

# Congress of the United States

Washington, DC 20515

June 27, 2022

Robert M. Califf, MD  
Commissioner  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, Maryland 20852

Dear Commissioner Califf:

We are alarmed about the opioid epidemic that continues to ravage our country and want to ensure we are continuing to do everything possible to combat this scourge.

One of the most effective ways to prevent drug misuse is to encourage the removal and disposal of unused, unwanted, or expired medication that may otherwise remain in our medicine cabinets. To achieve that goal, Congress gave clear direction in Section 3032 of the SUPPORT Act (P.L. 115-271) for the Food and Drug Administration (FDA) to use risk evaluation and mitigation strategies to improve safe storage and disposal of opioid medications.

While we appreciate the FDA's April 21 request for public comments on the proposal requiring all opioid prescriptions to be dispensed with a mail-back envelope to facilitate safe return of leftover medications, we believe that this proposal must be strengthened to meet the goals of the SUPPORT Act.

In light of our concerns, we ask for clarity on the following matters:

1. What was the process the FDA used to consult with other relevant departments and agencies, including the Substance Abuse and Mental Health Services Agency (SAMHSA), the Centers for Disease Control and Prevention (CDC), Office of National Drug Control Policy (ONDCP), Drug Enforcement Administration (DEA), and the Environmental Protection Agency (EPA) in developing this proposal?
2. If there was interagency interaction in the proposal development process, what feedback did SAMHSA, CDC, and ONDCP provide?
3. Did the FDA study the cost of implementing its mail-back proposal, and, if so, what are expected costs and which parties would bear those costs?
4. Press reports indicate that mail theft is rising in the United States.<sup>1</sup> We also understand a March 2022 U.S. Postal Inspection Service (USPIS) advisory issued to the Department of Justice noted a "significant increase" in the number of armed robberies of USPS letter carriers.<sup>2</sup> Did the FDA perform its own assessment of this risk as part of the mail-back proposal development?
5. Executive Order 13175 requires robust consultation with Tribal officials in the development of federal policies that have Tribal implications. As you know, the opioid crisis is particularly acute in Tribal and reservation communities. Did the FDA consult with Tribal officials when developing its mail-back proposal?
6. In many rural communities there is limited access to U.S. mail. Did the FDA assess the impact of its mail-back proposal on rural communities?

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<sup>1</sup> "Signed, Sealed, Snatched," *Businessweek*, March 28, 2022. <https://www.bloomberg.com/features/2022-mail-thieves-checks-scam/>

<sup>2</sup> "The stolen-mail scheme now targeting a wealthy D.C. suburb," *The Washington Post*, April 30, 2022. <https://www.washingtonpost.com/dc-md-va/2022/05/01/chevy-chase-mailbox-stolen-checks/>

Thank you for your prompt attention to this matter, and please know that our offices stand willing to work with your agency to develop the best and most responsible solutions for disposing unused medications.

Sincerely,



Tom Emmer  
Member of Congress



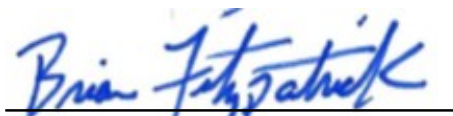
Ann McLane Kuster  
Member of Congress



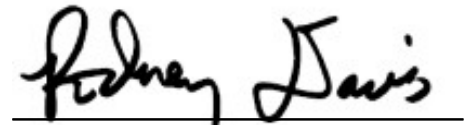
Don Bacon  
Member of Congress



Betty McCollum  
Member of Congress



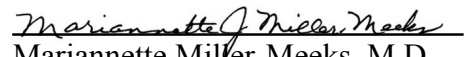
Brian Fitzpatrick  
Member of Congress



Rodney Davis  
Member of Congress



Chris Pappas  
Member of Congress



Mariannette Miller-Meeks, M.D.  
Member of Congress



Richard Hudson  
Member of Congress



David J. Trone  
Member of Congress

A handwritten signature in blue ink, reading "Michelle Fischbach". The signature is written in a cursive style with a horizontal line extending from the end of the signature.

Michelle Fischbach  
Member of Congress