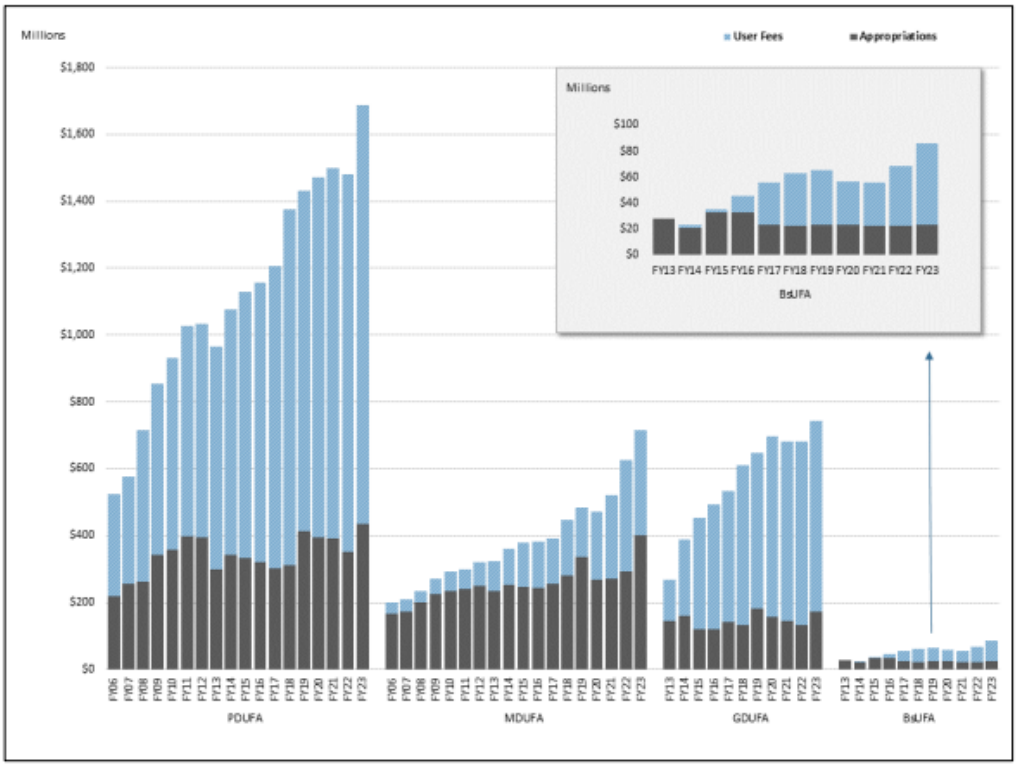
There has been considerable conversation regarding the impact the incoming Trump Administration and an HHS Secretary Robert F. Kennedy Jr could have on the FDA's User Fee programs. This stems from several comments and positions. For example:

- HHS nominee Kennedy stated that the President Elect has charged him with rooting out "the corruption and the conflicts out of the regulatory agencies" and to "return the agencies to the gold standard empirically based, evidence-based science and medicine that they were once famous for."
- HHS nominee Kennedy has been Board Chair and Chief Litigation Counsel of Children's Health Defense that states "user fees introduce potential conflicts of interest into the FDA's regulatory process." The group's Reform Pharma project has a 10-point plan to "restore healthcare integrity" and states that "drug companies [would] no longer fund the agencies that license and regulate them."[1]
- Calley Means, a thought leader close to Kennedy, told Fox News in Aug. 2024 that he favors an Executive Order directing that the FDA "should stop being funded by [pharmaceutical companies]."[2]

This brief unpacks the logistics behind user fees and the ways a new Administration may alter these processes.

Finances

Figure B-1. FDA Human Medical Product User Fee Programs: Total Costs, by Funding Source



Sources: Graphic created by CRS using data from FY2023 FDA User Fee Financial Reports at https://www.fda.gov/about-fda/user-fee-reports/user-fee-financial-reports; PDUFA Financial Report, Table 8, p. 18; MDUFA Financial Report, Table 8, p. 21; GDUFA Financial Report, Table 8, p. 17; BsUFA Financial Report, Table 11, p. 17.

Industry user fees make up a significant portion of FDAs medical product review center budgets (represented in blue in the graph above).[3] FDA's authority to assess and collect user fees is established in statute and subject to the Congressional appropriations process (for a refresher of these processes, CRS has a great report). The medical

[1] https://reformpharmanow.org/10-point-plan/
[2] https://www.youtube.com/watch?v=mUH4Co2wE-I
[3] Note there are also user fee programs in the food, over the counter drug, and tobacco regulatory schemes.

product user fee programs (PDUFA VII, MDUFA V, GDUFA III and BsUFA III) are currently *authorized* through September 30, 2027. The use of fees is *appropriated* each year in the normal government funding process. Said another way, both the agency's *authorit*y to collect fees and spend the fees are both acts of Congress.

Congress has exerted its authority to impact user fee programs –

- During the first Trump Administration, the FY2018 budget proposal suggested increasing the medical product user fees by over $1 billion:

  In a constrained budget environment, the Budget acknowledges medical product industries have sufficiently matured to assume a greater share of costs associated with FDA's administrative actions. User fees have been instrumental in allowing FDA to build capacity and improve the timeliness of the medical product review process without compromising the agency's high standards.[4]

  Congress ignored this budget request and proceeded to authorize user fees as negotiated before the President was elected.

- Congress passed a new user fee program in 2007 to support the review of DTC advertisements. Appropriators have blocked the implementation of that provision of the law and the collection of user fees in the years since. It's worth noting that the Reform Pharma project also seeks to ban pharmaceutical advertising.

User Fee Commitment Letter

FDA and industry will begin negotiations for PDUFA VIII in fall of 2025 and, if history holds, the negotiations will formally conclude with publication of a "commitment letter" for public comment in the summer of 2026 and transmission to Congress. Negotiating the commitment letter takes voluntary participation from both sides.[5] In theory, an FDA Commissioner opposed to user fees could take an active role in the negotiations by refusing to have FDA at the table or changing the unwritten parameters of negotiations or the letter. If FDA does not come to the table, a letter would not be completed and sent to Congress to inform the reauthorization process that would need to occur in 2027.

An Executive Order (EO) could also impact the negotiation process by pressing the FDA to take (or not take) certain actions, however EOs cannot change current law or cancel funds appropriated by Congress. FDA is not mandated by law to "come to the table," and there is broad discretion on the negotiation parameters.

If there is no commitment letter, that does not necessarily mean that the program lapses. Congress could still reauthorize the user fee collections at whatever levels it chooses and add new statutory language that encompasses timelines and other policy updates that historically have been included in the letter.

Bottom Line

FDAs user fees make up 47% of FDAs $6.9 billion budget. Eliminating the fees would require Congress to backfill $3.3 billion in annual appropriations, a number unlikely to be available in this fiscal environment. Even if the total budget was cut, and money was raised via a tax reform, a lack of fees creates a large budget shortfall. This, along with all the process hurdles described, makes it unlikely the user fee programs will be *eliminated*. There are, however, many ways an Administration can impact negotiations of the medical product user fees and Congress will play an instrumental role in providing checks and balances.

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[4] FY 2018 Budget in Brief - FDA | HHS.gov

[5] While Section 736B of the FFDCA outlines detailed reauthorization process requirements, it does not specifically mandate that the negotiation process begins.