Funding the FDA: General Information

Background

Every five years, Congress must pass legislation allowing the Food and Drug Administration (FDA) to collect user fees from industry. The User Fee Act (UFA), as this legislation is called, allows the FDA to collect these fees to better facilitate review of applications for FDA approval of new drugs, generics, devices, and other medical products. In the United States, these products require FDA approval before they can go to market. The fees fund the staff and other resources needed to review these products. User fees currently constitute about 70% of the FDA's total budget.

The FDA and industry began working on the current User Fee Act two years ago, following normal protocol for UFA reauthorization. They sketched out broad parameters for the legislation, including changes to user fee amounts, jurisdiction of the FDA, and some additional policy changes to FDA programs. This framework was sent to Congress eight months ago for legislators and staff to make changes before a vote on the bill.

During these eight months, Congressional leadership has been negotiating the details of reauthorization. Congress usually passes UFA legislation in July, leaving at least two months of buffer time before the fiscal year and current five-year-cycle for user fees ends. However, there has been more controversy than usual this round.

After weeks of public criticism from patient safety groups, the pharmaceutical industry, and medical researchers, Congress finally agreed to the policies in this user fee reauthorization on September 25, five days before the deadline. If the user fees are not reauthorized before September 30, then the FDA will be forced to furlough workers who are paid through user fee funding. This would lead to several negative consequences: application delays, administrative backlog, drugs not being approved, products not going to market. There could even be

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potential ripple effects in other parts of the agency. With critical dollars being re-assigned, functions like food imports inspection could also be reduced.

The last remaining piece of the UFA legislation that Congress needs to agree on is how to pay for the additional policy changes in the bill that are not funded by user fees. **If Congress does not find the necessary funding to pass this legislation and meet separate demands set by the President, the FDA will be forced to begin furloughing workers on October 1.**

The Current Situation

With the fiscal year deadline only five days away, leadership of the House Energy and Commerce (E&C) Committee and Senate Health, Education, Labor, and Pensions (HELP) Committee have gathered to discuss how to pay for the additional policies laid out in the legislation. The participants are the Chairwoman of E&C, Ranking Member of E&C, Chairwoman of HELP, and Ranking Member of HELP.

A recent report from the Office of the Assistant Secretary for Financial Resources at the Department of Health and Human Services, which oversees the FDA, suggests that the agency has some reserve user fees left from the previous cycle, which Congress authorized the agency to carry over until they are fully expended. This will allow the FDA to furlough reviewers in waves rather than all at once. Once the FDA begins furloughing workers, it has enough reserve funds to furlough only 800 staffers per day for five days, beginning with generic drugs and medical devices. After that, the agency will have to accelerate the pace as carry over funds run out, furloughing staff in all centers at a rate of 1600 per day for an additional five days. Therefore, the FDA has enough funding to pace furloughs for ten days. At its end, if a shutdown continues, experts believe that the FDA workforce will be reduced by 80%.

Passing this legislation requires $650 million in offsets for additional FDA-related policies. These are essential to obtaining votes for passage and must be paid for. E&C and HELP, as committees with jurisdiction over UFA and the FDA, must find enough offsets to cover the additional policies. **Additionally, the President has made clear that he will only sign the UFA bill if it also cuts FDA appropriations by $100 million, as he believes the increased user fees should cover more of the agency's operating budget.**

The White House identified the following programs for reducing spending in appropriations, stating that industry should foot more of the bill themselves:

- Food safety
- New medical data enterprise
- Generic drug development

- FDA Innovation Account

Given the tight deadline for funding the FDA, each Congressperson or Senator in this negotiation has had a conversation with leadership of their chamber and party regarding offsets. Therefore, each Member at the table has been deputized to make these decisions for the caucus to expediate the process and, hopefully, prevent any furloughs.

Passing legislation that meets these criteria ($650 million in offsets and $100 million of additional appropriations cut) will stop furloughs immediately and bring everyone back to work.

The Parties

E&C Chairwoman (Republican) is "the" Washington power player. She is also Chairwoman of the House Agricultural Appropriations subcommittee and has the ability to approve sufficient offsets and appropriations options to fully fund the FDA and meet the President's demands. She is sending her FDA staffer to these negotiations, who is broadly experienced on Capitol Hill. Within the House, the E&C Chairwoman has a strong relationship with the Speaker, who is working on a major energy bill for next year. Political experts believe that the Speaker currently has 90% support for the energy bill within her caucus.

HELP Chairwoman (Republican) has a long-time affiliation with the health industry and specifically the FDA, as she served as the CEO for a major pharmaceutical company before starting her career in public office. As such, her lead FDA staffer is one of the most expert on the Hill, having worked at the agency for nearly two decades before moving onto HELP. While the HELP committee does not have the capacity to contribute much towards offsets, the Chairwoman is the second-highest ranking Republican on the Senate Agricultural Appropriations subcommittee. The Chairwoman has a 53% approval rating in her home state.

E&C Ranking Member (Democrat) is a long-time Congressional leader on health policy issues. For these negotiations, the Ranking Member is sending an FDA staffer who has worked with him for nearly a decade. The Ranking Member and his staffer will seek to protect Medicare/Medicaid offsets, although it isn't yet clear if it is for the programs themselves or to use these offsets for something else in the future. The Ranking Member has been an advocate for an upcoming community health centers bill, which currently has 95% support within his caucus.

HELP Ranking Member (Democrat) is very interested in a fast resolution to this funding situation. With the FDA headquarters located in his home state, the Senator feels strongly that a catastrophe can be avoided if only the most influential powers will agree to cooperate. The Senator and his staffer leading this negotiation do not have the resources needed for

resolution. The HELP Ranking Member would rather see HELP resources invested in other ways, such as funding the newly created regulatory and enforcement authority for the FDA to thoroughly review cosmetics. The Ranking Member is expected to introduce legislation establishing and funding cosmetics review enforcement, which currently has 70% support, after UFA is passed.

Conduct of the Negotiation

All parties should discuss solutions to the situation with the FDA. There is not a "right" or "wrong" outcome to this negotiation. Parties should be creative and explore different options before choosing solutions that will conform to their priorities. You can choose to negotiate multilaterally or bilaterally, as long as you keep to the time constraint.

Mechanics

Timing: This exercise is divided into three rounds of 30 minutes each. The HELP Ranking Member is the timekeeper and must record in what minute a deal was reached.

- ROUND 1: All four parties meet before the end of the fiscal year.
    - *First 10 minutes:* Parties may choose to issue a press release on whether each member will contribute to funding the FDA.
    - *Next 20 minutes:* Parties will negotiate how to fund the FDA.
    - A deal signed during Round 1 will fund the FDA before the end of the current fiscal year, which prevents furloughs.
- ROUND 2: Days 1-5 of the FDA shutdown.
    - Six minutes represent one day.
    - 800 FDA employees are furloughed each day
    - Note: furloughs begin immediately in Round 2 – at the start of Round 2, 800 workers are furloughed, at minute 6, another 800 workers are furloughed
- ROUND 3: Days 6-10 of the FDA shutdown.
    - Six minutes represent one day.
    - 1,600 FDA employees are furloughed each day.
    - At the end of Round 3, 80% of FDA employees are furloughed and the exercise concludes.

Funding constraints: A successful deal must include $650 million in offsets and $100 million cut in additional appropriations.

- Offsets refer to government money that is currently allocated to be spent in a specific way. Using offsets to fund the FDA will redirect money from one program to the FDA.

- Appropriations refer to new government spending that must be authorized by Congress. The President insists that Congress cut $100 million from additional appropriations requests related to FDA programs.
- Money cannot be moved between offsets and appropriations.
- A deal that violates the constraints or is submitted late will be considered a no deal.

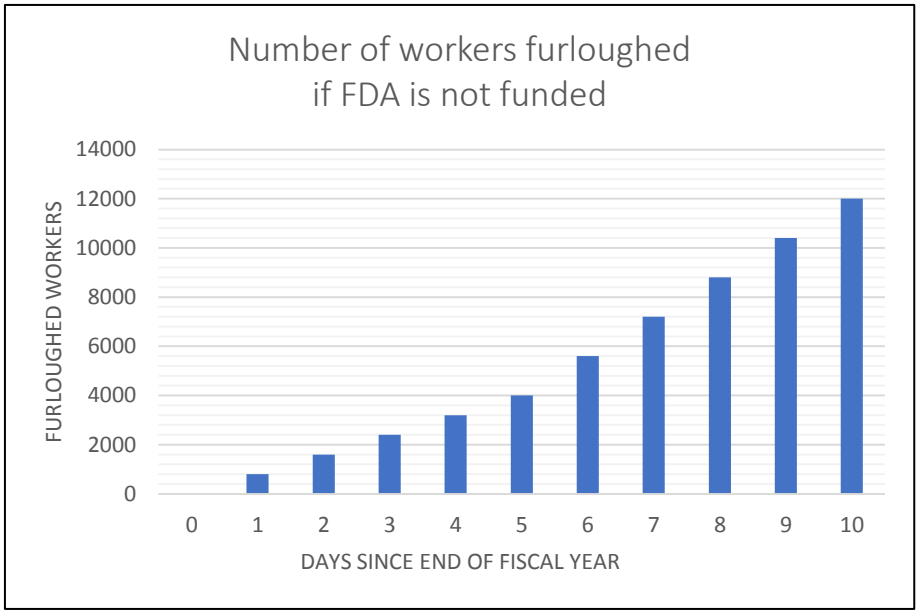
Sidebars: Parties are allowed to meet in smaller groups (sidebars) during the course of this negotiation.

Resources:

	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)
E&C Chair			90% support for energy bill
HELP Chair			53% approval rating
E&C Ranking Member			95% support for community health centers bill
HELP Ranking Member			70% support for cosmetics regulation enforcement bill
Total Needed	$650	$100	

Constraints to a successful deal:

$ millions in offsets	$650
$ millions cut from additional appropriations	$100

Furlough Rate:

Total FDA workers	15,000
Percent of FDA workers furloughed after day 10	80%
FDA reviewers furloughed per day (day 1 to 5)	800
FDA reviewers furloughed per day (day 5 to 10)	1,600