ALLIANCE FOR A STRONGER FDA

FDA Shutdown Tool Kit

Last Updated 09/22/2023

If Congress fails to pass a Continuing Resolution (CR) by midnight on September 30, 2023, the Food and Drug Administration (FDA) will enter into a "lapse period" in which no congressional appropriation exists to fund the agency. The lapse period will continue until the date of enactment of a Fiscal Year (FY) 24 appropriations bill or adoption of a FY 24 CR. The threat of a shutdown could recur whenever a short-term CR runs out.

During this lapse period, there are limited activities in which the FDA can engage. The activities that the agency can perform include: (1) activities necessary to address imminent threats to the safety of human life and (2) activities funded by advanced and carryover funds, notably but not exclusively, user fees.

The Alliance is a central resource for members of the Alliance for a Stronger FDA and for the media to understand the impact on FDA of a lapse in appropriated funding.

The Shutdown Tool Kit is current as of mid-day on September 22, 2023. It will be updated regularly as long as a shutdown threat continues.

A Shutdown Appears Likely

In most years, partisan disagreements about federal discretionary spending do not prevent passage of a Continuing Resolution to keep the government operating and temporarily funded when the new fiscal year starts on October 1.

This year, there is a fundamental conflict between a faction of the House Republican majority and the Senate on FY 24 federal discretionary funding. As a result, it is uncertain whether Congress will pass a Continuing Resolution by the end of the fiscal year on September 30.

As of September 22, a government-wide shutdown on October 1 seems likely. If a CR is passed in time to avoid a shutdown now, that may push the shutdown threat forward to the last day of the Continuing Resolution.

Eventually, solutions—both temporary and permanent—will have to be found and the government funded. It is in the nature of these kinds of disagreements that the resolution and timing are opaque until they happen. So, it is possible that a shutdown can be avoided at the last moment, but that seems less and less likely.

Background on the House and Senate positions on FY 24 appropriations, as well as the

status of Congressional action is contained in **Appendix A**.

For Further Information and Quotes Attributable to the Alliance

Alliance staff are available to talk directly with Alliance members and the media, and can be reached at:

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"FDA provides public health services that are core functions of government. When FDA is unable to perform them, the public is at unnecessary risk. The Alliance will continue to advocate for a prompt resolution of these issues and for minimum disruption to the mission of the FDA."

--Emily Holubowich, President of the Alliance for a Stronger FDA, and National Senior Vice President, Federal Advocacy, at the American Heart Association.

"The most critical FDA functions will be handled during this shutdown, and many user fee-funded activities will continue for a time. We hope that the Congress and the President will support enactment of the Agriculture/FDA appropriations bill to enable FDA to resume all its activities."

--Steven Grossman, Executive Director of the Alliance for a Stronger FDA,

Resources Directly from HHS and FDA

On the evening of September 21, HHS posted the FY 2024 contingency plan, including FDA materials.

HHS:
https://www.hhs.gov/about/budget/fy-2024-hhs-contingency-staffing-plan/index.html.

FDA:
https://www.hhs.gov/about/budget/fy-2024-fda-contingency-staffing-plan/index.html.

FDA Activities During a Shutdown

As described in the FY 24 FDA Contingency Staffing Plan, FDA's activities and limitations during a shutdown are as follows:

> The Food and Drug Administration (FDA) activities funded through carryover user fee funding will continue including certain activities related to the regulation of human and animal drugs, biosimilar biological products, medical devices, and tobacco products. User fee work specifically supports the review

and approval of new medical products, the review of requests to conduct important clinical research, the issuance of guidance, and other necessary activities to help patients have access to new therapies and important generic and biosimilar treatment options.

Additionally, activities that can be carried out with COVID-19 supplemental funding include work on emergency use authorizations to respond to the COVID-19 pandemic, mitigation efforts related to potential drug and medical product shortages and other supply chain disruptions, medical device infection control, work on enforcement actions for fraudulent, counterfeit and misbranded products related to COVID-19, and work on medical countermeasures, therapies, and vaccines and important generic and biosimilar treatment options.

All vital FDA activities related to imminent threats to the safety of human life will also continue. This includes detecting and responding to public health emergencies, continuing to address existing critical public health challenges, and managing recalls, including drug shortages, and outbreaks related to foodborne illness and infectious diseases. Other vital activities that will continue are surveillance of adverse event reports for issues that could cause human harm, the review of import entries to determine potential risks to human health, determining and conducting systems for cause and certain surveillance inspections of regulated facilities, and criminal enforcement work and certain civil investigations.

One interesting unknown: in the last shutdown (2018-2019) most agency websites were not updated. At the time, some portals were open and accessible electronically, but personnel who routinely responded to inquiries were not always available. This might have a greater impact on FDA today than it would have four years ago.

FDA Employees During a Shutdown

During a shutdown, all FDA employees will be assigned into one of three categories:

- **Exempt.** Employees are "exempt" from furlough if they are not affected by a lapse in appropriations. This includes employees whose functions are not funded by annually appropriated funds and would include employees carrying out activities funded by user fees and by advanced appropriations (such as "no year" money).
- **Excepted**. "Excepted" is used broadly to refer to employees whose work is funded through annual appropriations but who are not furloughed because they are performing tasks that, by law, are allowed to continue during a lapse in appropriations. The OMB guidance on this can vary from year to year, but basically, these will be FDA staffers who work in areas where their absence would constitute a threat to public health and safety or property.
- **Furloughed**. A furlough is the placing of an employee in a temporary non-duty, non-paid status because of lack of work or funds, or other nondisciplinary reasons. Again, year-to-year definitions might vary, but individuals who are involved in the development of regulations or the conduct of administrative or policy work are most likely to be furloughed.

The FY 24 plan reflects a higher staff count than the FY 23 plan. However, the key percentages are the same: 81% retained and 19% furloughed.

Here is our summary of FDA's status derived from text in the FY 24 FDA plan:

Staff Involved	FDA
Total on board staffing (extrapolated from other data)	19,250 (estimated)
Total staff exempt and excepted	15,602 (actual) (81%) (actual)
Exempt	12,300 (actual) (64%) (actual)
Excepted	3,302 (actual) (17%) (actual)
Number of staff to be furloughed (number extrapolated from other data; percentage actual from text)	3,658 (estimated) (19%) (actual)

NOTE: A key table that should be part of the HHS plan has not yet been released. When available, it will provide exact numbers in place of estimates.

Overall, HHS is furloughing 42% of its workforce. Only FDA and the Indian Health Service (which has an advanced appropriation for the first time) are furloughing less than the HHS average.

The FY 24 Contingency Plan: Other Considerations

No new user fees are accepted during a lapse period and FDA can only undertake user fee activities paid from the prior year's carryover funds. Depending on the duration of the shutdown, account balances and burn rates, there may reach a point where funds to carry out user fee-funded activities are not available, and employees are furloughed. This eventual phase-down will be different for each of the separate user fee programs.

As of September 22, we do not know the balances in the user fee accounts. However, we do not anticipate problems unless a shutdown is prolonged.

The distribution of employees who will continue to work in a shutdown will not be evenly distributed.

- The tobacco program is fully funded by user fees and presumably none of those employees will be furloughed.
- Medical product activities are supported by a mix of user fee and BA

appropriations and some individuals working in the medical product area will be furloughed.
- A higher percentage of employees working on food safety will be furloughed because their salaries are almost entirely paid through budget authority (BA) appropriations.

If a shutdown were to follow past patterns, individuals involved in the development of regulations or the conduct of administrative or policy work are more likely to be furloughed than others.

Conclusions from Comparing the FY 24 FDA Lapse Plan to the FY 19 Plan

Interpretation and implementation of "who works and doesn't work" are subject to change.

They were noticeably different a decade ago. As recently as 5-years ago, during the extended 2018-2019 shutdown, FDA had 17,397 employees, of whom 41% (7,053) were furloughed, according to HHS documents (available here). In contrast, the FY 24 plan provides for a furlough of just 19% (about 3,658 employees).

The line for staff normally paid from or shifted to carryover funding or advanced appropriations goes from 7,399 (FY 19) to 12,300 employees (FY 24). It is hard to know how much of the increase can be attributed to: 1/ growth in user fees, 2/ reinterpretation of policies that classify employees, or 3/ dramatic growth in the amount of advanced funding available to the agency (e.g., COVID funding).

Similarly, the number of employees who would be working because of their role in activities related to the safety of human health, maintenance of animals and protection for government property increased from 1,237 (FY 19) to 3,302 (FY 24). That would appear to be explained by the breadth of activities involved:
- detecting and responding to emergencies, managing recalls, pursuing criminal enforcement work and certain civil investigations,
- reviewing import entries to determine potential risks to human health,
- conducting for cause and certain surveillance inspections of regulated facilities,
- conducting surveillance of adverse events reports for issues that could cause human harm, and
- other critical public health issues as appropriate.

Excepted staff will also be responsible for continuing efforts to address other serious public health challenges, including drug shortages, and outbreaks related to foodborne illness and infectious diseases.

Here are a few conclusions based on this comparison:
- relative to the last major shutdown (2018/2019) significantly more staff will be working, representing a change (for the better) in service levels;
- medical products will be more robustly staffed, while food safety may be less thinly staffed than last time; and
- despite the larger number of employees who will be working, FDA's ability to do its job will be substantially compromised.

ABOUT THE ALLIANCE

The Alliance for a Stronger FDA is a multi-stakeholder coalition that advocates for increased appropriated funding for FDA and educates policymakers, media, and the public about FDA's expanding mission and growing responsibilities. The Alliance was founded more than 15 years ago, a period during which FDA's taxpayer funding more than doubled.

For more information, contact Steven Grossman (sgrossman@strengthenfda.org) or Phil Karsting (pkarsting@ofwlaw.com)

Appendix A---Background on the Funding Differences Between the House and Senate Positions

The Senate plans to spend in accordance with the budget limits in the Fiscal Responsibility Act of 2023 (FRA), passed earlier this year after negotiations between President Biden and House Speaker Kevin McCarthy. In addition to funds available under the FRA's spending ceilings, the Senate hopes to add additional disaster relief funds and additional military support for Ukraine, as requested by President Biden and widely supported in the Senate.

The Senate Appropriations Committee has approved 12 bipartisan appropriations bills, and they are being bundled into minibusses for floor consideration. The first combines 1/ Agriculture, Rural Development, Food and Drug Administration, and Related Agencies; 2/ Military Construction, Veterans Affairs, and Related Agencies; and 3/ Transportation, Housing, and Urban Development. As of September 22, procedural objections to the minibus were sustained and next steps in the Senate are unclear. Each bill may be taken up separately and/or compromises negotiated.

As of September 22, the Senate has not advanced a CR. However, Politico reported that "Senate Majority Leader Chuck Schumer has moved to begin debate on a House bill that could serve as a vehicle for a continuing resolution keeping the government functioning past September 30. The move to tee up the [House-passed] House FAA bill is a signal that Senators have lost patience with the House as it flounders in its attempts to pass any sort of appropriations legislation. With the chamber out Monday for Yom Kippur and a shutdown looming just four days later, Senators have no time to waste."

The House plans to spend considerably less money in FY 24 than the FRA ceiling (upon which the Senate bills are based). This would not necessarily stand in the way of a CR while differences are being worked out, although that is not the case this year.

A draft CR [here] has been advanced by a group of conservative and moderate Republican House members, with a rule for consideration having been approved by the House Rules Committee but not yet advanced to the full House. The CR would limit CR spending to the lower House total. There are also border security and immigration reform legislation attached.

To accomplish the necessary savings in the CR, defense and VA would be held at current levels and all other federal discretionary would bear a slightly more than 8% decrease for the duration of the CR. There is a group of House Republicans who have said they won't vote for this CR without additional spending cuts beyond those in the draft CR.

As of September 22, House Speaker McCarthy is still attempting to find a position that all House Republicans could support. He also must deal with increasing sentiment in the House against additional funds for the Ukraine war.

An alternative—though seemingly unlikely—pathway centers around a discharge petition for a traditional CR that continues government at current funding levels that has been signed by all 213 Democratic House members. If 5 House Republicans signed as well, it would force a floor vote on that alternative measure. Some House Republicans from districts won by President Biden have talked about signing the discharge petition if there

is no hope for any resolution other than a shutdown. Presumably, the threat gives them some leverage in the Republican caucus, but from a political perspective, it is nearly impossible to imagine them actually signing the petition.