

# **ADDENDUM TO THE REPORT ON THE POTENTIAL IMPACT OF DRUG IMPORTATION PROPOSALS ON U.S. LAW ENFORCEMENT**

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# TABLE OF CONTENTS

## ADDENDUM

Introduction	3
Dangers of Importation: A Recap	3
2017 Report Recommendations – Enforcement and Regulation	4
Progress Since June 2017	5
Worsening Conditions	8
Conclusion	9

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# ADDENDUM

## INTRODUCTION

It has been 18 months since I issued the *Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement*. The 2017 report analyzed the degree to which proposed drug importation legislation, if implemented, would impact law enforcement's ability to protect the public health and ensure the safety of our drug supply. The government has taken small strides in the direction of my recommendations, but there is still work to be done to enhance law enforcement's ability to protect the prescription drug supply. Despite my conclusion that drug importation laws would deplete already limited resources and force law enforcement agencies to make tough prioritization decisions that leave the safety of the prescription drug supply vulnerable, there are still federal and state initiatives being considered that would weaken the safeguards on our prescription drug supply.

## DANGERS OF IMPORTATION: A RECAP

Many countries suffer endemic drug counterfeiting because they lack the closed drug supply chain that the U.S. has in place. The FDA safeguards the integrity of the supply chain to protect consumers from exposure to counterfeit and substandard drugs and ensure that safe and effective drugs reach U.S. consumers. Americans can be exposed to the dangers of counterfeit, diverted, falsified or substandard drugs when drugs are purchased outside the closed system or when organized criminal groups acquire both controlled (e.g., opioids) and non-controlled (e.g., chronic disease medications) prescription drugs in order to reintroduce them back into the prescription drug supply chain for profit. The profit opportunity importation represents to criminal organizations is robust, given that criminals can disguise illicit drugs such as lethal fentanyl as almost any legitimate prescription drug. As such, importation would dramatically expand the potential for unapproved, substandard, counterfeit, and diverted drugs to enter the supply chain endangering public health and safety.

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## 2017 REPORT RECOMMENDATIONS – ENFORCEMENT AND REGULATION

With regards to enforcement, I recommended that there be an extensive review of the adequacy of law enforcement and other regulatory agencies' authorities (e.g., the U.S. Food and Drug Administration (FDA), U.S. Customs and Border Patrol (CBP) and U.S. Postal Services (USPS)) to address emerging threats and assess whether additional authorities are needed relative to compliance, investigative, and oversight responsibilities. I also recommended that a comprehensive assessment be conducted of the adequacy of FDA, CBP, and USPS resources to meet inspection needs and to identify potential improvements to the current inspection system to ensure sufficient resources and approach to inspecting packages that may potentially contain counterfeit drugs.

In addition, I noted the need for enhancements to be made to law enforcement training and awareness of counterfeit drugs, as well as greater efforts made to educate the American public on the dangers of illegitimate pharmaceuticals and online pharmacies.

4

Lastly, there must be increased grant funding and other support for local task forces and intelligence coordination and fusion centers so that information and intelligence can be shared quickly and efficiently (e.g., with goal of intelligence sharing on a real time basis) across the federal, state, and local levels about criminal organizations and trends, to expand focus beyond counterfeit drugs.

In the area of regulation, I recommended that there be a review of the adequacy of law enforcement's capacity to address emerging threats such as the growing dangers posed by rogue online pharmacies and increasingly sophisticated criminal organizations. I also recommended there be a GAO review of current bifurcated (state and federal) enforcement, investigation, and certification of prescription drug wholesalers. Such a review would help recommend approaches to eliminating inconsistencies across states in enforcement and inspections of FDA standards for wholesalers and secondary wholesalers.

In addition, changes to existing laws must be implemented to assist the CBP in establishing and improving an inspection protocol to deter counterfeiters from using the USPS to ship counterfeit drugs, i.e., (1) to require the provision of advance electronic information about shipments of non-letter class mail to the CBP; and (2) to remove the administrative burden on CBP and FDA in seizing and destroying counterfeit medications in the U.S. postal system.

Lastly, a review of current penalties for drug counterfeiting to ensure the criminal sanctions serve as a strong deterrent was warranted at the time of the report and remains urgent today.

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## PROGRESS SINCE JUNE 2017

Since 2017, positive steps have been taken by the federal government that appear to demonstrate commitment to installing a successful framework that ensures the safety of the U.S. drug supply system. However, additional steps are needed to ensure that there is sufficient prioritization of this threat and to enhance the capacity of law enforcement.

On March 29, 2017, President Donald Trump signed an executive order for the creation of the President's Commission on Combating Drug Addiction and the Opioid Crisis, chaired by former New Jersey Governor Chris Christie. On November 1, 2017, the Commission delivered their extensive report and provided numerous recommendations consistent with my recommendations.<sup>1</sup> In particular, the following recommendations were relevant to the effort to protect the prescription drug supply:

- The enhancement of federal sentencing penalties for the trafficking of fentanyl and fentanyl analogues.
- Federal law enforcement agencies expressly targeting Drug Trafficking Organizations and other individuals who produce and sell counterfeit pills, including through the internet.
- CBP and the U.S. Postal Inspection Service (USPIS) using additional technologies and drug detection canines to expand efforts to intercept fentanyl (and other synthetic opioids) in envelopes and packages at international mail processing distribution centers.
- Congress and the Federal Government using advanced electronic data on international shipments from high-risk areas to identify international suppliers and their U.S.-based distributors.
- A coordinated federal/DEA effort to prevent, monitor and detect the diversion of prescription opioids, including licit fentanyl, for illicit distribution or use.

While these recommendations are positive, they fail to highlight the fact that U.S. law enforcement does not have sufficient capacity to implement these measures without additional resources. Many of these recommendations have not yet been acted upon.

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<sup>1</sup> Report of President's Commission on Combating Drug Addiction and the Opioid Crisis, 1 Nov. 2017. Available at [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-1-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf)

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On October 1, 2018, the U.S. Department of Justice announced a \$320 million grant to combat the nation’s opioid crisis. The money is earmarked to assist in the prevention, treatment, and enforcement of the illegal manufacture, sale, and distribution of opioids. More specifically, the grant will provide the following assistance to law enforcement:<sup>2</sup>

- Augment U.S. Attorney offices with 300+ federal prosecutors and more than 400 additional DEA task force officers.
- Creation of a data analytics program called Opioid Fraud and Abuse Detection Unit to assist in “hot spot districts”.
- Development of new tools to enforce the law, ensure public safety, prevent and control crime, and ensure fair and impartial administration of justice.

The additional prosecutors and task force officers as well as the new technological tools are an example of ways to provide law enforcement with the assistance they will need to effectively counter the opioid crisis. With that said, federal prosecutors and the Drug Enforcement Administration are just two pieces to a much larger operation of screening and triaging potentially dangerous pharmaceuticals arriving to the U.S. through the mail system.

6

The United States Postal Service Office of Inspector General (USPSOIG) published a September 2018 report—in response to a Congressional inquiry—about the role the Postal Service plays in illicit drug distribution, including risks and vulnerabilities, and ways to improve. The Postal Service reports that drug seizures have been increasing since FY2014 and in FY2017, the agency seized approximately 40,000 pounds of illegal drugs. USPS stated that drug traffickers are motivated to use the mail system to ship illicit drugs because of its inability to open packages without a search warrant and its obligation to accept inbound international mail, regardless of the package information provided. Further, USPS is prohibited from opening international and domestic mail, including packages.<sup>3</sup>

To counter this threat, USPS and CBP were provided additional funding in 2018 for port and drug screening technologies and devices at land-based ports of entry, airports and international mail facilities with the passage of the Interdict Act.

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<sup>2</sup> Department of Justice, “Justice Department is Awarding Almost \$320 Million to Combat Opioid Crisis” 1 Oct. 2018. Available at <https://www.justice.gov/opa/pr/justice-department-awarding-almost-320-million-combat-opioid-crisis>

<sup>3</sup> U.S. Postal Service, “Use of Postal Service Network to Facilitate Illicit Drug Distribution”, 28 Sept. 2018. Available at <https://www.uspsaig.gov/sites/default/files/document-library-files/2018/SAT-AR-18-002.pdf>

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In October 2018, Congress passed the Synthetics Trafficking and Overdose Prevention (STOP) Act which would require that mail sent from foreign countries through USPS must provide “package level detail information” to CBP. This requirement on the USPS brings USPS in line with requirements placed on private shippers such as FedEx and UPS to gather this electronic data on most international shipments. This is the start of providing the CBP additional data to improve the screening process at international mail facilities.<sup>4</sup>

This additional funding and improved data sharing are small steps in the right direction. Even with this additional technology and authority, the Senate issued a report which stated that CBP has “4,000 Port Officers less than the number needed to staff all ports of entry.”<sup>5</sup> This is a vulnerability that will be exploited by international drug organizations.

Proponents of drug importation point to a lack of competition in the U.S. pharmaceutical industry, which may pose significant challenges with respect to patient access to certain critical drugs. For example, if the supply chain of a single-source drug is suddenly adversely impacted, patients may be denied access to the medicines they need to survive.

We understand patient access to be a major issue in the conversation of drug importation, but the introduction of foreign pharmaceuticals without a robust and ironclad plan inclusive of law enforcement considerations, will do more harm than good.

On July 19, 2018, HHS Secretary Alex Azar directed FDA Commissioner Scott Gottlieb, M.D. to establish a new working group to examine the feasibility of a narrow foreign drug importation limited to single source generic products that have had price spikes. The group is responsible for considering how the FDA and HHS will evaluate the need for foreign drugs, how the FDA will assess safety and effectiveness of foreign drugs, and how the FDA will ensure patient safety and address unsafe and illegal drugs introduced into the country.<sup>6</sup>

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<sup>4</sup> H.R.6 - 115th Congress (2017-2018): SUPPORT for Patients and Communities Act”. US Congress. 24 October 2018. Retrieved 14 January 2019.

<sup>5</sup> Combating the Opioid Epidemic, Intercepting Illicit Opioids at Ports of Entry, United States Senate Committee on Homeland Security & Governmental Affairs, May 10, 2018.

<sup>6</sup> Food and Drug Administration, “Statement by FDA Commissioner Scott Gottlieb, M.D., on the formation of a new work group to develop focused drug importation policy options to address access challenges related to certain sole-source medicines with limited patient availability, but no blocking patents or exclusivities”, 19 Jul. 2018. Available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm613931.htm>

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At this point, no findings or proposals have been published by the group. I am certain they cannot propose a solution that would effectively protect our prescription drug supply under any drug importation proposal, even if limited in nature.

## **WORSENING CONDITIONS**

Even with these latest developments, my previous key findings still hold true. Drug importation proposals would shift the costs and burden to law enforcement while opening the U.S. drug supply to dangerous adulterated and counterfeit drugs, undermining confidence in the security of the U.S. drug supply chain and increasing threats to public health. In addition, drug importation would increase the threat of illegitimate products entering the United States, fueling criminal organizations' activities and profits.

Law enforcement agencies like the CBP and Department of Homeland Security, Homeland Security Investigations (HSI) admit that drug traffickers ship products like fentanyl in such a way that it makes detecting the drugs extremely difficult for officers. In 2017, CBP officers and Border Patrol agents found more than 1,485 pounds of fentanyl at American ports of entries. Through August 2018, customs officers and border patrol agents were on track to exceed the amount of fentanyl seized in 2017.<sup>7</sup>

As it relates to opioids, drug importation proposals would worsen the opioid crisis – a crisis that has already grown substantially worse due to the powerful opioid fentanyl and fentanyl analogue-laced counterfeit pills being produced by illegal drug trafficking organizations, including in China, and reaching the United States through Canada and Mexico.

In October 2017, in Arizona, DEA and Tempe Police Department seized 30,000 counterfeit oxycodone pills that contained fentanyl at a traffic stop. In separate incidents, 26-year-old Jesus Madueno was arrested for selling 3,500 counterfeit pills to undercover detectives, and a woman was arrested for trying to smuggle 67 pounds of meth and 8 pounds of fentanyl over the border at Nogales.<sup>8</sup> Unfortunately, it appears these incidents are becoming routine. In November 2018, the Montville,

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<sup>7</sup> The New York Times, "U.S. Struggles to Stop Smuggling of Mail-Order Opioids", 30 May 2018. Available at <https://www.nytimes.com/2018/05/30/us/politics/drug-smuggling-mail-order-opioids.html>; CBP Enforcement Statistics FY2018. January 12, 2019. Available at <https://www.cbp.gov/newsroom/stats/cbp-enforcement-statistics>

<sup>8</sup> BrieAnna J. Frank, "Man Accused Of Selling Fake Oxycodone Laced With Highly Toxic Fentanyl," The Arizona Republic, September 6, 2017, <http://bit.ly/2BjwZv> and Donald Jordan, "Meth & Fentanyl Border Bust," KVOA Tucson, August 2, 2017, <http://bit.ly/2DLGunQ>



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NJ Police Department seized 27 pounds of fentanyl pills during a raid.<sup>9</sup> One month later, in December 2018, DoJ “executed fifty-one federal arrest warrants and search warrants on more than 50 buildings and 35 vehicles” in Washington State to break up a “multi-state drug trafficking network led by drug cartel members in Mexico.” The organization trafficked opioids, including counterfeit pills laced with fentanyl, cocaine and methamphetamine, in Washington State, New York, Arizona, Oregon, California, Tennessee, and Utah.<sup>10</sup>

As such, already overburdened law enforcement and regulatory capacity would be unable to ensure a safe prescription drug supply under drug importation at the consumer or retailer level.

## CONCLUSION

While various initiatives over the past year are a step in the right direction, the creation of an FDA working group to examine the feasibility of any drug importation scheme - even limited - is a step backwards. There have yet to be any concrete, effective proposals for increasing law enforcement capacity to effectively safeguard the U.S. drug supply from illicit foreign pharmaceuticals. Further, there have been no published initiatives taken to evaluate the effectiveness of inter-agency cooperation and tracking of illicit drugs via the mail system between USPS, CBP, DEA, and other agencies. Simply put, the steps taken by policymakers since The Freeh Group’s 2017 report have created momentum for drug import policy discussions, but the government has not done enough to evaluate and improve the capacity of *law enforcement* to deal with a new pipeline of drugs into the U.S. drug supply, all the while drug overdoses involving synthetic opioids increase and more and more illegal drugs are being shipped to the United States.<sup>11</sup> Passing any drug importation scheme would erase the little progress we have made and set law enforcement further back on their heels.

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<sup>9</sup> Patch, “NJ Couple Arrested, 2K Doses of Heroin, Fentanyl in Big Bust”, 12 Nov. 2018. Available at [https://patch.com/new-jersey/pointpleasant/more-2k-doses-heroin-fentanyl-big-nj-bust-cops?fbclid=IwAR32Sshvym-DaJqKDIhgikwFlw4JW6bTvTy0eSH\\_apNUlzFD1Q41mzskCBo](https://patch.com/new-jersey/pointpleasant/more-2k-doses-heroin-fentanyl-big-nj-bust-cops?fbclid=IwAR32Sshvym-DaJqKDIhgikwFlw4JW6bTvTy0eSH_apNUlzFD1Q41mzskCBo)

<sup>10</sup> Department of Justice, “Multi-State International Drug Trafficking Organization Targeted in 18-Month Investigation”, 6 Dec. 2018. Available at <https://www.justice.gov/usao-wdwa/pr/multi-state-international-drug-trafficking-organization-targeted-18-month-investigation>

<sup>11</sup> CNN, “Fentanyl is the deadliest drug in America, CDC confirms”, 27 Dec. 2018. Available at <https://www.cnn.com/2018/12/12/health/drugs-overdose-fentanyl-study/index.html>