

Congress of the United States

Washington, DC 20515

February 16, 2024

The Honorable Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, MD 20993

Dear Commissioner Califf:

We write with regard to the U.S. Food and Drug Administration's (FDA) flush list for certain opioids and non-opioid medications. This flush list contains disposal guidance for certain medications to prevent accidental ingestion or misuse. Despite stating that the FDA will continually evaluate and update the list, the last date the medications on the flush list and the guidance for disposing listed medications was updated on the FDA's website was in 2020.¹ Moreover, the flush list guidance was developed from an FDA study that was published in 2017, which used data from as early as 2010 and does not account for the recent rise in fentanyl and opioid use.²³ We are concerned that the flush list guidance is outdated and is likely negatively impacting Florida's public health and ecosystem. Considering the guidance coincides with rising reports of fish contaminated with opioids and other high-risk drugs throughout Florida, we request an update from the FDA on when a new study on the impacts of the flush list on public health and the environment will be conducted and when updated flush list guidance will be issued.⁴ We also request more information about how the FDA plans to update their guidance on a consistent basis.

According to the FDA, medications on the flush list are those "sought-after for their misuse and/or abuse potential and that can result in death from one dose if inappropriately taken."⁵ Recognizing the environmental impact that flushing these products may have, the FDA published a paper in 2017 that examined the environmental and human health risks associated with flushing the 13 active ingredients in the products on the flush list. The study concluded that the potential risk to the environment from these medications was negligible, but additional information is needed. While the FDA has noted that it "continually evaluates medicines for safety risks and will update the list as needed," further details have not been made publicly

¹ <https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-fdas-flush-list-certain-medicines>

² <https://nida.nih.gov/research-topics/fentanyl#:~:text=Over%20the%20past%20decade%2C%20fentanyl,found%20in%20the%20drug%20supply.>

³ <https://pubmed.ncbi.nlm.nih.gov/28787777/>

⁴ <https://www.bonefishtarpontrust.org/bonefishpharma/>

⁵ [https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-fdas-flush-list-certain-medicines#FlushingImpact:~:text=\(1\)%20sought%20after%20for%20their%20misuse%20and/or%20abuse%20potential%20and%20\(2\)%20that%20can%20result%20in%20death%20from%20one%20dose%20if%20inappropriately%20taken](https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-fdas-flush-list-certain-medicines#FlushingImpact:~:text=(1)%20sought%20after%20for%20their%20misuse%20and/or%20abuse%20potential%20and%20(2)%20that%20can%20result%20in%20death%20from%20one%20dose%20if%20inappropriately%20taken)

available about how the agency is carrying out these evaluations. The FDA study for which the flush list is based on described the concluding data as containing “limitations” and “uncertainties” about key conclusions and “additional testing may be needed to verify the potential of buprenorphine, oxymorphone, fentanyl, and methadone to bioconcentrate into fish plasma to levels known to yield therapeutic effects in humans.” Assessments concluding that more information is required, or there was not enough data to fully evaluate, appear numerous times throughout the study. As of February 2024, it is not clear that any additional efforts have been taken to collect the necessary additional information for the agency to have a full picture of the drugs impacts.

Another development within the last decade that the FDA flush list does not account for is the rise in fentanyl and fentanyl laced counterfeit pills. The current flush list urges Americans to flush any drug with “fentanyl,” indicating that all fentanyl pills should automatically go down the drain. However, the high cost of many drugs has pushed many Americans to look for cheaper alternatives from less reputable sources, which have been increasingly known to sell drugs laced with fentanyl. This issue is very prevalent in Florida, with more than 5,000 fentanyl overdose deaths in 2022, the second highest state for fentanyl overdose deaths in the country.⁶ As the overall amount of fentanyl has increased in our wastewater system from illicit fentanyl and fentanyl-laced drugs, the FDA must ensure they are accounting for this significant increase when enforcing its flush list guidance.

While we appreciate the efforts made by the FDA to prevent and reduce accidental ingestion of opioids and other high-risk drugs, we are concerned that not all the risk factors involved with flushing drugs down the drain have been properly assessed or evaluated. The current flush list is based on outdated data with significant gaps that require additional research. As more reports are shining light on the impacts of opioids, and other drugs found in wildlife and waterways throughout Florida and their potential effect on public health, it is imperative that the FDA review its flush list guidelines and update its research to reflect the current environment.

As such, we request a comprehensive update on status of FDA efforts to modernize the flush list research and guidelines, including answers to the following questions:

1. Outside of the 2017 study cited on the FDA website, what data was used to determine which drugs were chosen in the 2020 flush list?
2. How often does the FDA update its flush list? When is the FDA expected to release an updated flush list?
3. Who will be conducting the research and guidance development for the updated flush list?
4. How has the FDA accounted for the increased prevalence of fentanyl, fentanyl-laced medication and other opioids in crafting its flush list?
5. Does the FDA utilize data from testing fish and aquaculture?
6. How does the FDA plan to share information with the public about the updated list of drugs on its flush list?

⁶ <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#:~:text=1%3B%20natural%20and%20semisynthetic%20opioids,4%3B%20cocaine%2C%20T40.>

Thank you for your attention to this important matter. We look forward to your prompt response.

Sincerely,



Marco Rubio
U.S. Senator



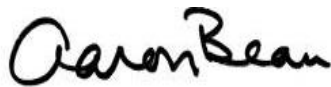
Rick Scott
U.S. Senator



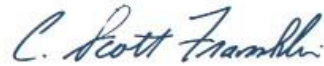
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