[6] On April 1, 2025, reports showed the Department of Health and Human Services (HHS) Secretary Robert F. Kennedy fired another 3,500 workers from FDA.[7] Along with the 3,500 initial layoffs, there were an "unspecified number of retirements, voluntary buyouts and resignations."[8] Then FDA Commissioner Marty Makary claimed, in an interview on April 17, 2025, that there "were not cuts to scientists, or reviewers, or inspectors. Absolutely none."[9] However, these broad terminations included the negotiators and their project managers, who are critical to the discussions for the upcoming

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[3] Food and Drug Administration, *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027* (https://www.fda.gov/media/151712/download) (accessed July 13, 2026).

[4] *Id.*

[5] Food and Drug Administration, *MDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027* (https://www.fda.gov/media/158308/download) (accessed July 13, 2026).

[6] The Associated Press, *FDA to rehire fired staffers who booked inspection trips, but other workers remain in limbo* (May 1, 2025) (https://apnews.com/article/fda-staff-cuts-inspections-safety-b2b9bcc71b647afe896fe331f89cfd6c).

[7] STAT, *What was lost at the FDA* (May 7, 2026) (https://www.statnews.com/2026/05/07/fda-rebuilding-after-doge-former-regulators-speaking-out/).

[8] *See 6.*

[9] CBS News, *FDA head falsely claims no scientists laid off, as agency shutters food safety labs* (April 23, 2025) (https://www.cbsnews.com/news/fda-head-falsely-claims-no-scientists-laid-off-as-agency-shutters-food-safety-labs/).

reauthorization activities that were set to begin in 2025, commencing with the public meetings. [10] Terminations also included staff that booked travel for inspectors, some of which the agency also later rehired.[11] Reports showed that FDA rehired the negotiators and support staff for inspectors after the mass layoffs.[12]

However, reports on the exact number of staff that remain at the agency were uncertain for far too long. It is still unclear which positions or programs were cut in the mass layoffs. After over a year of congressional inquiry, HHS reported that as of April 13, 2026, FDA's workforce appeared to decrease by 4,550 compared to FY 2025, representing almost a 22 percent decrease in staff. These numbers were also posted on the Office of Personnel Management (OPM) Federal Workforce Changes database, which accounts for the cuts including "early retirement incentives, reductions in force, and the Deferred Resignation Program."[13] As of May 7, 2026, reporting indicates that despite efforts to hire an additional 3,200 scientific reviewers and investigators, only 350 have been hired.[14] Further, data indicates that FDA's drug centers, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), continued to experience staff losses in the first and second quarters of FY 2026.[15]

FDA is required to submit a financial report on each of the user fee programs, which must include the amount of fees that were spent on payroll.[16] Despite the RIF actions, there are unexplained increases in payroll expenses between FY 2024 and FY 2025 for several of the medical product programs.[17] For example, for PDUFA, FDA reported FY 2024's payments for payroll as $918,155,812. Conversely, the FY 2025 payroll payments are listed as $971,766,208.

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[10] Reuters, *FDA fires most negotiators for pharma user fee talks, sources say* (April 17, 2025) (https://www.reuters.com/business/healthcare-pharmaceuticals/fda-fires-most-negotiators-pharma-user-fee-talks-sources-say-2025-04-17/); Food and Drug Administration, *PDUFA VIII: Fiscal Years 2028 – 2032*, (https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032) (accessed July 13, 2026).

[11] *See 6.*

[12] BioSpace, FDA Rehires User Fee Negotiators After Mass Employee Layoffs (May 5, 2025) (https://www.biospace.com/fda/fda-rehires-user-fee-negotiators-after-mass-employee-layoffs-reuters); *see* note 6.

[13] OPM, *Workforce Changes*, https://data.opm.gov/explore-data/analytics/workforce-changes

[14] *See* note 7.

[15] Food and Drug Administration, *Center for Drug Evaluation and Research & Center for Biologics Evaluation and Research Net Hiring Data (FY 2023-2027)* (https://www.fda.gov/industry/fda-user-fee-programs/center-drug-evaluation-and-research-center-biologics-evaluation-and-research-net-hiring-data-fy-2023) (accessed July 13, 2026).

[16] Food and Drug Administration, *User Fee Financial Reports* (https://www.fda.gov/about-fda/user-fee-reports/user-fee-financial-reports) (accessed July 13, 2026).

[17] Food and Drug Administration, *Prescription Drug User Fee Amendments FY 2025 Financial Report to Congress*, (https://www.fda.gov/media/190768/download?attachment) (accessed July 13, 2026).

Similarly, for the Biosimilar User Fee Amendments (BsUFA), payroll for FY 2024 is listed as $32,806,350 while FY 2025 is reported higher at $34,879,223.[18]

In the PDUFA reauthorization financial meeting on February 19, 2026, industry noted the increase in the payroll reported between FY 2024 to FY 2025 in the PDUFA Financial Report. FDA responded that PDUFA funds were used to pay for "lump sum leave payouts, severance payments to eligible staff who performed PDUFA-covered work and were separated due to the Reduction-in-Force…." Further, FDA noted that payroll for FY 2026 is also likely to be higher than anticipated because some separated staff continue to receive severance pay. [19]

Despite FDA stating that no reviewers were impacted by the terminations, I understand that there has still been an impact on support staff, which may have received their salary through user fees. There was also an impact on user fee-funded employees through the other staffing reduction efforts, including retirements, voluntary buyouts, and resignations. This was made clear in the same meeting minutes from February 19, 2026, where industry noted that the number of full-time equivalent employees had also increased. FDA explained that those figures were as high as they were because they included employees on administrative leave.[20]

I am concerned that upheaval to the user fee programs through staffing cuts or any mismanagement of user fee funds will further hasten the movement of investment in medical product development out of the United States. As the medical product user fee programs are set to expire on September 30, 2027, it is critical that Congress understand how FDA is acting as a steward of the funds that industry is paying as part of the user fee agreements.

To provide clarity on whether proper procedures have been followed and the effect on the medical product review programs at FDA, I request GAO analyze the impact of the RIF efforts on the user fee programs. Specifically, I request GAO focus on the following considerations:

1. Staff attrition at FDA since 2025 with specific focus on staff that were funded, in part or whole, through user fee dollars. In providing this information, please clarify—

    a. The roles of these staff, including which center and office they came from, and how those departures are likely to impact successful implementation of the user fee programs.

    b. How many staff have been recused from medical product reviews, either due to employment discussions with external parties or otherwise, and the impact of those recusals on user fee activities.

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[18] Food and Drug Administration, *Biosimilar User Fee Act FY 2025 Financial Report to Congress* (https://www.fda.gov/media/190773/download?attachment) (accessed July 13, 2026).

[19] Food and Drug Administration, *Prescription Drug User Fee Act (PDUFA) Reauthorization FDA and Industry Finance Subgroup* (https://www.fda.gov/media/191643/download?attachment) (accessed July 13, 2026).

[20] *Id*.

c. The degree to which these staffing changes and user fee operations are impacting industry investment in development of medical products to bring to market in the United States.

2. Which separation methods were used for reduction in the staff, including involutory termination or other voluntary separation methods that were offered in conjunction with DOGE's RIF efforts. In considering the methods used, please also provide—

   a. Staffing levels in each of the user fee programs, vacancies in each of the programs, and to what extent FDA has been behind on the hiring goals.

   b. The number of staff that were separated under each method (e.g., early retirement incentives, reductions in force, and the Deferred Resignation Program).

   c. To what extent the RIF actions have impacted FDA's ability to meet the hiring obligations.

3. The amount of severances or other separation dollars paid to employees impacted by the RIF efforts or other separation efforts and the specific funding source used (e.g., appropriated funds under budget authority, user fee dollars, or operational overhead that is carried over from either).

   a. In reporting this information, please also account for the amounts that were paid for each of the different categories of separation (e.g., RIF, Deferred Resignation Program, Voluntary Early Retirement Authority, or other separation modalities).

4. For each source of funding for the severance, what is the agency's justification for use of those funds for the separations?

5. Whether the use of user fee dollars for the payment of staff separation, as described above, is lawful use of those funds.

Democratic Committee staff requested this information directly from FDA but have not received a response. By focusing on these questions, GAO can provide Congress with important details to ensure funds are not being mismanaged by the federal government and that FDA is being a good steward of the authorities provided to it by Congress.

Thank you for your attention to this matter. Please have your staff work with Jennifer Black of the Committee's Democratic staff on the scope and details of your work. I trust that you will prioritize this study and eagerly await your response.

Sincerely,

Frank Pallone, Jr.
Ranking Member