

REPORT ON THE POTENTIAL IMPACT OF DRUG IMPORTATION PROPOSALS ON U.S. LAW ENFORCEMENT

FREEH, SPORKIN, AND SULLIVAN LLC
FREEH GROUP INTERNATIONAL
SOLUTIONS, LLC



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Louis J. Freeh
Freeh Group International Solutions, LLC
3711 Kennett Pike
Suite 130
Wilmington, DE 19807

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Throughout my career, I have had the opportunity to work with public and private sector leaders in the U.S. and across the globe to help address the challenges posed by the proliferation of counterfeit, diverted and substandard medicines.

Recently, The Freeh Group was asked by the Partnership for Safe Medicines to conduct an investigation into the degree to which current drug importation proposals, if implemented, would impact law enforcement's ability to protect the public health and ensure the safety of our drug supply. Based on my review, I have concluded that drug importation proposals would deplete and overburden already limited resources. In particular, importation proposals would force law enforcement agencies to make tough prioritization decisions that leave the safety of the U.S. prescription drug supply vulnerable to criminals seeking to harm patients.

Additionally, with illegal drug traffickers producing and distributing fake opioids, including fentanyl laced with other drugs that contribute to a national crisis worsening by the day, it is my strong belief that any efforts on the part of our elected officials should focus on improving and enhancing existing law enforcement capacities to prevent potentially-dangerous products from entering the U.S. drug supply in the first instance.

The following report is intended to serve as a resource for policymakers, law enforcement agencies and anyone tasked with helping to keep the U.S. drug supply safe. As long as the threat of illegal drugs exists, the American people's safety must remain our top priority.

Sincerely,

A handwritten signature in black ink that reads 'Louis Freeh'.

Louis Freeh

Over the past 10 years, there have been a number of legislative solutions put forth that attempt to address the problem of rising healthcare costs, and specifically the cost of prescription drugs. One policy proposal, which has appeared over time in various forms, would permit drug wholesalers, licensed U.S. pharmacies, and individuals to import prescription drugs from Canada, and eventually from Europe and other parts of the world. Proponents of this concept tout the potential for Americans to save on the costs of prescription drugs, but they overlook concerns that there may be unintended consequences that would outweigh any potential benefits.

Given its personnel's substantial law enforcement experience and in-depth knowledge of the role, capabilities, capacity and complexities of protecting public health, and based on concerns expressed by law enforcement, **Freeh, Sporkin, and Sullivan along with Freeh Group International Solutions, LLC, conducted an investigation into the degree to which importation proposals, if implemented, would impact law enforcement's ability to protect the public health and ensure the safety of the U.S. drug supply.** In addition to a review of the available data and research on potential threats to the U.S. closed drug supply system, a critical component of the investigation was interviews with a range of current and former law enforcement officials from the Federal Bureau of Investigation (FBI), Drug Enforcement Administration (DEA), and Food and Drug Administration (FDA). Freeh Group International Solutions, LLC, also obtained state and local law enforcement input on the complexity of fighting the growing problem of diverted and counterfeit pharmaceutical products and their impact on the public health and law enforcement capacity.

There have been a multitude of studies conducted on the U.S. drug supply and the impact of counterfeit drugs on the global drug supply. This report focuses on the impact of drug importation on law enforcement's ability to protect the United States from substandard, adulterated, counterfeit, and diverted pharmaceuticals referred to as illegitimate pharmaceuticals in this report. Some of the most important insights into this challenge of illegitimate pharmaceuticals were gained from discussions with law enforcement officers who have dedicated their careers to combatting illegitimate pharmaceuticals.

As Former Secretary-General of the International Criminal Police Organization (Interpol) Ronald Noble observed, "Although the United States has one of the safest drug supplies in the world, it is not immune to the threat posed by international criminal organizations determined to market fake or counterfeit drugs in the U.S. It will take continued cooperation between law enforcement, public health officials and the pharmaceutical industry across the world to combat this threat."

“Drug importation proposals that permit wholesalers, patients, and pharmacies to import drugs directly into the U.S. would place many U.S. citizens at risk of purchasing or consuming fake, counterfeit or adulterated drugs,” Noble said.

A. Key Findings

It is critical that the United States address access and affordability issues for prescription drugs. **The findings of this investigation found, however, that drug importation proposals would do nothing but shift the costs and burden to law enforcement and open up the U.S. drug supply to adulterated and counterfeit drugs.** The potential for lower drug prices for a small percentage of Americans would pale in comparison to the potential costs to the safety of American consumers and the integrity of the prescription drug supply chain, as well as the increased burden on U.S. law enforcement that would impact communities across the country.

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The investigation’s key findings are detailed throughout this report and in its conclusions, but can be summarized as follows:

- **Drug importation would increase the threat of illegitimate products entering the United States, fueling criminal organizations’ activities and profits.**
 - There was an overwhelming consensus that proposals to allow drug importation from or through Canada would turn the advantage from law enforcement to criminal organizations. Drug importation would result in increased flow of potentially illegitimate pharmaceutical products entering the U.S. drug supply undetected due to the inability to sufficiently inspect the volume entering the United States.
 - Interviewees agreed that drug importation would increase financial incentives for individuals and criminal organizations to transship products through Canada that are likely to be counterfeit, diverted, adulterated, sub-standard and/or other non-FDA-approved products.
 - Legalized importation at the national level raises serious concerns regarding the ability of law enforcement to keep up with the threat and to maintain adequate investigatory and prosecutorial capacity to eliminate these criminal enterprises if drug importation was permitted at the consumer, pharmacist or wholesaler level.

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- **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.**
 - Interviews and research raised serious concerns that large-scale importation of pharmaceutical products from outside the United States would only strain law enforcement’s already overburdened resources that have been focused on the opioid crisis.
 - By providing a new, unregulated pipeline into the United States, law enforcement sources believe drug importation has the potential to create opportunities for criminal organizations to profit by smuggling illicit drugs, such as fentanyl and its analogues, masked as legitimate prescription drugs into the United States.
 - While a common stipulation of most drug importation proposals is that controlled substances would be ineligible for importation, this report found that importation would actually increase threats in this area, due to the masking/mislabeling of illegal opioids, increased profit opportunities, low penalties faced by criminals, and insufficient law enforcement resources.

 - **Already overburdened law enforcement and regulatory capacity would be unable to ensure a safe prescription drug supply under importation.**
 - Law enforcement sources cited drug importation as removing the last and potentially most critical line of defense of a closed prescription drug supply. The same sources state it is unrealistic to expect that the FDA and law enforcement will still be able to ensure a safe prescription drug supply despite the increased challenges posed by drug importation.
 - Drug importation at the patient, doctor or even wholesaler or middleman level, would greatly overburden U.S. and international law enforcement capacity to keep up in terms of investigating even a small portion of what would be a greatly increased volume of illegitimate products entering into the United States.

- A key concern raised was the insufficient focus by policymakers on addressing counterfeit drugs due to the misperception that counterfeit and diverted or adulterated pharmaceuticals are less harmful than illicit drugs like heroin. Interviewees also raised concerns that recent budget proposals would eliminate funding from certain federal agencies at a time when agencies are challenged to address existing threats. This plays a factor in how the nation's law enforcement agencies devote resources to the counterfeit drug problem.
- Because the nature of the pharmaceutical market has drugs change hands repeatedly in the supply chain, one potential for wide-scale diversion in the U.S. system is via the secondary wholesale market, the middleman between the manufacturers and the pharmacies. In addition, since individual states are responsible for licensing and oversight of these wholesalers, there are inconsistent licensing requirements and diverse levels of enforcement and inspection, this allows unscrupulous individuals to act under a shroud of legitimacy. This problem coupled with drug importation would drastically increase the risk of drug diversion in the U.S. drug supply.

B. Recommendations

This research effort highlighted not just the potential large-scale threats to the U.S. drug supply system and public health from drug importation, but also brought to light the growing challenges faced by overburdened and under-resourced law enforcement agencies at the local, state and federal levels. **This research should serve as a call to action to redouble the focus on improving and enhancing existing law enforcement capacity to prevent counterfeit drugs from entering the U.S. drug supply in the first instance, and ensuring law enforcement has sufficient resources, expertise, and authority to protect the public health and ensure the integrity of the U.S. drug supply.**

The reality is that once the contraband enters the United States, the complexity and magnitude of investigating the crimes can overwhelm law enforcement resources. There are a multitude of state and local law enforcement agencies working alongside federal agencies across the country that conduct successful investigations and prosecutions to prevent illegal pharmaceuticals from entering the U.S. drug supply. The challenges facing law enforcement of taking down criminal enterprises involved in illicit drugs, insurance fraud, money laundering, and other criminal activities, would all be exacerbated by the opportunities created under an importation program.

Below are selected recommendations for policymakers to consider enhancing existing law enforcement capacity and capabilities to keep the U.S. drug supply secure from counterfeit, diverted, adulterated, substandard and/or other non-FDA approved products.

1. ENFORCEMENT

- Direct the Department of Justice to assess the adequacy of current interagency efforts, namely those of the FDA, Customs and Border Protection, and United States Postal Service, to determine ways to improve the current inspection system of packages that may potentially contain counterfeit drugs. This assessment should also evaluate whether additional enhancements, including new resources, are needed to detect and deter counterfeiters, particularly those seeking to ship counterfeit drugs via the U.S. postal system.
- Expand and enhance the capabilities of intelligence fusion centers to facilitate the timely collection and sharing of intelligence and other information on criminal organizations.
- Require an assessment of the adequacy of current penalties and U.S. Federal Sentencing guidelines related to drug counterfeiting to ensure that the criminal sanctions are a sufficient deterrent, particularly given the magnitude of the socioeconomic impacts of drug counterfeiting, as well as the diversion and sale of adulterated and substandard pharmaceuticals.

2. REGULATION

- Provide the FDA Office of Criminal Investigations with administrative subpoena power for the purpose of investigating counterfeit drug cases and enforcing counterfeit drug laws.
- Ensure adequate funding of FDA implementation of efforts to strengthen the U.S. drug supply, such as the provisions of the Drug Supply Chain Security Act.
- Require a third-party review, such as by the Government Accountability Office, of state and federal enforcement, investigation, and certification of prescription drug wholesalers to recommend ways to standardize inspections and facilitate enforcement of FDA requirements for primary and secondary wholesalers across states.

A. Scope of Work

Freeh, Sporkin, and Sullivan (“FSS”) was retained by the Partnership for Safe Medicines to perform an investigatory review of current law enforcement efforts to counter the proliferation of counterfeit drugs, as well as the threat posed by diverted, substandard, and adulterated pharmaceutical products. As background and context for the review, we have examined numerous articles and commentaries on counterfeit drugs from various sources and experts. A key component of this effort was interviews with numerous current and former law enforcement officials from the FBI, DEA, and FDA, as well as state and local law enforcement.

In addition, because law enforcement works closely with the pharmaceutical industry in protecting the integrity of the closed distribution system for pharmaceuticals, Freeh Group International Solutions (“FGIS”), acting at the direction of FSS, interviewed security officials at the major pharmaceutical companies. Finally, given the large international component to the counterfeit pharmaceutical market, we spoke to former investigators involved with international law enforcement to better understand the challenges of identifying, tracking and possibly apprehending those coordinating their illegal activities from around the globe.

Much of the information from our interviews corroborated the findings from the research conducted. Both data streams yielded overall indicia of the problem, the difficulties for law enforcement, and the need for additional resources and strategies about how to address threats to the integrity of the pharmaceutical supply chain. It quickly became clear that a key area of concern for law enforcement was how implementation of drug importation would impact its ability to combat illegitimate pharmaceuticals. This perspective is reflected in our conclusions and recommendations. Because examples from past and ongoing cases provide insights into the extent of the crimes and organized criminal organizations involved as well as the complexity of solving these complex multi-jurisdictional crimes, many such case studies are included below.

DEFINITIONS AND TERMS

The terminology of the non-FDA approved pharmaceuticals market can be as complex as the problem itself. Many terms are used interchangeably and the terms are not mutually exclusive. For example, a drug can be counterfeit and substandard, and both are non-FDA approved.

- **COUNTERFEIT DRUGS:** A counterfeit drug as defined by the FDA is a fake medicine that may be contaminated or contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose.
- **SUBSTANDARD DRUGS:** A substandard drug is a drug that fails to meet established quality standards of the country where it is being marketed and includes any drugs that are expired or degraded.
- **FALSIFIED:** Falsified drugs provide a false representation of the product's identity or source or both. Falsified medications may meet the standard of the nation where it is marketed, but nevertheless sold with a false representation, which may be the packaging, source, ingredients, or dosage.
- **UNREGISTERED:** An unregistered product lacks market authorization from the relevant, national regulatory authority. Though it may be a medicine of good quality, an unregistered product would be considered illegal.
- **DIVERSION:** Most broadly defined, a diverted drug is a prescription drug that has been transferred from a lawful distribution channel to an unlawful channel of distribution.
- **ADULTERATED DRUGS:** Any drug that fails to conform to established standards related to quality, strength, or purity required by the FDA.

For purposes of this report, we will often use the collective term "illegitimate pharmaceuticals" when referring to the above group of definitions, while using more specific term whenever appropriate.



DANGER OF ILLEGITIMATE PHARMACEUTICALS

A. Strengths of the U.S. Prescription Drug Supply

By all accounts the U.S. prescription drug supply is the safest and most controlled system in the world. It has been referred to as the “Gold Standard” for ensuring safe and effective prescription drugs. U.S. consumers take for granted that when they fill a prescription at a pharmacy in the United States they will receive the medicine prescribed by their doctor in the requisite form, quality, potency, and dosage.

This assurance is a result of a strong regulatory framework to ensure quality manufacturing, a closed distribution system, and appropriate oversight of the drug supply chain. Additionally, the U.S. had built over time a strong law enforcement capacity to identify illegitimate pharmaceuticals, including diverted prescription medicines, and to prevent them from entering the closed distribution system. Of course, these combined efforts to protect the quality and security of FDA-approved medications come at a substantial cost to law enforcement and the FDA. However, the American public has benefitted immeasurably from the safest prescription drug supply in the world. The FDA and other government agencies work diligently to prevent the infiltration of the supply chain by illegitimate pharmaceuticals.

One pharmaceutical chief of security interviewed stated that, at present, they do not worry about the U.S. drug supply chain as much as other countries because of the nature of its closed supply system. The expert further stressed that this safety net will dramatically change if drug importation is permitted. Counterfeiters certainly understand that the U.S. market is highly profitable and will readily exploit any deregulation of currently strict drug importation laws as a means to get their illegitimate products into the U.S.

B. Evolution to a Closed-System Based on Tragic Incidents

Today, the U.S. prescription drug distribution system is a closed network of manufacturers, suppliers and retailers managed and overseen by the FDA. Over time, Congress has expanded the FDA’s regulatory role in ensuring the safety and efficacy of drugs prior to approval and distribution to consumers. This regulatory framework has evolved as a response to tragedies where substandard or unapproved drugs have caused the death of patients. Examples include:

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- The Elixir Sulfanilamide tragedy in 1937 when over 100 people died after they used a drug formulated and dissolved in a toxic substance.
 - The Thalidomide tragedy in the 1950's where thousands of babies were born deformed after their mothers had taken a sleeping pill marketed to patients as an anti-nausea pill with no warning for pregnant women.
 - Counterfeit drug cases involving birth control and antibiotics in the 1980's.

In 1987 Congress passed the Prescription Drug Marketing Act ("PDMA"), which limited the importation of drugs by a drug manufacturer, except in emergency cases and as approved by the FDA. This law was in response to cases of counterfeit, adulterated, misbranded, sub-potent, and expired prescription drugs entering the U.S. system. The benefit of this law for law enforcement and the prior legislation passed to close the U.S. supply system is the advantage of managing a smaller, supply importation route by oversight and enforcement at the manufacturers level. In addition, this law established the 'pedigree requirement' for prescription drugs. According to the PDMA, "a drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them."¹ The pedigree includes the dates the drugs transferred hands and the parties to each transaction. Criminals trying to introduce counterfeit or diverted drugs back into the closed system will have to fabricate the pedigree, making the illegal drug easier to detect.

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Drug importation laws would open up the avenues through which drugs can be imported throughout the entire supply chain, permitting importation all the way down to the individual consumer. This, in turn, would vastly increase for law enforcement the challenge of oversight, enforcement and investigations. As demonstrated throughout this report, law enforcement is currently stretched thin in ensuring the safety of the U.S. prescription drug supply. The challenges posed by importation were made crystal clear when four former heads of the FDA stated that the FDA would lack the resources necessary to oversee a drug importation program.²

It has taken over a century to evolve the U.S. prescription drug distribution system towards a closed network of manufacturers, suppliers, and retailers under the oversight and management of the FDA. This trend towards a closed supply system

¹ Prescription Drug Marketing Act Pedigree Requirements under 21 CFR Part 203, Compliance Policy Guide and Guidance for Industry. 21 CFR §§203, 205. (15 Nov. 2006)

² Califf, Robert M., MD, Mark B. McClellan, MD, PhD, Margaret A. Hamburg, MD, and Von Eschenbach Andrew, MD. Letter to Members of Congress. 16 Mar. 2017.

has been based on incidents that threatened the health and safety of U.S. citizens. Based on these tragic incidents, Congress and the FDA have consistently moved towards tightening the system in order to protect U.S. consumers from substandard, adulterated, diverted, or counterfeit drugs. These lifesaving controls need to continue rather than be reversed. Current legislative proposals under consideration would allow drug importation of prescription drugs in order to reduce costs to U.S. consumers for prescription drugs, but at too high a cost by undermining many of these protections put into place by Congress and the FDA over the last century.

Congress has acted aggressively over the past five years by passing legislative solutions to improve the FDA's ability to ensure the safety of the U.S. prescription drug supply. For example, following a number of deaths and serious illnesses associated with contaminated heparin from China in 2008 and an outbreak in 2012 of an epidemic of fungal meningitis linked to a compounded steroid, Congress enacted the Drug Quality Safety and Security Act. This law outlines steps for implementation of an electronic and interoperable system to identify and to trace certain prescription drugs throughout the U.S. supply system. Most recently, Congress passed legislation that would result in an electronic, interoperable system to track medicines from manufacturer to patient. It takes time, resources and focus for the FDA and law enforcement to implement these responsible safety solutions.

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An effective closed system will more likely prevent the above-described tragedies and will counter current efforts by criminal organizations to penetrate the market with illegitimate and unsafe drugs. Although the model of a closed supply system has been the goal, it has been difficult to maintain and enforce based on the size of the U.S. market, the financial incentive for counterfeits, and limited state and federal resources for enforcement and oversight. The web of enforcement is spread over federal, state, and local law enforcement agencies with limited resources for inspection and enforcement.

C. Growing Challenges to Securing the U.S Drug Supply

1. INTERNATIONAL AND DOMESTIC THREAT

The extent and severity of the illegitimate pharmaceutical problem is borne out by the numbers and accounts of the kinds of contraband being moved through international markets and how certain items find their way to U.S. consumers.

- The World Customs Organization estimated that the global market for counterfeit drugs was about \$200 billion.³
- Interpol reported that while its Operation Pangea seized 2.4 million illicit pills in 2011, by 2015 that number had grown to 20.7 million illicit pills seized.⁴
- In 2013, an estimated 122,350 deaths in children under 5 years old in 39 sub-Saharan African countries could be connected with the administration of poor quality anti-malarial medication—this represented 4% of all deaths among children under 5 years of age in the region.⁵ For example, in June 2012, a shipment of loudspeakers arrived in a port in Luanda, Angola from Guangzhou, China. The speakers contained 1.4 million packets of counterfeit medication; the pills were labeled as being artemether-lumefantrine (used to treat malaria), but testing revealed that they contained no active ingredient.⁶
- In 2013, the Indian media connected more than 7,800 deaths at a hospital in the northern state of Jammu and Kashmir with counterfeit antibiotics. Indian regulators found that the hospital was providing patients a pill labeled as Maximizin-625, which was supposed to contain 500 milligrams of Amoxicillin, actually contained zero. The investigation found approximately 43 drugs being sold in that same region that were either “spurious or substandard.”⁷

Many countries suffer endemic drug counterfeiting because they lack the closed system that the U.S., through the FDA, has created to protect American patients. That said, the dangers of counterfeiting affect American citizens when drugs are purchased outside the closed system. The fact that the integrity of our medicines are taken for granted leaves Americans more vulnerable to those trafficking in illegitimate pharmaceuticals. These products that could include substandard, adulterated or counterfeit drugs may be purchased on the street or through an unlicensed online pharmacy, and can be deadly either by actively poisoning or by failing to treat serious and life-threatening illnesses.

³ Sample Ian, “Surge in Illegal Sales of Drugs as Gangs Exploit ‘Phenomenal Market’ Online” The Guardian 28 Dec. 2014 available at (<https://www.theguardian.com/society/2014/dec/28/drugs-medicines-sold-illegally-online-internet>).

⁴ Ossola, Alexandra, “The Fake Drug Industry is Exploding, and We Can’t Do Anything About It” Newsweek 17 Sept. 2015 available at <http://www.newsweek.com/2015/09/25/fake-drug-industry-exploding-and-we-cant-do-anything-about-it-373088.html>.

⁵ G. Nayyar et al., The Global Pandemic of Falsified Medicines: Laboratory and Field Innovations and Policy Perspectives, *Am J Trop Med Hyg.* (June 3, 2015); 92 (Suppl 6): 2-7 available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4455081/>.

⁶ Newton, Paul, “Unregulated Fake Medicines are Threatening the Fight Against Diseases Like Malaria” *NewStatesman*, 29 Aug. 2014 available at <http://www.newstatesman.com/world-affairs/2014/08/unregulated-fake-medicines-are-threatening-fight-against-diseases-malaria>.

⁷ Wani Riyaz, “Valley Falls Prey to Deadly Spurious Drugs” *Tehelka* 27 Apr. 2013 available at <http://www.tehelka.com/2013/04/valley-falls-prey-to-deadly-spurious-drugs/>.

CASE STUDY: DIVERTED AND COUNTERFEIT FENTANYL

Overdose deaths are drastically rising with an estimated 50,000 overdose deaths in 2016.⁸ The drug overdose epidemic is the worst epidemic in American history spurred by easier access to prescription opioids and heroin, rising levels of drug abuse, and an introduction of potent synthetic opioids like fentanyl into the opioid and heroin drug supply.⁹

For instance, according to the DEA, the U.S. has seen a sharp increase in incidents of death and overdose from counterfeit prescription drugs containing fentanyl. Fentanyl is a synthetic opioid with an extremely small lethal dose (approximately 2 milligrams).¹⁰ Fentanyl is 50 times more powerful than heroin and, if an addict or patient ingests fentanyl, the high potency of the drug decreases the time first responders can intervene if there is an overdose.

While fentanyl has been commonly mixed with heroin, law enforcement has now seen it in counterfeit prescription opioid medications as well as in anti-anxiety medicines. The results have been deadly: in the winter of 2016, Pinellas County, Florida saw nine deaths from counterfeit Xanax and ten people died in Sacramento, California from counterfeit Norco in March and April 2016. In March 2017, law enforcement reported that 32 people in Metro Phoenix had died from counterfeit OxyContin pills.¹¹

DEA has stated that illegitimate suppliers in China are shipping fentanyl precursor chemicals and pill presses to the U.S., Canada and Mexico. Many counterfeit pills are then synthesized and pressed in Canada and Mexico before being smuggled to the United States. The counterfeits detected have been primarily sold on the street at this point. The proliferation of these counterfeits is undercutting the DEA efforts to fight opioid abuse, while simultaneously expanding, the overall market for counterfeits.

The consensus is that any solution will require a large-scale coordinated effort among public health officials, medical professionals, and law enforcement. Law enforcement's task would be to conduct a large-scale effort aimed at targeting the supply of heroin and illicitly manufactured fentanyl from China and Mexico, thereby further eroding the level of resources available to combat counterfeit prescription drugs.

⁸ Chicago Tribune, "More than 50,000 Overdose Deaths: A Grim Tally Soars to All-Time U.S. High" 8 Dec. 2016. available at <http://www.chicagotribune.com/news/nationworld/ct-us-overdose-deaths-20161208-story.html>

⁹ New York Times, "Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis" 6 Jan. 2017. available at https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html?_r=0

¹⁰ Drug Enforcement Administration, "Counterfeit Prescription Pills Containing Fentanyls: A Global Threat" (July 2016) available at https://content.govdelivery.com/attachments/USDOJDEA/2016/07/22/file_attachments/590360/fentanyl%2Bpills%2Breport.pdf.

¹¹ U.S. News and World Report, "32 Deaths in Metro Phoenix Attributed to Counterfeit Pills" 21 Mar. 2017. available at <https://www.usnews.com/news/best-states/arizona/articles/2017-03-21/32-deaths-in-metro-phoenix-attributed-to-counterfeit-pills>.

CASE STUDY: COUNTERFEIT CANCER MEDICINE

According to a 2015 indictment, U.S. physicians bought counterfeit cancer medications from an online pharmacy based in Canada. The company's U.K. subsidiary shipped counterfeit versions of Avastin and its Turkish equivalent, Altuzan, to both doctors and suppliers in the United States.

Avastin and Altuzan are brand names for bevacizumab, which blocks the formation of new blood vessels inhibiting tumor growth in patients suffering from brain, lung, ovarian and other types of cancer. Studies have shown, for example, that colon cancer patients who took bevacizumab along with chemotherapy lived one-third longer than those on chemotherapy alone.¹²

The drugs shipped from the Canadian online pharmacy, however, contained no bevacizumab. As the FDA Commissioner at the time stated: “[f]or patients with cancer, combating the disease is difficult enough. But to learn that the cancer drug you were taking to save or prolong your life might be nothing but a counterfeit is unthinkable.”¹³

To make matters worse, the Canadian pharmacy need not have even intended to ship counterfeit cancer medication to become an unwitting distributor of the counterfeit drugs. As the indictment said: “[t]he reality was that CanadaDrugs did not know where the drugs it purchased were being manufactured, or who had been handling the drugs it purchased prior to delivery.” For instance, the cancer medication had been purchased by a Canadian company through its U.K. subsidiary from a Danish operation that had purchased portions of it from a supplier in Egypt.¹⁴

Therefore, assisted by increased drug diversion, unscrupulous drug wholesalers, easier access to the foreign markets, and a robust online presence, the market for illegitimate pharmaceuticals, already thriving in countries without strict controls, can pose risks to the United States closed system. The examples above show the dangers to consumers, but we must also account for the challenges that counterfeiting poses for law enforcement.

2. DRUG DIVERSION

Organized criminal groups acquire both controlled (e.g., opioids) and non-controlled (e.g., chronic disease medications) prescription drugs in order to reintroduce them for profit back into the closed U.S prescription drug supply chain. These criminal groups often acquire the prescription drugs by large-scale theft, purchasing expired drugs from corrupt wholesalers, obtaining drugs through insurance fraud schemes, theft, truck heists, or other illegal means. The diverters then repackage the substandard and adulterated drugs and are able through the theft of pill presses, and other equipment,

¹² Los Angeles Times, “FDA Approves Genetech’s Avastin Colon Cancer Medicine” 27 Feb. 2004 available at <http://articles.latimes.com/2004/feb/27/business/fi-avastin27>.

¹³ FDA Blog, “Improving the Integrity of the Drug Supply in a Global Marketplace” 10 Apr. 2012 available at <https://blogs.fda.gov/fdavoices/index.php/tag/altuzan/>.

¹⁴ *U.S. v. CanadaDrugs.com Ltd., et al*, CR 14-27-BU-DLC (District of Montana), Superseding Indictment (July 17, 2015) at 17-19.

to create counterfeit drugs that are often impossible to distinguish from legitimate products with the naked eye, as well as to develop realistic-looking packaging. The products are then reintroduced into the legitimate supply chain with false invoices and pedigree that may lead the purchaser to believe that they are legitimate prescription drugs. The criminal enterprise will then sell the diverted and counterfeit prescription drugs to doctors, pharmacies and drug wholesalers at a fraction of the market cost. Some of those involved in diversion may be working under a legitimate business properly registered in a state with weaker oversight of drug wholesalers, or with completely fabricated registration, certifications, and corporate documents.

In order to quantify the problem, the Pharmaceutical Security Institute (“PSI”) tracks counterfeit incidents reported through a variety of sources, including open media reports, member submissions and public private sector partnerships.¹⁵ PSI reported over 3,000 incidents of pharmaceutical-related crime, two-thirds of which were theft/diversion crimes, during 2015 in 128 different countries. This was nearly a 30% increase over 2014 and a 51% increase since 2011. PSI reported that the amount seized in each reported incident is also increasing.

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The Institute of Medicine conducted an extensive review of counterfeit drugs and concluded that even in the closed U.S. system there are areas that require law enforcement resources and focus. The U.S. drug wholesale market is made up of large national and regional wholesalers, as well as thousands of secondary whole-salers. Because the nature of this market causes medicines to be exchanged back and forth between wholesalers depending on demand, the potential for wide-scale diversion is at its highest. In addition, since individual states are responsible for the licensing and oversight of these wholesalers, there are inconsistent licensing requirements and diverse levels of enforcement and inspection, which allow unscrupulous individuals to act under a shroud of legitimacy.¹⁶



¹⁵ “Counterfeit Situation” Pharmaceutical Security Institute, 17 Mar. 2017 available at <http://www.psi-inc.org/counterfeitSituation.cfm>.

¹⁶ See Gostin, Lawrence O., Buckley, Gillian J., Countering the Problem of Falsified and Substandard Drugs. Institute of Medicine. (2013).

CASE STUDY: DRUG DIVERSION ACROSS PUERTO RICO AND SEVERAL STATES

In December 2012, federal prosecutors from the District of Puerto Rico indicted 24 defendants for alleged drug diversion and money laundering which resulted in the sale of \$440 million worth of illegitimate drugs to American distributors and pharmacies.

The indictment stated that Mr. Thuna ran the scheme through his companies in Puerto Rico, Arizona, and Tennessee. According to the allegations, Mr. Thuna purchased his drugs, in part, from entities technically licensed in New Hampshire and Pennsylvania but operating from California. The charges also stated that these entities were run by Mikhail Rozenberg, his sons, and associates: Mikhail Kemel, Svyatslav Sherman, and Ararat Ovasapyan ("the Rozenberg Group"). The Rozenberg Group allegedly bought and sold diverted pharmaceuticals. They manufactured forged pedigrees falsely stating that the drugs were coming from McKesson Corporation, which is a legitimate company distributing pharmaceuticals at the re-tail sales level.

By buying diverted pharmaceuticals from entities like the Rozenberg Group, Mr. Thuna was allegedly able to sell to doctors and pharmacies at well below market rates. The problem was that while Mr. Thuna's customers thought they were getting a bargain, the indictment stated that in reality they "received drugs of unknown quality and origin whose false pedigrees made it practically impossible to trace or determine the true source of the pharmaceuticals they were receiving."¹⁷

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3. INTERNATIONAL PRODUCTION OF ILLEGITIMATE DRUGS

There has been a drastic increase in the production of counterfeit or illegitimate drugs worldwide that is best evidenced by the increasing size of seized illegitimate drugs, and the increase in counterfeit incidents. In September 2016, the World Customs Organization and the International Institute for Research Against Counterfeit Medicines announced that in one operation involving the cooperation of 16 African countries, over 113 million illicit and potentially dangerous pharmaceutical products were seized. Among the seized products were antimalarial drugs, anti-inflammatories, antibiotics, and analgesics, gastrointestinal medicines, and anti-cancer drugs.¹⁸

Our investigation revealed concerns among law enforcement that there are misperceptions among some policy makers that counterfeit, diverted and adulterated medicines are somehow less harmful than illicit drugs like heroin. Yet a 2015 study showed that lifesaving medicines, such as anti-infectives, cardiovascular

¹⁷ See U.S. v. Martin Thuna, et al. (12-922 (DRD) (District of Puerto Rico), Indictment (Dec. 7, 2012) at para. 23.

¹⁸ World Customs Organization, "New record seizures of illicit medicines in Africa" 20 Jan. 2017 available at <http://www.wcoomd.org/en/media/newsroom/2017/january/new-record-seizures-of-illicit-medicines-in-africa.aspx?p=1>

agents and other categories, “represent the majority (52.8%) of all detected counterfeit medicines reported as penetrating the legitimate supply chain in CIS (Counterfeiting Incident System) reports.¹⁹” The reality is that most detected counterfeits are of medicines that are meant to save lives, with consequences in some cases more deadly than illicit drugs. Interpol estimated over 1 million lives are lost a year to fake medicines.²⁰

Over the past twenty years, Congress has granted the authority to the Secretary of Health and Human Services to permit the importation of drugs if the Secretary can certify that adequate safety could be maintained and costs reduced significantly. No Secretary under either a Democratic or Republican administration has exercised this authority and certified the safety of drug importation from other than the FDA-regulated manufacturers.²¹

There are large amounts of medicines being produced for other countries that may meet another country’s standards, but would fall short of FDA standards. In addition, criminal organizations, drawn by the high profit margins, have begun to produce fake medicines to be sold in both developing and developed countries. A pharmaceutical company security chief stated that the majority of the company’s efforts to deal with counterfeiting are now directed at developing countries and China. As these supplies of substandard and fake drugs increase, criminal organizations will look to introduce them into markets across the world.

4. PROLIFERATION OF ILLEGITIMATE ONLINE WEBSITES

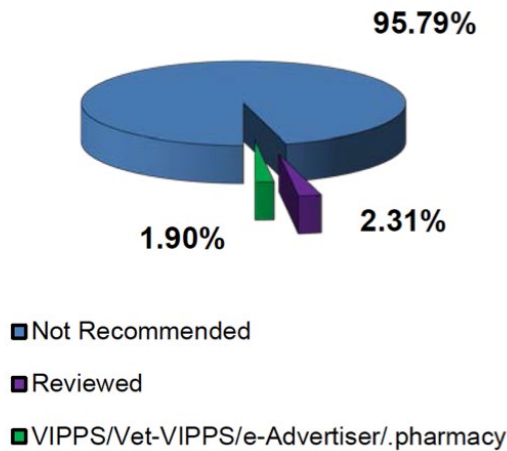
Another pharmaceutical company security expert stated that the industry and law enforcement professionals have been playing a game of “whack-a-mole” with illegal online websites. New websites pop up every day with appearances to consumers that are often difficult to distinguish from legitimate websites. Pharmaceutical companies’ product security teams allocate substantial resources to identifying rogue websites based on trademark infringement. Sending warning letters to shut down the websites is a standard action protocol, but such missives are unable to disrupt and eliminate the sources of supply. These rogue website operators often simply reappear just after a few months under another web address.

¹⁹ Mackey, Tim K. et al. “Counterfeit Drug Penetration into Global Legitimate Medicine Supply Chains: A Global Assessment.” *The American Journal of Tropical Medicine and Hygiene* 92.Suppl 6 (2015): 59–67. PMC. Web. 18 May 2017.

²⁰ Southwick, Natalie, “Counterfeit Drugs Kill 1 Mn People Annually: Interpol” *Insight Crime* 24 Oct. 2013.

²¹ Califf, Robert M., MD, Mark B. McClellan, MD, PhD, Margaret A. Hamburg, MD, and Von Eschenbach Andrew, MD. Letter to Members of Congress. 16 Mar. 2017.

Internet Drug Outlets Reviewed by NABP



Source: NABP

With tens of thousands of Internet drug outlet websites, the American consumer is solicited with an immense number of outlets for purchasing pharmaceuticals online, almost all of which are operating illegally. The National Association of Boards of Pharmacy (“NABP”) created the Verified Internet Pharmacy Practices Sites (“VIPPS”) to certify compliant online pharmacies from which consumers could purchase their prescriptions legally. VIPPS, Vet VIPPS, e-Advertiser, and .pharmacy top level domain names are certifications by the NABP established in an effort to provide consumers the ability to identify safe and legal online pharmacies. According to a 2016 NABP report, a survey of 11,299 online pharmacies found that 95.79% were “Not Recommended.” As depicted above, only 1.9% were certified by NABP as meeting their standards for compliance under one of their certifications.²² Currently, just 56 online pharmacies are VIPPS certified.

²²NABP, Internet Drug Outlet Identification Program: Progress Report for State and Federal Regulators (July 2016).



Stopping the spread of counterfeit, adulterated, diverted, and other illegitimate pharmaceuticals is uniquely difficult for law enforcement due to the nature of the criminal conduct and the complexity of conducting effective investigations. These obstacles are made worse by a severe lack of resources to prevent counterfeit products from being imported and to investigate and prosecute counterfeiting cases.

A. Nature of the Crime

1. VICTIMS ARE OFTEN UNKNOWN AND UNAWARE OF THE HARM

21 One of the biggest challenges for law enforcement is the fact that the victims have no means to verify the authenticity of medicines they have purchased outside of legal channels and, if purchasing online, they may have no reason to suspect the product they are receiving is not legitimate. In the U.S. system, pharmacists play a key role in ensuring that the drug dispensed is the proper form, potency, and dosage as prescribed by the medical professional. In addition, the pharmacist or medical professional will have better expertise to discern suspicious products of questionable origin.

If a counterfeit/mislabeled drug has been introduced into the supply chain or consumers are permitted to legally import drugs directly, the patient cannot be assured that the product received is the prescribed medication. For example, the patient will be unable to ascertain if the medication is expired, contains the wrong dose, has been improperly shipped or stored, or is fake.

If the patient has an adverse reaction or the medication does not successfully treat the condition, the patients and the medical professionals prescribing the product will most likely not attribute the result to counterfeit or substandard medications. The professional caregivers may simply shift the patient to a new or alternate medication, thus increasing the health care costs. In the worst case, if a patient dies as a result of ingesting a fake, adulterated or sub-potent drug, the death may be attributed to the patient's failing health and not suspect that a tragic and unnecessary death is the direct result of an illegitimate drug being ingested.

In Veracruz, Mexico, children with cancer received a counterfeit chemotherapy treatment that contained no active ingredients.²³ Although the investigation is ongoing, it is likely that fake cancer drugs had been discovered as early as 2010 and there were at least eight cases of children that could have survived cancer had they not received fake medications. These deaths likely would have never been attributed to fake medications had the issue not been pushed to the forefront by corruption charges against the former governor.

Criminals driven by profit will likely never see the impact of their activities on patients so will continue to be driven solely by profit. In a case in Los Angeles County, a woman who suffered from chronic pain purchased unlicensed medications from a 'currandero' or medical man. After receiving injections for the pain she told her sister she did not feel well enough to go to church. By the time her sister returned from church, she was dead. Her autopsy came back as 'no known cause' so they were only able to charge the currandero with the unlawful dispensing of medications without a license. She had received fake drugs likely made with toxic chemicals. A former DEA official stated that as law enforcement arrested the man at his home, a family with a ten-year-old child had arrived to have the child "treated" for pain.

In addition, counterfeit or adulterated drugs are often not reported to the FDA or law enforcement with perpetrators going undetected. Consumers currently utilizing illegal online pharmacies to obtain prescription drugs may also not report these incidents to law enforcement because of their own fear of criminal prosecution.

Aside from the individual cases, such systematic underreporting to law enforcement reduces opportunities to identify trends or "hot spots" for effective enforcement, reducing opportunities to effectively target and build a case against the criminals behind these crimes.

²³ Telesur, "Children Treated with Fake Chemotherapy in Veracruz, Mexico." 17 Jan. 2017 available at <http://www.telesurtv.net/english/news/Children-Treated-with-Fake-Chemotherapy-in-Veracruz-Mexico--20170117-0010.html>



2. ILLEGAL ACTIVITY DIFFICULT TO DISCERN

Local law enforcement officials with whom we spoke stated that many local law enforcement officials without the requisite knowledge of FDA regulations may not know that they have stumbled into a counterfeit prescription drug scenario and crime. Oftentimes the prescription drugs will be in an innocuous-looking container, or the suspect is able to produce counterfeit paperwork or successfully claim that the subject is a legitimate wholesaler. Improving awareness of drug counterfeiting for law enforcement at all levels would help improve state and local law enforcement's ability to spot the 'red flags' worthy of additional investigation or referral for prosecution.

3. ROGUE ACTIVITIES COORDINATED ONLINE AND ANONYMOUSLY

A retired FDA investigator reported that while finding the seller among rogue online pharmacies was remarkably difficult, finding the illegal producer seldom occurred. The official explained that online domains often lead to proxy servers and entities registered under fake names. When they could be traced to a location, the sites were being operated from jurisdictions where information was difficult to obtain. For example, the FDA found that CanadaDrugs.com, the company behind counterfeit cancer medications, had more than 3,700 different website addresses.²⁴

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CASE STUDY: ILLEGITIMATE WEBSITE

In the spring of 2015, U.S. authorities extradited from Germany and arrested Mr. Juniad Qadir for multiple charges of illegal importation and sale of misbranded and unapproved drugs.²⁵ With his brother, Mr. Qadir allegedly operated a business from Karachi, Pakistan that falsely claimed access and license to import pharmaceuticals into the U.S. and whose products were administered to numerous American citizens.

Mr. Qadir allegedly used business-to-business Internet website platforms to sell the illegitimate drugs to online pharmacies which would, in turn, sell them to consumers. Using a number of fake email addresses, the accusations stated that Mr. Qadir would fulfill the orders using suppliers in Pakistan, India, the U.K. and China, and then ship the drugs through the U.S. mail, using fraudulent customs documents and hiding pills in vitamin and water bottles. Much of the profits were later allegedly laundered through Western Union payments to Pakistan and later through banks in the United Arab Emirates and elsewhere.

²⁴ FDA, Warning Letter (Sept. 21, 2012) Re: Internet Marketing of Unapproved and Misbranded Drugs available at <https://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm321068.htm>.

²⁵ FDA, February 1, 2016: Pakistani Man Makes Appearance in U.S. District Court in Denver Following Indictment and Arrest for Sale and Distribution of New, Misbranded and Counterfeit Prescription Drugs (Press Release) available at <https://www.fda.gov/ICECI/CriminalInvestigations/ucm484462.htm>.

4. FOR CRIMINALS: LOW RISK/HIGH REWARD

For the criminals endeavoring to ship illegitimate pharmaceuticals across borders or to sell them to doctors and patients, they can generate large illicit profits and, if caught, may receive relatively small penalties. The incentives to commit these crimes are therefore very high and the perceived risks of detection and severe punishments are very low.

a. Large Profits

A well-organized, criminal illegitimate pharmaceuticals enterprise with sufficient online presence and international suppliers can make profits as large as a major corporation. From 2009 until 2012, for example, CanadaDrugs.com had at least \$78 million in gross proceeds from the sale of illegitimate pharmaceuticals, including counterfeit, misbranded or unapproved drugs.²⁶

Even smaller operations, however, can still yield large profits. In March 2017, 55-year old Kelly Luanne Schaible of Henderson, Nevada, was arrested for marketing misbranded drugs used for reducing wrinkles, including Botox and Juvederm. Ms. Schaible would order the illegitimate products from China and then market them on her website as the genuine therapies. Her efforts generated more than \$2.3 million in illegal profits.²⁷

Most drug importation proposals specifically ban the importation of controlled substances, but our interviews revealed that law enforcement believes importation would still worsen the problem. The profit opportunity importation represents to criminal organizations is simply too good to pass up, given that criminals can disguise illicit drugs like fentanyl as almost any legitimate prescription drug. Permitting an opportunity for the shipment of large volumes of prescription drugs into the U.S. provides perfect cover for illicit, disguised drugs as well.

b. Insufficient Penalties for Counterfeiting

One pharmaceutical security officer stated that penalties for counterfeiting should be enhanced relative to illicit drugs due to (i) the grievous harm to public health

²⁶ U.S. v. CanadaDrugs.com Ltd., et al, CR 14-27-BU-DLC (District of Montana), Superseding Indictment (July 17, 2015) at 24.

²⁷ FDA, March 9, 2017: Internet Business Owner Indicted for Selling Non-FDA Approved and Misbranded Versions of Botox and Juvederm Related Products (Press Release) available at <https://www.fda.gov/ICECI/CriminalInvestigations/ucm545872.htm>.

and (ii) the fact that there is a great albeit hard to assess harm to patients who are not receiving their prescribed medications. A former FDA official interviewed also pointed to the minor penalties meted out for these serious crimes, stating that it was often difficult to charge dealing misbranded drugs as more than a misdemeanor without proving mail or wire fraud.

It is difficult to establish the exact trend on punishments for drug counterfeiting based on the multitude of different statutes that may be charged both at the state and federal levels. The federal statute for counterfeiting is Title 18, United States Code, Section 2320, which would be one way a prosecutor would charge counterfeit drug dealing. This statute prohibits the trafficking in counterfeit goods and provides for a sentence of imprisonment of up to 20 years imprisonment.²⁸ In reality, however, the sentence imposed is often much lower than the stated maximum. Our interviews suggests that the criminal penalty under the Food Drug and Cosmetic Act will not sufficiently deter those wanting to use legalized drug importation from importing substandard drugs. Many times, prosecutors in such cases would instead have to charge the case under the “misbranding” and/or “unapproved new drugs” provisions of the Food Drug and Cosmetic Act, which only carries a three-year maximum imprisonment. However the prosecutor would still be required to prove that there was a specific intent to defraud or to mislead. If the Government cannot prove such a specific intent, then the violation would constitute a misdemeanor, punishable only by a maximum of one-year imprisonment.

The FDA has attributed the growth of counterfeit drugs partly due to the relatively low criminal penalties as compared to other federal crimes.²⁹ A former Interpol investigator reported that penalties for these crimes in different countries also vary greatly based on whether a country addresses the problem of counterfeit drugs as a public health issue, a criminal threat, or as an intellectual property issue.

²⁸ 18 U.S.C § 2320 (2016)

²⁹ United States. Cong. House. Committee on Energy and Commerce Subcommittee on Oversight and Investigations, Feb. 27 2014. Hearings on Counterfeit Drugs: Fighting Illegal Supply Chains (Statement of Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy, Food and Drug Administration. available at <https://www.fda.gov/NewsEvents/Testimony/ucm387449.htm>

B. Complexity of Illegitimate Pharmaceutical Investigations

Investigating and prosecuting counterfeit drug cases is complex and poses an immense challenge to federal, state and local law enforcement agencies. The press releases by FDA and INTERPOL of major seizures and arrests are encouraging but represent the result of years of dedicated and focused investigation and surveillance. Investigating a complex counterfeit drug case will demand unique investigative steps and require expertise, investigative time and resources that many criminal cases do not require. By their nature, these cases will require a high level of expertise in a number of different investigative areas, including financial transactions, FDA drug regulations, organized crime, forensic drug identification, and computer forensics.

In the area of counterfeit drug cases, the initiatives are being developed across local, state and federal agencies, as well as the pharmaceutical industry, in order to protect the public health. For every press release regarding a successful multi-jurisdictional law enforcement operation, there may have been hundreds of cases pursued and developed that may have fallen by the wayside because of some obstacle in the investigative process. This level of complexity, investigation and coordination, outlined below is applicable to all types of drug cases including those involving opioids such as fentanyl, illicit drugs, drug diversion, rogue online pharmacies, as well as, prescription drug counterfeiting.



1. ENSURING A ROBUST WORKING INTELLIGENCE NETWORK

Prior to cases and leads being developed, there has to be an efficient means to collect and to assess leads, and to share such information across the supply chain with regulators, healthcare providers, industry, and law enforcement. As information is gathered and shared, it must be analyzed and synthesized into a usable and shareable product to provide actionable information for other agencies to use.

There are numerous informal networks within the pharmaceutical industry and the Government that currently serve this purpose. This is a critical capacity, which requires dedicated resources in order to keep up with the information flow and to develop leads and identify trends based on the analysis of the information by other agencies. A lack of focus and resources in the area of intelligence building for any period of time, keeps law enforcement “in the dark” as to where the next threat may be coming from regarding counterfeit drugs. This intelligence network is key to allowing law enforcement to be proactive rather than simply reacting when undetected counterfeit drugs cause serious injury or death.

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Many times, law enforcement will structure itself as a ‘standing task force’ because building an information network requires a wide range of skill sets from different agencies in order to offset the limited resources and expertise in a single smaller agency. The task force structure facilitates information sharing on a timely basis to counteract the ‘stovepipe’ nature of some law enforcement agencies wherein numerous different agencies may be responsible for investigating similar crimes in overlapping jurisdictions. In this usual circumstance it is essential that separate enforcement agencies establish cooperative, working relationships with the ability to share information efficiently. Any lack of resources for intelligence gathering, analysis and dissemination places law enforcement at a vast disadvantage in any given area of organized crime.

Input from pharmaceutical company security officials and law enforcement officials experienced in counterfeit drug cases indicated that fighting counterfeiting requires a high level of intelligence information to identify and to fully understand the likely production and supply routes to inform their investigations. Through numerous interviews, it was clear that it can take a great deal of time to understand the players, trends and meaning of much of the indicators or red flags. Their perception was that U.S. law enforcement resources were already stretched thin in trying to build a strong intelligence network in this program area.

2. PROCEDURAL CHALLENGES

In addition to the need to develop a sophisticated intelligence network, interviewees explained that law enforcement also faces numerous procedural challenges when investigating and eventually charging illegitimate pharmaceutical cases. These procedural challenges either cause delays or require additional resources. Law enforcement officials emphasized the length of time it took to develop a case and to marshal evidence from foreign jurisdictions, noting that even then holding responsible parties accountable was far from guaranteed. In one interview, a former OCI agent from FDA referenced a case that began in 2010 and was still open seven years later.

a. Confidential Informants and Cooperating Witnesses

As the cases develop, investigators always work hard to develop confidential informants or cooperating witnesses. In fact, many drug cases would never be developed without a witness or participant willing to cooperate with authorities. This is a critical skill and tool for investigators to employ in these types of cases, both from a developmental and administrative authorization perspective.

The administrative requirements are critical and must be followed to protect the case and to ensure the admissibility of evidence at trial. There is a very structured procedure in law enforcement for handling an informant or cooperating witness, and failure to do so can compromise a prosecution. There are also numerous reporting requirements and authorization steps in operating an informant, which could result in a failed criminal case if contravened.

b. Surveillance

At some point, the case will mature to the point where some level of surveillance may be required. This may range from simple observation of a suspect or location to a controlled buy or undercover operation. In a more complex case, the investigators may need to resort to court-ordered electronic surveillance, which is a time-consuming and very expensive technique. Many law enforcement agencies lack the experience and operational capacity to undertake such investigative steps to advance a case involving illegitimate pharmaceuticals.

c. Issuing of Subpoenas

At an early, critical point in the investigation, the investigator will need to start gathering information from suspects and third parties. This will require issuing a grand jury subpoena or an administrative subpoena to obtain telephone records, bank records or other documentary information. Banks or businesses may then challenge the subpoenas. Once the subpoena is approved, the additional time needed to receive responsive records will increase the length of the investigation.

Next, the document productions that result from these subpoenas contain a large amount of unorganized information. One or more experienced and well-informed investigators must painstakingly examine the universe of data, and cull the responsive materials for the items most relevant to the case. As one former high-level FBI executive stated, “A lot of times law enforcement will put out a wide net for information through subpoenas and the responses bring the investigation to a standstill as investigators try to manage the information.”

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Our interviews highlighted one critical issue unique to FDA OCI, the group that coordinates counterfeit drug investigations. Unlike the FBI and the DEA, the FDA OCI does not possess this authority to issue an administrative subpoena. According to interviewees, this means that in order to gather important information at the early stages, FDA OCI must either partner with other agencies or seek the information through a grand jury convened by the local U.S. Attorney. Investigators interviewed indicated that when they felt like they had marshaled the facts to the extent possible, they then had to “pitch” the merits of the case to the local U.S. Attorney’s Office in hopes of obtaining a subpoena and other resources. According to a former FDA OCI investigator, FDA OCI was at a disadvantage because this approach to federal prosecutors had to occur before the issuance of a subpoena had allowed the case to be fully developed.

d. Search Warrants

The issuing and execution of search warrants to seize evidence is also time-consuming and burdensome. Law enforcement must work to establish probable cause that the items connected to that crime are likely to be found at a specified location. Probable cause is established through the preparation of detailed affidavits documenting facts gathered up to that point. The affidavits are then submitted to a judge for review. These steps all require time, manpower, and expertise.

The execution of the warrant will require additional resources and coordination. Once the evidence is seized, the investigative team will have to digest and organize the evidence obtained to establish its relevance. In the case of counterfeit drugs, an even more specialized level of expertise of the FDA regulations will be required to seek the search warrant and then understand the significance of evidence seized. Prosecutors and investigators interviewed stated that large amounts of potential evidence may sit idle because departments lack the resources to review and to analyze the material, or lack the expertise in drug counterfeiting or diversion to do so properly.

e. Computer Forensics

As noted above, the illegitimate pharmaceutical case nearly always has an information technology component that is critical to the scheme. Therefore, when electronic or computer evidence is seized, the investigator will have to seek expertise in order to access, interpret and preserve the electronic information. Interviewees stated that criminals will utilize electronic drop boxes, encryption, and other techniques to mask electronic information making the computer forensic tasks exponentially more difficult. Interviewees also noted that online outlets for illegitimate pharmaceuticals would often lead to proxy servers in a diversity of jurisdictions, thus adding international complexity to the process.

f. Financial Investigations

As one senior FBI executive stated, all drug investigations must “follow the drugs and follow the money.” Investigators must not only be able to seize bank records or financial information, but have an understanding of the many aspects of financial crimes, including how perpetrators use credit card transactions, insurance fraud, and money laundering. For example, to launder illicit proceeds from the sale of counterfeit drugs, criminals utilize sophisticated techniques involving a web of financial institutions, multiple intermediaries, shell corporations and various international partners. These financial aspects of the crime thus require forensic accountants and other experienced financial crime investigators to find and to understand the anomalies in seized financial records.

g. Chain of Custody for Seized Evidence

Again, all of the evidence obtained will require a chronological documentation of the seized evidence and any transfer, analysis or disposition of the physical or electronic evidence. This administrative burden takes time and focus and, if not done correctly, can jeopardize a case at trial.

h. Identification of Counterfeit Drugs

For any drugs seized in illegitimate pharmaceutical investigations, the investigator or prosecutor will have to establish whether the seized substance is actually something other than a legitimate drug. In counterfeit drug cases, this may require that the prosecutor establish that the seized drug is counterfeit, adulterated or substandard. This will require experts to analyze the drug's packaging to establish that it is counterfeit. In the more complicated cases, it may require expensive, time-consuming scientific analyses to establish the drug's components in order to determine if it is fake, adulterated, or substandard. The complication for prescription drugs is that the seized drug may be one of thousands of possible prescription drugs. This aspect of the case may require yet another specialized expert from industry or the Government to assist in proving whether the seized evidence is illegitimate.

If local law enforcement does not have the requisite knowledge of whom to call for an expert opinion or funding for the forensic testing of seized drugs, the case may not be pursued. A pharmaceutical company security officer confirmed that many local law enforcement agencies lack basic technology to assist in the identification of seized prescription drugs.



CASE STUDY: SALE OF ILLEGITIMATE DRUGS BY CANADADRUGS.COM

In July 2015, the U.S. Attorney's Office for the District of Montana indicted CanadaDrugs.com Ltd. ("CanadaDrugs.com") and thirteen other related entities and individuals including, CanadaDrugs.com CEO, Kristjan Thorkelson.³⁰ Mr. Thorkelson founded the online pharmacy in 2001 and, according to the indictment, in 2009, began selling unapproved and misbranded drugs directly to physicians and doctor's offices in the U.S. CanadaDrugs.com sold numerous illegitimate pharmaceuticals to U.S. physicians including the counterfeit versions of Avastin and its Turkish counterpart, Altuzan, as discussed above.

The alleged scheme was uniquely complex for law enforcement to untangle. The accusations involved CanadaDrugs.com and its subsidiaries in the U.K. and Barbados, thus creating its own global supply chain for illegitimate drugs in addition to separate channels for laundering profits from the operation. The network involved international suppliers from a diverse set of countries including Denmark, the U.K., and Egypt working with U.S. drop-shippers in Illinois, Washington, and Tennessee. The alleged activities included smuggling the unapproved drugs, falsification of customs declarations and money laundering using banks in the U.S., Barbados, and Canada.

Any doubts about the difficulty of law enforcement's task in bringing such a case might be dispelled by the fact that, eight years after the misconduct and almost two years after federal indictment, CanadaDrugs.com is still operating in some form and Mr. Thorkelson is apparently still serving as its CEO.

3. LAW ENFORCEMENT COORDINATION CHALLENGES

a. Various Legal and Regulatory Regimes

Counterfeit drug cases require a high level of expertise at the investigative level to understand the federal, state, and local rules pertaining to the regulation of prescription drugs. In addition, the crimes cross public health, intellectual property, state and federal regulatory frameworks that make the cases require even more specialized investigative capacity. Interviewees emphasized the time it takes to develop this level of knowledge, expertise and experience needed to identify leads and to develop cases.

³⁰ See U.S. v. CanadaDrugs.com Ltd., et al, CR 14-27-BU-DLC (District of Montana), Superseding Indictment (July 17, 2015).

b. Awareness Across All Levels of Law Enforcement

A basic level of awareness is required across all jurisdictions so that local police officers can spot the red flags and know when a routine stop may be the key development in a counterfeit case that can result in the saving of a life. This basic awareness may require a level of understanding of counterfeit drugs so that they can distinguish legal from illegal possession of prescription drugs, knowing what critical information to gather and, more importantly, knowing what to share. This level of awareness across law enforcement requires consistent training, from the smallest to the largest police agencies across the United States.

c. Multi-Jurisdictional Investigations

Virtually all of the cases will be multi-jurisdictional cases, which will require coordination among the different law enforcement agencies. As an example, if one were to pick a single spot in Los Angeles such as the Los Angeles Coliseum, a minimum of eight separate law enforcement agencies may hold some jurisdiction or authority over that location. The multi-jurisdictional aspect of these cases requires law enforcement to coordinate and de-conflict investigations.

This coordination requires agencies to have an established network of investigators in other jurisdictions willing and able to assist with investigative resources. Unless the investigator is an experienced counterfeit drug investigator with an established network of contacts, or is working as part of a task force operation, this burden of coordinating support among agencies may stifle the case from the outset.

Bringing these cases to conclusion may often involve coordination among the DEA, the FDA, the Internal Revenue Service, the Department of Homeland Security, and CBP. However, the FDA investigators reported that other law enforcement agencies, as well as patients, medical professionals, and prosecutors, were often simply unaware that FDA had a criminal investigation unit. Even though the unit has been in existence for over twenty years, investigators reported that FDA OCI would have to be proactive in interjecting themselves in prescription drug counterfeit cases, at times even reviewing news reports on police activity to know where such cases might be developed.

CASE STUDY: DRUG DIVERSION IN FLORIDA

A recent case in Florida demonstrates the complexities and challenges to state and federal authorities posed by these investigations. Authorities had worked closely to investigate a criminal enterprise whose method of operation consisted of the illegitimate acquisition of pharmaceuticals, antipsychotic, cancer, and HIV medicines, in order to divert them and re-introduce them back into the pharmaceutical supply chain.

Many of the main suspects had been under law enforcement scrutiny for over seven years for various health care related frauds. Two separate DEA offices, the FDA, and the Miami Dade Police Department had to coordinate each step of the investigation based on the fact that the enterprise involved a licensed pharmacy in Florida, a licensed drug wholesaler in Puerto Rico, and numerous wholesalers across the country. Over the span of six months, investigators performed multiple 'trash covers' where agents had to dig through piles of trash to gain critical evidence of drug diversion such as used glue guns, used cotton balls, empty glue stick packages, discarded patient prescription labels, empty pharmaceutical product boxes, and critical financial records. As evidence was developed, investigators were required to perform surveillance to confirm that the enterprise was shipping diverted drugs out of the facility. Investigators started to understand the trends and operation when investigators observed the suspects making routine deliveries to local shipping stores at the end of the day. Investigators coordinated with the FDA OCI in order to conduct visits with licensed drug wholesalers located in other states who were purchasing pharmaceuticals from the distributor.

Eventually, search warrants were required to search multiple shipments. One of the primary breaks in the case was the intercepted shipment of over \$250,000 worth of diverted pharmaceuticals, sold and being shipped to New Jersey and Georgia secondary wholesalers. None of the indicted co-conspirators had the required license or certification to sell pharmaceuticals in the State of Florida but had made cosmetic attempts to feign legitimacy. The enterprise had fabricated licensing from different states and pedigree papers for the drugs they sold around the country. Because they were not licensed but were able to feign legitimacy for wholesalers, they were able to move their contraband easily while never falling under the scrutiny of Florida regulatory agencies.

An analysis of the seized financial ledgers of the criminal enterprise indicated tens of millions of dollars in profits in the span of eighteen months. Seized as part of this search were approximately \$6.5 million worth of illegitimate drugs, \$1 million in assets, and bank accounts holding \$3.5 million. After search warrants were issued and executed, hundreds of possible leads developed from the seized evidence, including cell phones records, computer files, and documentary evidence.

As a result of this joint investigation, in August 2016, Dr. Rafael Prats pleaded guilty to a twelve-count of conspiracy to commit theft of medical products, conspiracy to commit wire fraud, and conspiracy to commit money laundering. He is yet to be sentenced. Several of the other co-conspirators have been charged with Florida state offenses

4. CHALLENGES WITH GLOBAL INVESTIGATION AND ENFORCEMENT

Any U.S. domestic investigation of counterfeiting or diversion presents the numerous challenges noted above, but because much of criminal activity occurs in other countries, these problems are exacerbated.

a. International Smuggling

The law enforcement interviewees were unanimous in describing the importance of getting international cooperation in drug counterfeiting and other illegitimate drug investigations. Former law enforcement officials stated that the raw materials and finished products that became these fake, adulterated or substandard items originated abroad. Law enforcement agents stated that counterfeiters would often migrate to the countries with lax enforcement and limited law enforcement resources in order to produce the counterfeit drugs. They then establish supply chains to have their counterfeit drugs reach the most profitable markets.

35 A former INTERPOL official explained that criminals separate the functions of counterfeiting across different countries to make it more difficult for law enforcement to trace and ultimately prosecute. Multinational criminal organizations often divide functions among various players with one country producing the counterfeit medications, one country producing the packaging, and yet another creating the labeling. The counterfeiter will attempt to consolidate the items either within the targeted country, such as the U.S., or in a bordering country like Mexico and Canada. This process will make it more difficult for law enforcement as many of the shipments will not raise suspicion as they cross borders, and a seizure of a single part of the chain will not destroy the integrated criminal syndicate.

Private sector security directors and U.S. law enforcement officials also stated that the detection challenge and burden of tracking the source of the drugs outside the United States is greatly increased once the illegitimate pharmaceuticals cross international borders. A former FDA investigator stated that the focus of the FDA has shifted from a reactive agency that responded to adverse events to trying to work proactively with international partners to locate the source of the counterfeit drugs. Even with success in international cooperation, there is still a flood of counterfeit drugs inbound to the U.S. which requires substantially more resources devoted to the international aspects of these crimes.

b. International Coordination

It is immensely challenging for law enforcement to coordinate collective efforts across national borders as the understanding of the problem will vary from country to country. The language, definitions, and approach toward counterfeit drugs will vary immensely. With traditional, controlled illicit drugs, all countries can communicate and cooperate easily because the approach is more standardized and consistent across countries. United Nations conventions and treaties define these illicit substances and the law enforcement infrastructure and contacts already exist to combat such drug trafficking. With counterfeit drugs, each country may approach it differently as a public health, law enforcement or intellectual property issue. Consequently, the level of resources, focus and time committed to countering illegitimate pharmaceutical trafficking will greatly vary. Another interviewee explained that building an international intelligence network among various nations is dependent upon people, relationships, and trust. However, both the nature of the threat regarding illegitimate pharmaceuticals, and the agreed means to combat them, make this subject matter a difficult area for effective international cooperation.

A former INTERPOL official stated that, although there have been great strides made in the fight against international counterfeiting, there is still a tremendous level of effort required to get developing countries engaged. This lack of focus may be based on a perception that counterfeiting is not harmful. Moreover, often it is indicative of a lack of resources or a low prioritization of illegitimate pharmaceuticals by national law enforcement agencies.

Another former FDA agent noted that some countries might be reluctant to cooperate fully when it meant exposing a counterfeit problem within its own borders to American scrutiny. He added that countries that wanted to be known for manufacturing legitimate drugs for reputable companies might not want their region to be branded as a source for illegitimate pharmaceuticals as well.

The U.S. and most of Europe have defined mutual legal assistance treaties (“MLATS”) that facilitate the sharing of information. An MLAT is an agreement between countries for the purpose of gathering and exchanging information to assist law enforcement agencies of both countries to enforce criminal laws. These agreements allow law enforcement to share intelligence and scientific evidence. Officials stated that the challenge was recognizing that each nation has a different standard (‘data privacy’) on how much financial and banking information can be shared with other countries. Also, certain countries place limits on how much information can be shared with law enforcement based on domestic public health laws. If this does not put the investigation on hold permanently, it will at least mean increased demands on negotiations about how the information can be shared and used. In addition, if an investigation requires any information sharing with countries that are not part of an MLAT with Europe or the United States, it will create a long delay with protracted requests for information.

CASE STUDY: INTERNATIONAL COUNTERFEITING AND ILLEGAL DRUG OPERATION

Operation Pangea is a collaborative effort between the FDA, the U.S. Department of Homeland Security, National Intellectual Property Rights Coordination Center, INTERPOL, the World Customs Organization, the Permanent Forum of International Pharmaceutical Crime, Heads of Medicines Agencies Working Group of Enforcement Officers, the pharmaceutical industry and national health and law enforcement agencies from 115 participating countries.

The target of investigators for Operation Pangea is the online sale of counterfeit and other illicit medicines. The operation brings together officials from national agencies including customs, health regulators, law enforcement, and the pharmaceutical industry. Representatives from over 190 police, customs and regulatory agencies are now participating. The focus is to target the components of the illicit online pharmacies, such as the internet service providers, payment systems and the delivery services.

In 2016, Operation Pangea resulted in the seizure of more than \$53 million worth of illegitimate pharmaceuticals and the arrest of nearly 400 suspects. The seized medications included fake cancer medication, substandard HIV and diabetes testing kits, counterfeit dental equipment and illicit surgical equipment. The operation resulted in the suspension of approximately 5,000 websites.³¹

This operation has been conducted since 2008 with an increasing amount of illegitimate websites shut down, counterfeiters arrested, and drugs seized each year. As a former INTERPOL investigator opined, this is the result of improved coordination but is more indicative of the growing threat of counterfeit drugs. This operation also illustrates how complex and increasingly sophisticated multinational criminal organizations are becoming and the substantial resources and time required across geographic borders to successfully disrupt these criminal activities.

³¹ Europol. “Online Sale Of Fake Medicines And Products Targeted In Operation Pangea IX.” Europol News-room. 10 June 2016. Web. 5 May 2017. <https://www.europol.europa.eu/newsroom/news/online-sale-of-fake-medicines-and-products-targeted-in-operation-pangea-ix>.

CASE STUDY: INTERPOL INVESTIGATION OF COUNTERFEIT DRUGS

INTERPOL assisted U.S. law enforcement in the investigation of the international organized trafficking of imported counterfeit medicines in Europe that were manufactured in China. The two leaders of the organized ring were the manager of an offshore company based in Mauritius and the head of a company based in Nice, France. The criminals distributed their products in Belgium, the U.K. and Germany. The counterfeit medicines were manufactured in China in a factory belonging to a contractor from Texas.

The investigation was initiated in 2009. According to the analysis of transport documents, more than a ton of drugs were imported into Europe via Singapore and Switzerland. The suspects were sentenced to five years in prison in April 2017. The U.S. co-conspirator had been sentenced to six and a half years in prison in the U.S. for international trafficking of counterfeit medicines in a related case. The complexity of this case was immense, requiring extensive coordination among eight nations.

C. Resource Challenges

Nearly all interviewees reported that the resources allocated to the problem of illegitimate pharmaceuticals does not match the scope of the problem or the significant challenges that law enforcement faces in trying to bring these criminals to justice.

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1. PRIORITIZATION CHALLENGES

The perception from pharmaceutical security officials interviewed was that drug counterfeiting is often not a priority for law enforcement based on other demanding priorities such as terrorism and illicit drugs. One pharmaceutical security officer stated that the companies' security teams often develop cases for referral to law enforcement but that it is often difficult for law enforcement to assume the cases based on limited resources or lack of staff with requisite expertise. According to one retired senior executive of the DEA, placing additional anti-counterfeiting investigative demands upon the DEA and other agencies without a significant increase in allocated resources would be a "recipe for disaster."

Some law enforcement officers we spoke with echoed concerns regarding the low prioritization of illegitimate pharmaceuticals for law enforcement organizations.

Interviewees stated that much of the resources, staff, and training occurs around illicit drugs, at the expense of finding illegitimate pharmaceuticals. Even accounting for the need to maintain or increase the focus on illicit drugs and controlled substances, the public health threat posed by fake or fraudulent prescription medications cannot be ignored despite the inherent difficulties.

Based on our assessment, the current opioid crisis, which has been exacerbated by counterfeit opioid products entering the U.S., and the continuing challenges related to illegal drugs are placing a growing strain on scarce law enforcement resources, thereby making it more challenging to pursue illegitimate pharmaceutical investigations. One local police officer stated that even with the tremendous success, which his 10-officer anti-counterfeiting team enjoyed, within two years his team had dwindled down to two officers based on the need for the officers in higher priority units and efforts. The opioid crisis will likely require a concerted effort by law enforcement to cut off the supply routes, which will require significant resources for law enforcement.

2. CHALLENGES RELATED TO INSPECTIONS AT INTERNATIONAL MAIL FACILITIES (“IMF’S”)

The U.S. Postal Service (“USPS”) delivers more than 153 billion mail pieces to more than 156 million addresses in every state, city and town in the United States.³² For context purposes, an estimated 217 tons of illegal narcotics are consumed in the U.S. annually, while as part of their effort to ensure that the USPS is not being used by criminal organizations, the USPS seized over 37,000 pounds of illegal narcotics. Likewise, the U.S. market for illicit drugs is approximately \$100 billion and postal inspectors seized \$23.5 million from drug trafficking groups using the USPS. Even with this success in seizing illegal narcotics by the USPS, this is a de minimus amount compared to the scale of illicit drugs being used and smuggled into the U.S.³³

There are serious concerns about whether CPB and the USPS have the resources necessary to combat the problem of counterfeit drugs shipped in the U.S mail system. As one U.S. Senator most recently commented: “With an estimated 340 million pieces of international mail entering the U.S. in 2016, there are legitimate

³² United States Postal Service, “Size and Scope” 5 May 2017. available at <https://about.usps.com/who-we-are/postal-facts/size-scope.htm>

³³ *Ibid*; ONDCP: What America’s Users Spend on Illegal Drugs: 2000-2010 (2014) available at https://obamawhitehouse.archives.gov/sites/default/files/ondcp/policy-and-research/wausid_results_report.pdf

concerns that CBP simply does not have the resources to adequately screen non-letter class mail entering the U.S. from foreign postal services.”³⁴

The sheer number of parcels processed by the USPS poses a near insurmountable task for CBP and FDA inspectors to reasonably inspect any portion that may contain dangerous illegitimate pharmaceuticals. Interviewees conceded that, based on the quantity of packages shipped containing prescription drugs, it makes more sense for law enforcement to go after the source of the shipments as opposed to trying to stop the illegal shipments at IMF’s. However, as detailed above, there are numerous difficulties with finding the perpetrators.

Therefore, law enforcement must try to stop this contraband from coming in at both fronts and, according to interviewees, the inspection protocol and information sharing from USPS or the CBP has been insufficient because of a lack of resources for inspection, lack of information on contents of suspect packages, and burdensome notification requirements under current law.

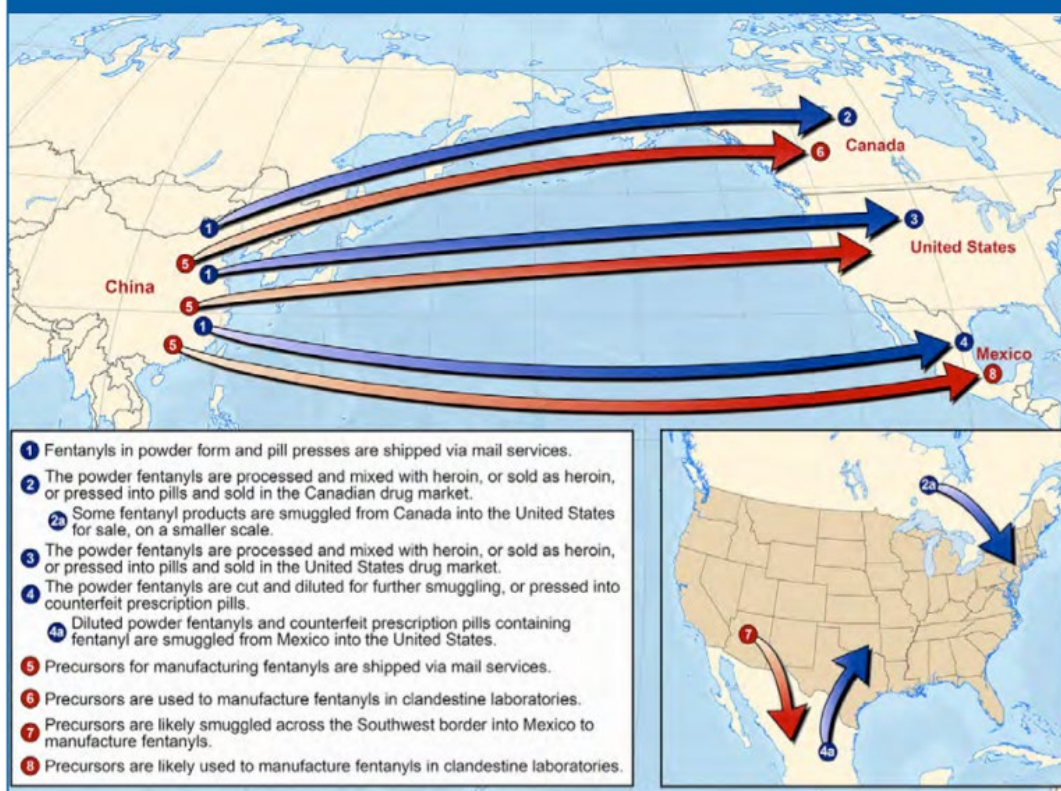
A former FDA official reported that IMF’s are inundated with thousands of packages containing pharmaceuticals, and while many shipments may in fact be legitimate drugs, there is no assurance because they are not approved for the U.S. and have never been subject to FDA inspections or requirements. In addition, the FDA cannot and will not inspect most shipments because the agency can only examine a small fraction of imports before they are passed onward to place like clinics, nursing homes or U.S. distributors.

Even the small portion of inspections that take place may provide little information because the shipments have often been moved through several distributors in multiple countries with little indication as to the original producer. A July 2016 DEA report regarding fentanyl and fentanyl precursors arriving from China explained that a Chinese supplier will go first to a freight forwarder, who will then pass the cargo to another freight forwarder who presents the package for export. The DEA noted that “the combination of a chain of freight forwarders and multiple transfers of custody makes it difficult for law enforcement to track these packages” which often “intentionally” arrive with incomplete or inaccurate information.³⁵

³⁴ Senator’s Urge Administration to Address Trafficking of Synthetic Drugs and Illicit Goods Through Mail Service. 16 Sep 2016 available at <https://www.ernst.senate.gov/public/index.cfm/2016/9/senators-urge-administration-to-address-trafficking-of-synthetic-drugs-and-illicit-goods-through-mail-service>

³⁵ Drug Enforcement Administration, Counterfeit Prescription Pills Containing Fentanyl: A Global Threat (July 2016) available at https://content.govdelivery.com/attachments/USDOJDEA/2016/07/22/file_attachments/590360/fentanyl%2Bpills%2Breport.pdf

Figure 83. Illicit Fentanyl and Fentanyl Precursor Flow Originating in China



Source: U.S. Drug Enforcement Administration, "Counterfeit Prescription Pills Containing Fentanyls: A Glob-al Threat," July 2016, <https://www.dea.gov/docs/Counterfeit%20Prescription%20Pills.pdf>.

As depicted above, the DEA has determined the likely smuggling routes for Fentanyl's reaching the United States, many simply being shipped via mail services. For example, in May 2015, Chinese customs officials seized several kilograms of fentanyl and acetyl fentanyl that had gone through five freight forwarders before arriving at customs in a cargo container bound for Mexico. By the time these drugs find their way to the ultimate consumer, discovering the origin becomes nearly impossible for law enforcement.

There are not enough law enforcement resources to detect and interdict the expanded volume of packages entering the United States. This creates the risk that criminal organization could exploit this vulnerability and ship illicit opioids (e.g., fentanyl and its analogues) masquerading as legitimate medicines or criminals trying to penetrate the legal supply chain with counterfeit, substandard or adulterated prescription drugs. Keeping up with existing volumes of goods entering the U.S. is daunting now. Under a drug importation regime, the volume of illicit drugs coming into the U.S. would undoubtedly increase.

3. REGULATIONS REGARDING PHARMACEUTICAL SHIPMENTS

The Food and Drug Administration Safety and Innovation Act § 708 (“FDASIA”) eliminated the requirement that counterfeit or unapproved drugs imported via an IMF that were refused admission were required to be returned to the sender by the USPS. Officials interviewed said that this was a step in the right direction as, many times, sellers who received the returned packages simply attempted to mail them back in the hopes that they would slip through the IMF on a second try.

Although this improvement helps the FDA, our research suggests that the new rule does not go far enough and still requires the FDA to follow a burdensome, multi-step notification and hearing process that delays the destruction of the drugs and creates more administrative burden on the FDA and CBP when seizing forfeited drugs at IMF’s. In addition, there is little to no data gained and shared from any inspection protocol to assist FDA OCI in establishing sources of illicit products and gathering trend data.

4. CURRENT INSPECTION RESOURCES

Interviewees estimate that there are only 8-10 total FDA inspectors at all the IMF’s which are tasked with assisting CBP in the inspection of incoming packages that may contain counterfeit or unapproved drugs. After a package is identified for inspection, FDA is required to notify the owner of the package prior to inspection or destruction. This inspection protocol makes it so administratively burdensome that it may serve as a disincentive for inspectors to act so gaining intelligence from the process is nearly impossible.



U.S. law enforcement is facing numerous challenges across the spectrum of illicit and counterfeit drugs. The proliferation of access to online medicines has complicated the investigative and regulatory problem by opening up illegal importation sources for American consumers. The opioid crisis has and will continue to consume major resources for U.S. law enforcement. As law enforcement resources are shifted to countering this epidemic, our prescription drug supply will become increasingly vulnerable to drug diverters and counterfeiters from across the globe who target the U.S. market for enormous profits.

Policymakers must realize that they are dealing with criminals that are driven by profit and have little or no regard for human life. As mentioned above, these are individuals and organizations capable of counterfeiting the drug, the pedigree, the packaging, and anything else necessary in order to put dangerous medications into a patient's hands. Separated from the harm by time and distance, they continue to dispense dangerous drugs in order to build their wealth and criminal enterprises. Laws and regulations have to be tailored based on this lowest common denominator. Resources have to be provided to law enforcement to deal with this type of criminal who will exploit the vulnerabilities in our systems to make a profit.

KEY FINDINGS

The investigation's key findings are:

- **Drug importation proposals would shift the costs and burden to law enforcement while opening up the U.S. drug supply to adulterated and counterfeit drugs.**

Allowing wholesalers, doctors, and patients to import direct from sources in Canada and Europe will increase the enforcement and investigative scope for U.S. law enforcement and regulators when they are already stretched to the limit dealing with these agile and creative criminal organizations. As law enforcement continues to investigate and to tackle this increasingly complex problem, the increased risks to public health and the safety of our borders posed by importation proposals pose too great a threat to our citizens.

Drug importation would greatly complicate an already complicated law enforcement job by introducing legal ways to import drugs at the patient, doctor, or wholesaler level. This will increase the complexity of counterfeit drug investigations by requiring investigators to validate or disprove purported drug supply sources that have come in under a new drug importation scheme

Our review finds that counterfeit and diversion investigations often occur over many years involving multiple different law enforcement entities. A very real concern is the ability of already resource-limited law enforcement to keep up with the threat and to maintain adequate investigatory and prosecutorial capacity to handle these complex and protracted investigations. Criminal enterprises are not resource limited as long as they can continue to realize the huge profits available in drug counterfeiting so they will continue to utilize advanced technology and techniques to run their complex enterprises.

- **Drug importation would increase the threat of illegitimate products entering the United States, fueling criminal organizations' activities and profits.**

The U.S. faces a substantial and growing threat from the diversion of prescription medicines as well as from the repackaged and potentially adulterated prescription medicines, and from counterfeit pharmaceuticals circumventing a robust system of regulatory and law enforcement oversight. In addition, drug importation would create financial incentives for individuals and criminal organizations to transship products through Canada that are likely to be counterfeit, diverted, adulterated, substandard and/or other non-FDA-approved products.

- **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.**

The opioid crisis is growing and will likely get worse before it gets better. Any effort to stop the flow of opioids or fentanyl and fentanyl-laced counterfeit pills will require a major effort by U.S. law enforcement to stop the production and illegal shipment into the U.S. These efforts will further drain limited law enforcement resources from those that are dedicated to protecting the U.S. drug supply from fake, substandard, adulterated, and counterfeit drugs. At the same time, importation will exponentially

increase the resources needed given the huge volume increases in drugs (both licit and illicit) certain to be coming from overseas. In addition, the creation of a new, unregulated drug importation pipeline into the United States would create unprecedented opportunities for criminal organizations to profit by smuggling fentanyl and its analogues, masked as legitimate prescription drugs, into the United States.

- **Already overburdened law enforcement and regulatory capacity would be unable to ensure a safe prescription drug supply under importation.**

Drug importation legislation that would expand importation beyond the current level greatly increasing the investigative burdens on the FDA and law enforcement and create new opportunities for multinational criminal organizations to access our supply system. Our regulatory and law enforcement personnel face substantial and ongoing resource challenges to effectively investigate and to prosecute existing laws and regulations aimed at protecting the U.S. prescription drug supply. Policymakers need to prioritize enhancements for an illegitimate pharmaceutical epidemic already killing and harming Americans, rather than pursuing drug importation laws with the promise of reducing costs to the health delivery system.

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The greatest risk for widescale diversion in the U.S. pharmaceutical system is at the wholesale and sub-wholesale level based on the high level of transactions that cause drugs to change hands frequently. The bifurcated system between state and federal licensing requirements, and inconsistent licensing and enforcement standards between states, allows for unscrupulous wholesalers to operate under a shroud of legitimacy.

There are a multitude of federal, state, and local law enforcement agencies working alongside federal agencies across the country that conduct successful investigations and prosecutions in preventing illegal pharmaceuticals from entering the U.S. drug supply. Drug counterfeiting and diversion is one aspect of a bigger problem for law enforcement that includes criminal enterprises involved in illicit drugs, insurance fraud, and other economic crimes.

RECOMMENDATIONS

This report should serve as a call to action to redouble the focus on improving and enhancing existing law enforcement capacity to prevent counterfeit drugs from entering the U.S. drug supply in the first instance, and ensuring law enforcement has sufficient resources, expertise, and authority to protect the public health and ensure the integrity of the U.S. drug supply. Congress should support law enforcement's effort through funding, and legislation in the following areas:

Enforcement:

- Review the adequacy of law enforcement and other regulatory agencies' authorities (e.g., FDA, CBP, USPS):
 - » To address emerging threats such as rogue online pharmacies and increasingly sophisticated criminal organizations which traffic in illegitimate pharmaceuticals.
 - » To determine whether they have sufficient authority relative to compliance, investigative, and oversight responsibilities mandated by current laws related to the management and security of the nation's drug supply, and provide recommendations regarding potential statutory changes.
- Assess the adequacy of resources related to:
 - » FDA, CBP, and USPS resources to improve the current inspection system of packages that may potentially contain counterfeit drugs.
 - » Enhance law enforcement training and awareness of counterfeit drugs both domestically and internationally.
 - » FDA's ability to oversee implementation of an electronic, interoperable system to track medicines from manufacturer to patient.
 - » 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 on criminal organizations and trends, to expand focus beyond counterfeit drugs.
 - » Nationwide effort to improve awareness and education of the American public on the dangers of illegitimate pharmaceuticals and illegitimate online pharmacies.

Regulation:

- Review 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.
- Order a GAO review of current bifurcated (state and federal) enforcement, investigation, and certification of prescription drug wholesalers to recommend approaches to eliminating inconsistencies across states in enforcement and inspections of FDA standards for wholesalers and secondary wholesalers.
- Implement changes to existing laws 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.
- Review current penalties for drug counterfeiting to ensure the criminal sanctions serve a strong deterrent effect.
- Provide the FDA OCI with administrative subpoena power for the purpose of investigating counterfeit drug cases and enforcing counterfeit drug laws.

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Based on these findings, recommendations, and the seriousness of the threats we face, we believe that opening the floodgates of drug importation would have disastrous public safety and law enforcement consequences. Conversely, lawmakers should substantially enhance both the resources and legal authorities of the FDA and all relevant law enforcement authorities to combat the existing public health threat of illegitimate pharmaceuticals. Drug importation at the patient, doctor, or even wholesaler level would 1) greatly overburden U.S. law enforcement capacity to properly regulate and to investigate these serious crimes; 2) cause a drastic increase in the importation of both legitimate and illegitimate pharmaceutical imports to the U.S.; and 3) create financial incentives for criminal organizations across the globe to meet the increased demand for drugs from Canada. As has been shown in previous cases, this will provide the necessary incentive for global criminal organizations to meet this demand by transshipping products through Canada that are likely to be counterfeit, diverted, adulterated, or otherwise illegitimate pharmaceuticals.