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The FDA's Troubling Plans to Dispose Opioids Via the U.S. Mail

By Paul Steidler

The Food and Drug Administration (FDA) is set to <u>launch a program</u> in 2024 that will put hundreds of millions of opioid pills in the U.S. mail as consumers mail unused narcotics back to drug companies for destruction.

At best, this will be an expensive, inefficient way to dispose of these highly addictive substances. It is quite likely a significant amount of opioids will be stolen and sold illegally, resulting in many increased addictions and deaths.

At a minimum, the mail-back program should be halted for comprehensive re-evaluation. Simultaneously, increased emphasis should be placed on easy, low-cost, and proven ways to dispose of unused opioids, which get rid of them more expeditiously than putting them in the mail.

These include daily take-back programs at pharmacies and police stations along with periodic community events. Relatedly, there need to be expanded education programs so that the opioids can be turned into junk at home by combining them with bleach, kitty litter, coffee grinds, or other unpalatable pollutants, and then thrown in the trash. Opioids, though, should not be crushed.

There are also commercially available in-home disposal options that are inexpensive and easy to use, such as those sold by <u>Walmart</u> since 2018. And, if necessary, opioids can be flushed in the toilet. Though numerous states are weary of that due to environmental concerns, flushing is better than triggering or starting an addiction.

Background

According to the Centers for Disease Control and Prevention (CDC), there were <u>142</u> <u>million prescriptions</u> for opioids dispensed in 2020. The number of prescriptions has been falling and is down 34 percent from 2006.

However, billions of opioids are still out there. At a court case on Tuesday, September 12, information was made public from the U.S. Drug Enforcement Administration. The <u>Associated Press</u> reported, "It showed that in 2019 8.8 billion dosage units – pills, patches, and lollipops – were shipped for 12 common opioids."

The need to get rid of unused opioids out of the home is clear and compelling. When opioids are no longer being taken to address severe pain issues, they can lead to addiction, whether taken by the patient or someone else in the household.

On April 3, 2023, the <u>FDA announced</u> it is "requiring manufacturers of opioid analgesics dispensed in outpatient settings to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers." In plain English, the drug manufacturers will bear these postal costs and must provide the prepaid envelopes to pharmacies and other dispensers, who then are to provide them to patients. The program is expected to start in 2024 with additional steps and approval processes.

In commenting on the planned action, FDA Commissioner Dr. Robert Califf said, "We believe these efforts will not only increase convenient disposal options for many Americans, but also reduce unfortunate opportunities for nonmedical use, accidental exposure, overdose and potential new cases of opioid use disorder."

Existing, Effective Opioid Disposal Methods

The need to eliminate unused opioids has long been recognized and addressed.

A 2019 U.S. Government Accountability Office (GAO) <u>study</u> discussed how opioids could be disposed of through take-back events, permanent collection sites, flushing, and proper trash disposal. And speed is key to disposal. Keeping opioids around another day or two before bringing them to a mailbox or post office means they are less likely to be disposed.

The GAO report said, "Officials from FDA said that the primary goal of these recommendations is to remove dangerous substances from the home as soon as possible to reduce accidental poisoning, which also may address issues related to intentional misuse."

GAO continued, "Our analysis of DEA and U.S. Census Bureau data shows that as of April 2019, 71 percent of the country's population lived less than 5 miles from a permanent collection site, and in 42 states, at least half of the population lived within 5 miles of a site. This number has increased since our April 2017 report, when we found that about half of the country's population lived less than 5 miles away from a site. Our analysis also shows that 90 percent of the population lives within 15 miles of a site."

The Danger of Cannibalizing Successful Disposal Efforts

The FDA's strong emphasis on promoting a mail-back program since 2022 may already have the unintended consequence of cannibalizing other successful return efforts and/or stymying their growth. South Carolina Attorney General Alan Wilson and 13 other Attorney Generals expressed these concerns and more in a June 21 letter to the FDA.

"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 mail."

It continues, "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."

There does seem to have been significant progress in the past five years on the number of unused opioids being properly disposed of as public awareness and related programs have gained attention. In 2019, <u>GAO reported</u>, "three studies examined how patients disposed of unused opioids and found that between 12 and 41 percent of patients disposed of them using a federally recommended method."

In 2022, a <u>study</u> in the medical journal *Cureus* found that 94 percent of patients receiving opioid prescriptions reported having leftover, unused opioids. 69 percent claimed to dispose of their prescription opioids, while 31 percent did not.

Potential Size of Opioids in the Mail

The FDA's program could easily lead to hundreds of millions of opioids going in the mail annually.

For example, if just 20 percent of the 140 million annual prescriptions are mailed back, and there are 12 pills on average per shipment, there would be 336,000,000 opioids in the mail annually.

On a related note, on June 26, the <u>FDA said</u>, "In a recent systematic literature review examining patient-reported opioid analgesic use after surgical procedures, most studies reported 50 to 70 percent of tablets went unused." Put more simply, there are billions of pills at issue.

The Crime Wave Impacting the U.S. Postal Service

Another important issue to consider is that the U.S. Postal Service is facing a crime wave of historic proponents. On May 9, <u>USPS announced</u> "expanded actions to protect ... the security of the nation's mail and packages as threats and attacks on letter carriers and mail fraud incidents have escalated concurrently with a national rise in crime."

This comes from brazen attacks on mail carriers and the mail system itself and from some criminals within USPS. Additional information about the latter appears in the Appendix.

Relationship to the COVID Test Kit Distribution

Among the important questions that Congress and other investigators should ask is: Who came up with this idea?

USPS did undertake a major program for the U.S. Department of Health and Human Services (HHS) to distribute 280 million COVID test kits. These were sent at "no cost" to recipients, though American taxpayers paid for the kits.

The Biden Administration asked USPS to conduct this program exclusively. While the program went rather well, had the distribution of the kits been competitively bid among major retailers and other shipping companies, the program costs likely could have been lower and distributions more efficient.

Numerous Issues to Address

There are numerous issues that policymakers should ask of the FDA and USPS, including the following.

What is the projection for the number of opioids to be mailed back each year? How was this determined?

What is the expected cost, and how has this been determined?

What actions and steps will be taken to ensure that mail-back measures will not reduce or cannibalize other successful disposal methods?

Will the packages be scanned and tracked from start to finish? If not, why not?

Will there be separate packaging for mailing the opioids? If so, will this make it easier for thieves and bad actors to identify these packages?

How many envelopes are likely to be produced but not used? What will be the environmental impact of this waste?

How will those postal workers making deliveries to drug manufacturers (the recipients of these items) be protected? How will USPS ensure that its employees making these deliveries are law-abiding?

Has the USPS Office of Inspector General, which has an excellent record in fighting drug trafficking, been asked for their views and recommendations on this program?

What are the expected revenues to USPS from the program?

How much time and effort is the FDA putting into, and planning to put into, promoting the mail-back program compared with other disposal initiatives?

What steps is the FDA taking to work with state and local governments to ensure maximum disposal of unused opioids?

Summary

In addition to getting these answers promptly, in writing, and sharing the information publicly, Congress should hold hearings with the FDA and USPS to vet these issues. With the opioid crisis continuing to ravage America and hundreds of billions of pills not being used, the need for aggressive, systemic, and immediate disposal efforts is critically important.

<u>About the Author:</u> Paul Steidler is a Senior Fellow with the <u>Lexington Institute</u>, a public policy think tank based in Arlington, Virginia. Ethan Shapiro provided research and related assistance. He is Program Manager with the Lexington Institute.

The two-page appendix follows.

Recent Drug Trafficking and/or Mail Theft Arrests Involving the U.S. Postal Service (USPS) Federal Law Enforcement Announcements (Partial List)

Title of News Release	Issuant	Date	Summary
West Sacramento Resident and Former Postal Service Employee Sentenced for Theft of Mail and Possession with Intent to Distribute Marijuana	U.S. Attorney's Office, Eastern District of California	August 1, 2023	Postal service employee Shabina Debbie of West Sacramento stole 18 mail parcels that had been entrusted to her in the course of her duties at the Sacramento Main Post Office. Debbie was sentenced to five months in prison for theft of mail by a Postal Service employee and possession with intent to distribute marijuana, U.S. Attorney Phillip A. Talbert announced.
USPS Employee Pleads Guilty to Theft of Mail	U.S. Attorney's Office, District of Maine	July 20, 2023	Andrew Fossett, 45, a Portland native and U.S. Postal Service employee, entered a guilty plea to theft of mail. According to court records, Fossett destroyed mail to steal gift cards, scratch tickets, and money.
Logan County Man Sentenced to Prison for Federal Drug Crime	U.S. Attorney's Office, Southern District of West Virginia	June 26, 2023	42-year-old USPS employee Anthony Ryan Webb of Logan County admitted to distributing more than 50 grams of methamphetamine to a confidential informant while working for the United States Postal Service.
Postal Worker Supports Fentanyl Addiction with Stolen Mail	United States Postal Service Office of Investigations	June 14, 2023	United States Attorney Roger B. Handberg announced that 27-year-old Live Oak, Florida postal worker Mikah Nathaniel Strickland pleaded guilty to stealing cash deposits from the mail to buy illegal drugs. Strickland faces a maximum penalty of five years in federal prison.
Former Postal Carrier Sentenced to Over Six Years for Distributing Cocaine Packages Sent to Her Postal Route	U.S. Attorney's Office, Middle District of Florida	May 24, 2023	Natasha Michelle Prieto, a former United States Postal Carrier, and her co-defendant, Angel Hernandez Coss, orchestrated a scheme by which Prieto provided addresses on her delivery route to Coss, who used those addresses to secure shipments of cocaine from Puerto Rico. As a result, kilogram quantities of cocaine were shipped in packages to these addresses.

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Indictment Charges Postal Employee with Cocaine Distribution, Mail Theft	U.S. Attorney's Office, District of Connecticut	April 27, 2023	USPS employee Shawn R. Fuller, 36, of Hamden, was indicted on cocaine distribution and mail theft offenses. Court documents and statements show that Fuller, a mail carrier in Meriden, was under investigation for stealing mail packages when police caught him with four kilos of cocaine at a traffic stop.
Postal Employee Sentenced To 5 Years in Federal Prison for Possessing With the Intent to Distribute More Than 11 Kilograms Of Fentanyl	U.S. Attorney's Office, Middle District of Florida	April 17, 2023	53-year-old Theodore Garlow, a postal employee from Lehigh Acres, was sentenced to five years in federal prison for possessing with the intent to distribute more than 400 grams of fentanyl.
Former U.S. Postal Service Mail carrier Sentenced for Scheme to Deliver Drugs Through the Mail	U.S. Attorney's Office, Northern District of Georgia	March 30, 2023	Former mail carrier Robert Elliot Sheppard was sentenced to three years of prison for recruiting fellow mail carriers and teaching them how to deliver packages of cocaine and marijuana while he was on disability leave.
Lowell Postal Carrier Sentenced for Attempting to Bribe Supervisor to Divert Packages of Cocaine	U.S. Attorney's Office, District of Massachusetts	March 22, 2023	On November 1, 2022, 61-year-old former USPS mail carrier John Noviello of Nashua, N.H., pleaded guilty to one count of bribery of a public official and one count of distribution of cocaine.