



ALAN WILSON
ATTORNEY GENERAL

June 21, 2023

U.S. Food and Drug Administration
Attn: Dockets Management Staff
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No: FDA-2023-N-0917, “In-Home Disposal Systems for Opioid Analgesics;
Request for Information”

To Whom it May Concern,

As Attorneys General of our respective States, we are actively involved in fighting the opioid epidemic ravaging our communities. The fight against this epidemic requires an all-hands-on-deck approach, and we are thankful for the efforts of federal authorities as partners in this fight.

We write today to comment on the FDA’s Request for Information regarding In-Home Disposal Systems for Opioid Analgesics. As an initial matter, we note our appreciation for the FDA’s efforts to increase the availability and promotion of in-home drug disposal, but it is critical the FDA reconsider its unproven one-size-fits-all mail-back proposal and instead choose to promote and educate Americans on all available in-home disposal options.

It is no secret that the opioid epidemic is exacerbated by a “black market supply of opioids” contained in countless homes across the nation.¹ We know that as many as 92% of patients don’t use their entire opioid prescription, and that only approximately 10% of patients properly dispose of these prescriptions. These opioids represent a ticking time bomb for millions of Americans.

As law enforcement officials, we must confront this challenge head on. In doing so, we must use mitigation strategies that provide real solutions. To the greatest extent possible, these solutions should not leave room for increasing numbers of illegal opioids to be distributed on the streets and infiltrate our communities.

¹ Tim Mullaney, “Americans are hoarding a ‘massive’ black market supply of opioids,” *CNBC*, <https://www.cnbc.com/2017/09/13/american-hoarders-helping-push-up-rates-of-opioid-addiction-overdose.html> (Sept. 13, 2017).

With this goal in mind, we encourage the FDA to consider an approach toward opioid disposal that prioritizes safety of American families, including the use of in-home disposal products. Such an approach recognizes the seriousness of the problem we collectively face and acknowledges that increasing proper drug disposal requires more than a one-size-fits-all solution.

In-Home Disposal Products

Strong evidence supports the efficacy of non-mail-back in-home single-use drug disposal products. Studies show pairing education with these products can increase proper drug disposal to at least 92%.² Studies also show that patients prefer in-home single-use products to mail-back programs.³ Various in-home disposal products are commercially viable and provide safer, convenient, more effective, and more environmentally friendly disposal options than those previously recommended by the FDA. These products are just as effective at minimizing the risks associated with having these medications left in the home as mail-back options.

Further, the FDA's consideration of requiring drug manufacturers to make in-home disposal products available to patients under a risk evaluation and mitigation strategy (REMS) should include evaluation of the cost effectiveness of the program and alternative at-home disposal solutions.

Disadvantages of a Mail-Back Approach

While a mail-back option could be part of an all-of-the-above approach, we have several serious concerns with a mail-back option.

First, we are concerned about the possible complicating effect a mail-back approach could have on our existing enforcement efforts. In recent months, many of our offices have attempted to highlight our ongoing efforts to keep illicit drugs out of the mail. As you well know, drug traffickers frequently exploit the USPS and other common carriers to traffic their supply of drugs.

Recent headlines reinforce this concern. For example, *The Washington Post* published the results of its in-depth investigation in an article entitled "The flow of fentanyl: In the mail, over the border."⁴ According to that investigation, "Chinese drug traffickers had some advice for American buyers of fentanyl: Let us ship it to you by regular mail. It might be slower than FedEx or UPS, but the opioid is much more likely to reach its destination through the U.S. Postal Service." Relatedly, in the five years since the *New York Post* ran the headline "Chinese drug traffickers love

² De-An Zhang, et al., *Preventing Opioid Diversion and Abuse by Using an At-home Opioid Disposal Method: An Improvement Project in Pediatric Outpatient Surgical Center*, JOURNAL OF THE PEDIATRIC ORTHOPAEDIC SOCIETY OF NORTH AMERICA (Feb. 2021), <https://www.jposna.org/index.php/jposna/article/view/150/152>.

³ Adam C. Adler, et al., *Mail-Back Envelopes for Retrieval of Opioids After Pediatric Surgery*, 145(3) PEDIATRICS 3 (Mar. 2020), <https://doi.org/10.1542/peds.2019-2449> (indicating only 19.3% of opioid patients used mail-back envelopes for disposal).

⁴ Sari Horwitz and Scott Higham, "The flow of fentanyl: In the mail, over the border," *The Washington Post* (Aug. 23, 2019), <https://www.washingtonpost.com/investigations/2019/08/23/fentanyl-flowed-through-us-postal-service-vehicles-crossing-southern-border/>.

the US Postal Service,”⁵ the presence of “synthetic opioids, like fentanyl, seized from the U.S. Mail has increased 10-fold.”⁶

Disturbingly, other reports indicate “drug cartels and fentanyl merchants openly advertised on the Internet their preference for using USPS for shipments.”⁷

Given the prevalence of illegal shipping, we are concerned that a mail-back approach could create a game of whack-a-mole for various law enforcement agencies and further exacerbate the problem.

Our second concern with a mail-back approach is the insecurity of mailboxes and inconvenience for many rural Americans. A critical component of providing any in-home disposal option is providing a solution that will immediately rid the home of the medication in question. These in-home commercial products are an immediate method of medication unavailability. With a mail-back solution, the unused medication maintains its integrity throughout its journey to incineration, subjected to countless opportunities for misuse and diversion.

We are not alone in raising these and other concerns. Last year, Congressional letters⁸ were among the 167 comments filed in response to the FDA’s April 2022 request regarding its proposal to require all opioid prescriptions be dispensed with a mail-back envelope to facilitate safe return of leftover medications. The Congressional letters asked critical questions based on previous actions designed to discourage putting opioids in the mail.

The bipartisan questions to the FDA in 2022 included:

- Did the FDA consult with 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?
- What feedback did SAMHSA, CDC, and ONDCP provide?
- 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?
- Press reports indicate that mail theft is rising in the United States. We also understand a March 2022 U.S. Postal Inspection Service (USPIS) advisory issued to the Department of

⁵ Jade Scipioni, “Chinese drug traffickers love the US Postal Service,” *New York Post* (Apr. 20, 2017), <https://nypost.com/2017/04/20/chinese-drug-traffickers-love-the-us-postal-service/>.

⁶ “Sending fentanyl through the mail is increasing,” WTSP (May 21, 2023), <https://www.wtsp.com/video/news/national/sending-fentanyl-through-the-mail-is-increasing/67-eb277441-03b9-438a-8ebc-629b6a93d1e9>.

⁷ Paul Steidler, “Stop Fentanyl Shippers From Exploiting the U.S. Postal System,” *The National Interest* (Mar. 19, 2023), <https://nationalinterest.org/blog/buzz/stop-fentanyl-shippers-exploiting-us-postal-system-206319>.

⁸ See Congressional Letter to Robert M. Califf, M.D., Commissioner of U.S. Food and Drug Administration, June 27, 2022, https://emmer.house.gov/_cache/files/a/1/a12a1c32-c114-45f7-becc-c7897e4cc20d/99C4F4794FBF335AF3CCAB67BC0FFF1D.opioid-mail-back-guidance-letter.pdf (house.gov).

Justice noted a “significant increase” in the number of armed robberies of USPS letter carriers. Did the FDA perform its own assessment of this risk as part of the mail-back proposal development?

Other comments filed in April 2022 show an overwhelming majority opposed the idea of a mail-back only option. Specific concerns ranged from press reports that mail theft is rising, to noting Congressional actions to keep opioids out of the mail, to suggesting mail-back programs could thwart efforts to mitigate illicit counterfeit and synthetic opioids such as fentanyl sent in bulk from China.

While we applaud the FDA for its work towards helping the numerous Americans with left-over prescription drugs at home dispose of those drugs properly, we believe an approach providing flexibility to choose in-home single use products would achieve better public health and public policy results. We urge the FDA to work with States in reviewing innovative programs across the country designed to increase proper drug disposal while mitigating the risk of nonmedical use or overdose.

Sincerely,



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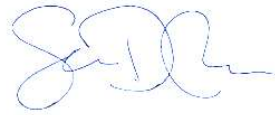
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