Monday, March 2, 2020

The Honorable Alex M. Azar II
Secretary of Health and Human Services
c/o Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Comments on Notice of Proposed Rulemaking titled "Importation of Prescription Drugs," FDA-2019-N-5711, 84 Fed. Reg. 70796 (December 23, 2019)

Dear Secretary Azar:

In response to the U.S. Food and Drug Administration's (FDA) proposed amendment to its regulations to implement section 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 384(b)-(h), to allow importation of certain prescription drugs shipped from Canada, the Alliance for Safe Online Pharmacies (ASOP Global; www.BuySafeRx.pharmacy) is pleased to provide you the following written response.

On behalf of our more than 40 international member and observer organizations, and in the interest of protecting public health and patient safety, ASOP Global is writing to express concern regarding this notice of proposed rulemaking (NPRM) allowing for the importation of certain prescription drugs. While we recognize the priority that this Administration has placed on reducing the costs of prescription medicines for American consumers, believe that this rule is not the solution.

ASOP Global's comments are based on our more than a decade of deep experience in consumer safety, counterfeit drugs, and illegal online drug sales. We therefore respectfully submit that the NPRM should be withdrawn for the following reasons:

1. It fails with respect to the Canadian drug supply.
2. It fails because it creates new public health and safety risks to Americans, both online and offline.
3. It fails to save American consumers money.

We hope to work with Congress and the Administration to find long-term solutions to address concerns around prescription drug prices while also enhancing patient safety and consumer protection online. Please do not hesitate to contact us to discuss further as we stand ready to serve as a resource to you and your office.

Respectfully,
Elizabeth Baney, JD

On behalf of the Alliance for Safe Online Pharmacies (ASOP Global)
Libby.Baney@FaegreDrinker.com

ABOUT ASOP GLOBAL

Founded in 2009, the Alliance for Safe Online Pharmacies (ASOP Global)[1] is a nonprofit organization based in Washington, D.C. dedicated to addressing the public health threats posed by illegal online drug sellers and counterfeit medications. Convening more than 40 national and international partners, ASOP Global engages in public health and patient safety efforts throughout the United States, Canada, Latin America, Europe, India, and Asia. Core areas of activity include: (1) research, (2) education and public awareness, (3) advocacy, and (4) collaboration.

Through the traditional, legitimate supply chain, medicines are one of the most highly regulated products in the world. The United States pharmaceutical supply chain serves as the preeminent example of safety, security and innovation worldwide. This is in stark contrast to the illegal distribution of medicines online through social media, stand-alone websites, and online marketplaces.

We understand and appreciate the Administration's efforts to distinguish personal importation – including from online purchases – from the wholesale drug plan as proposed. However, for more than a decade ASOP Global has studied the realities of patient purchasing behaviors and the online pharmacy market. We thus know that despite the letter of the law, Americans do and will continue to go online to look for "Canadian medicine." When they do, they will find thousands of sources falsely claiming to sell legitimate Health Canada approved medicine, putting their health at risk. As discussed herein, this is not a theoretical harm. As such, this alone should prevent this rule from going into effect as the law requires that importation be done safely.

A. CANADA WILL NOT ALLOW THE U.S. TO RAID ITS PHARMACEUTICAL SUPPLY

While ASOP Global appreciates and supports efforts to find new ways to increase patient access to safe, affordable prescription medicines, this notice of proposed rulemaking (Docket No. FDA–2019–N–5711) allowing for the importation of certain prescription drugs, if finalized, still does not directly address the core issue of domestic prescription drug prices and provides further opportunities for infiltration of substandard and counterfeit products into our otherwise closed U.S. supply chain.

Canada simply does not have a sufficient quantity of drugs to fill America's needs. The proposed rule allows Health Canada approved prescription drugs to be importation from Canada—a country one-tenth the size of the United States and whose citizens use far fewer drugs than Americans. As a result, the supply of prescriptions drugs that could theoretically be redirected to the United States is limited. If just 20% of Americans were to import prescription drugs from Canada, the 2015 Canadian prescription drug supply would be exhausted in 151 days.[2] Even if a 20% surplus is added to the Canadian drug supply, it would only last 183 days or about six months.[3] A September 2019 report by Dr. Brett Skinner noted that, in some instances, Canadian drug supplies could be exhausted in as little as a few weeks with a majority of drug supplies depleted in less than 100 days.[4]

Canada's current pharmaceutical supply system, the subject of national price negotiation and regulation, is designed to serve the Canadian population of just 37 million people. In contrast, the four states that have passed importation legislation thus far - Florida, Vermont, Maine and Colorado combined have a population of 29 million

1 Alliance for Sale Online Pharmacies, ASOP Global, February 2020, https://buysaferx.pharmacy/
2 Mary D. Shepherd, Drug importation into the United States: impact on Canada, Canadian Medical Association Journal, September 2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5621936/
3 *Ibid.*
4 Brett Skinner, Founder and CEO of Canadian Health Policy Institute (CHPI), Potential impact of U.S. demand on the Canadian supply of 46 prescription drugs, Canadian Health Policy, September 2019, https://www.canadianhealthpolicy.com/products/potential-impact-of-u-s--demand-on-the-canadian-supply-of-46-prescription-drugs-.html

people- more than 80% of Canada's total population. This figure does not include the several other states that have indicated an interest in submitting an importation proposal to the Department for consideration.

Drug importation from Canada is unrealistic in practice. Canada is in the midst of a serious medication shortage crisis. Pharmacies are struggling to fill prescriptions and supplies remain at a dangerously low level. The shortage has been a known issue in Canada since 2010 and has progressively gotten worse since. In a 2018 study analyzing the data, researchers found that 1 in 10 drugs sold in Canada are back-ordered or discontinued. Health Canada, recognizing the continued challenge of shortages, implemented mandatory reporting of actual or potential drug shortages and/or discontinuations by manufacturers. As of February 2020, there are close to 2,000 drug shortages in Canada, according to Health Canada's mandatory reporting website.[5] And according to the Canadian Pharmacists Association, one in four Canadians have either personally experienced or know someone who has experienced a drug shortage in the last 3 years.[6]

Canada is one of a few developed countries in the world with a 'universal' healthcare system but does not have a single national prescription drug formulary. The gap is partly because Canada's system was designed in the 1960s, when prescription medication was less of a focus for healthcare. While Canada's Patented Medicine Prices Review Board (PMPRB) a quasi-governmental agency, controls manufacturers' prices of patented drugs -- it does not control prices on generics. In fact, the average retail price for generics has been found to be higher in Canada than the U.S. In 2016, a PMPRB report concluded Canada's generic drug prices are too high — 19 to 31 per cent above prices in Europe, the U.S., Australia and New Zealand. Meanwhile in the U.S., 90% of retail and mail order prescriptions were dispensed as generic drugs.[7]

To protect the Canadian drug supply, the Canadian government can – and has previously – sought to revoke the license to operate from wholesalers that agree to export Health Canada-approved prescription drugs.[8] Similarly, other Canadian government officials, patient-advocacy groups and healthcare professionals have been vocal in their disapproval of U.S. drug importation bills. *See video here.*

The fact that the Canadian Government is unlikely to permit mass export of their drug supply to Americans does not mean that HHS should expand the proposed rule to allow importation from other countries too. Just the opposite, as other countries are similarly motivated to protect their own price-controlled drug supply, preserving it for their citizens instead of risking shortages. As soon as HHS or a SIP seeks to authorize importation from e.g. Germany, the United Kingdom, or elsewhere, we should expect that those governments will likewise move to protect their citizens' access to regulated medicine. This foreseeable geopolitical outcome thus only benefits drug counterfeiters and other criminals willing to skirt drug safety laws and sell through grey market channels, profiting at patients' expense. This risk is discussed further below.

B. WHOLESALE DRUG IMPORTATION CREATES NEW RISKS TO PATIENT SAFETY IN THE U.S.

Even before the NPRM is implemented, Americans will be put at risk by illegal online "Canadian" drug sellers. ASOP Global appreciates and applauds the FDA's acknowledgment of the dangers of rogue online pharmacies. The NPRM put it well, finding these online sellers are

5 Drug Shortages Canada, Drug Shortages Homepage, February 2020, https://www.drugshortagescanada.ca/
6 Drug Shortages Canada, Summary Report, February 2020, https://www.drugshortagescanada.ca/rws-search?perform=1
7 Medicine Use and Spending in the U.S., April 2018,https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf
8 First Session, Thirty-eighth Parliament, 53-54 Elizabeth II, October 4, 2004 - November 29, 2005. House of Commons of Canada, House Government Bill C-83. https://www.parl.ca/LEGISInfo/BillDetails.aspx?billId=2136806&Language=E&View=10

> …often run by sophisticated criminal networks that knowingly and unlawfully cause the importation of adulterated, counterfeit, misbranded and unapproved drugs into the United States. These rogue online pharmacies are often run by sophisticated criminal networks that knowingly and unlawfully cause the importation of adulterated, counterfeit, misbranded and unapproved drugs into the United States. These criminals frequently use sophisticated technologies and are backed by larger enterprises intent on profiting from illegal drugs at the expense of American patients. NPRM, pages 17-19.

Despite that warning, we fear that news of these actions may lead consumers to go online looking to "import Canadian medicines," as Americans are so accustomed these days to buying nearly everything online. When they do, Americans will find dozens if not hundreds of sellers falsely offering promises of safe Canadian medicine. U.S. consumers buying medications from alleged 'Canadian online pharmacies' rarely, if ever, receive the same regulator-approved products provided to Canadian consumers. Indeed, FDA has found that 85% of the drugs being promoted as "Canadian" came from 27 other countries around the globe. As the NPRM finds, "these products are smuggled into the United States after being transshipped to third party countries, such as Canada in an effort to avoid detection and create a more trustworthy appearance." NPRM, pages 18-19. Medicines from other countries put patient safety at risk as foreign products are not manufactured in compliance with FDA's standard for quality drug manufacturing, safety, and efficacy.

Our primary concern is that Americans will go online to "buy Canadian" and instead be sold counterfeit medicines**.** Counterfeiting criminals prey on patients' need for medications and make a big profit doing so. Throughout the world, criminals manufacture and sell counterfeit and unsafe prescription drugs online and through other illegitimate venues. They have no regard for the safety, efficacy, or quality of the medicines they are selling to unsuspecting patients. Illicit prescription drug sales are estimated to be between $163 billion to $217 billion per year.[9] Put in even simpler terms, the international counterfeit drug trade serves as the largest sector of the global illicit markets, exceeding arms dealing and human trafficking.

It is, therefore, not surprising that the Internet is the largest venue for counterfeit prescription drug sales, which also encompasses products that are misbranded or contain false or misleading claims. At any given time, there are approximately 30,000-35,000 active online pharmacy websites operating on the open web, of which approximately 96% are operating out of compliance with state and federal law and relevant pharmacy practice standards.[10] Illegal online drug sellers have been found to offer counterfeit, misbranded, and unapproved prescription drugs, often without a prescription or the required pharmacy licensures.[11]

Regardless of what the final rule permits, we know that Americans will nonetheless go online to find cheaper Canadian medicine. We know this because we've studied consumer behavior and perception and found the following startling facts:[12]

- One-third (1/3) of respondents had *already* purchased prescription drugs on the Internet for themselves or someone under their care.

9 Fighting counterfeit pharmaceuticals: New defenses for an underestimated - and growing – menace, January 2017. https://www.strategyand.pwc.com/gx/en/insights/2017/fighting-counterfeit-pharmaceuticals/fighting-counterfeit-pharmaceuticals.pdf
10 The National Association of Boards of Pharmacy, Proposed Legislation Brings Risk of Imported Counterfeit Medications, Bypasses Regulatory Safeguards, August 2017, Pages 6-8, https://nabp.pharmacy/wp-content/uploads/2016/07/Innovations-August-2017.pdf
11 National Association of Boards of Pharmacy, Internet Drug Outlet Identification Program , Progress Report for State and Federal Regulators: February 2018, February 2018, https://buysaferx.pharmacy//wp-content/uploads/2018/02/NABP-Internet-Drug-Outlet-Report_February-2018.pdf
12 ASOP Global: Online Pharmacy Behavior and Perception Survey Results, September 2017. https://buysaferx.pharmacy//wp-content/uploads/2017/09/us_sept2017-1.pdf

- 89% of respondents who *have* bought medicine online *never* discussed it with their healthcare provider. This puts patients at risk of incorrect dosing and adverse events (including drug-drug, drug-supplement, and drug-food interaction). Further, patients may unknowingly be receiving counterfeit or substandard products from online sellers and, because they fail to tell their healthcare provider, the provider may simply change treatment regimens (e.g. amending dosages, prescribe additional products, order additional testing, etc.) without realizing the true cause of the original treatment failure. This adds costs to the healthcare system, harms patients, and frustrates good clinical practice.

- Less than 5% of consumers are aware of tools available to help them find safe online pharmacies. This again is great cause for concern given the thousands of illegal online sellers masquerading as legitimate sources of Health Canada approved medicine online.

- What is more, research from Purdue University found that *even licensed pharmacists* typically cannot differentiate legitimate from illegal online pharmacies just by looking at a website.[13] This is especially troubling given pharmacists prominent role in the proposed wholesale importation plan, where U.S. pharmacists may be the "importer" working in collaboration with the SIP.

- When looking for an online pharmacy, one in five previous online pharmacy users said they simply typed the name of their medication into a search engine and *chose a website at random*, rather than ordering from a pharmacy site associated with their local pharmacy, utilizing an approved site offered by their insurance plan, or searching the list of pre-approved sites made available through NABP.

Given these facts, it is foreseeable that any announcement that the U.S. Government permits wholesale drug importation will only drive more Americans online under the false believe they can find safe Canadian medicine themselves.

Consumers, we fear, won't wait for the rule to be implemented (which could take years, given the complexity and costs of the proposed system), but instead take matters into their own hands – as they already are doing – and go online to seek alternative "Canadian" sources. This would be a direct consequence of this importation rule. As such, the rule on its own terms should fail as it increases risks to patient safety.

Canada licensed wholesalers have harmed Americans in the past. This rule invites them to try again. Just a few years ago a licensed Canadian wholesaler was indicted and plead guilty to making millions selling misbranded and/or counterfeit cancer medications to Americans. [14], The work of U.S. law enforcement and prosecutors on this case took *eight* years and what one can only imagine to be millions in taxpayer dollars – for this one case. And while the NPRM seeks to distinguish this case, the CanadaDrugs case from what is being proposed, ASOP Global fears the draft regulation opens the door to copy-cat criminals following this business model, getting rich while skirting safety laws and endangering Americans.

Importation makes America reliant on foreign governments to regulate and police the pharmaceutical supply chain outside the U.S., while implying to consumers that it is safe to buy any medicine from foreign sources generally. This raises two problems: (1) foreign governments, including Canada, are not in the business of

13 John B. Hertig, PharmD, MS, and Nikki Sebahar, PharmD Candidate, Evaluation of Pharmacists' Awareness of the Prevalence and Negative Consequences Associated with Illegal Internet Pharmacies, Case Management Society of America, May 2017, https://buysaferx.pharmacy//wp-content/uploads/2017/05/CMSA_whitepaper_rphonlinelegitimacy.pdf

14 Department of Justice, U.S. Attorney's Office District of Montana, Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States, April 2018, https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs

protecting Americans. That's our governments' job. Health Canada has already stated as much: "Health Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future."[15] This was made clear in the CanadaDrugs case referenced above, where international collaboration on the investigation and prosecution took nearly a decade despite solid evidence that a licensed Canadian wholesaler was putting Americans at risk. (2) Americans cannot assume that medicines outside the jurisdiction of the US FDA are safe and effective for use. Drugs made in places like India and China – often sold under the guise of being from Canada – can be manufactured in unsafe conditions; contain too much, too little, or no active ingredients; and/or may be made using dangerous and sometimes deadly substances, including fentanyl and other poisons.[16]

The NPRM undermines the Drug Supply Chain Security Act (DSCSA), a law enacted in 2013 and still being implemented, in order to protect Americans from prescription drug diversion and counterfeit medicines. The DSCSA creates a closed supply chain to track and trace prescription drugs as they move from manufacturer to distributor to pharmacy. This tracing system allows U.S. regulators and supply chain trading partners to prevent counterfeits from entering the U.S. drug supply. The proposed importation plan breaks this closed supply chain. In its place, FDA's proposed rule creates a patchwork of interim supply chain measures that introduce gaps and loopholes in the supply chain as drugs are distributed from Canada into the U.S. The proposal undermines the DSCSA's protections by introducing unsecure foreign prescription drug packages into our drug supply and commingling them with secure FDA-approved products.

U.S. law enforcement and regulators already struggle to detect and stop counterfeit and otherwise unsafe medicine from entering the country through International Mail Facilities (IMFs). The U.S. Customs and Border Protection has repeatedly expressed its concern regarding safety risks that arise in regards to inbound international mail, stating "significant risk exists to the U.S. through mail importation of illicit goods, narcotics and the possibility of radioactive materials that could pose a threat to national security."[17] In February, FDA Commissioner Stephen M Hahn, M.D. announced Operation Broadsword, the first bilateral enforcement operation with India, that stopped approximately 500 shipments through the international mail in just 3 days.[18] "With standards and regulations varying in each country, U.S. consumers face hazards when they order drugs and other FDA-regulated products from unauthorized foreign sources and receive them through the international mail system. Consumers and physicians purchasing medicines cannot be assured the products they are receiving are legitimate, safe or effective if they are obtained from outside of the FDA-regulated pharmaceutical supply chain. It is vital that we aggressively stop illicit products from entering the country that may place patients' health at risk, and we are pleased to call the Government of India a partner in this effort." said FDA Commissioner Stephen M. Hahn, M.D.[19] Increasing the volume of drugs from other countries would stress an already overburdened law enforcement and regulatory safety system. The risks of increased counterfeits and illicit drugs entering the U.S. as a result of importation were well document in a report by former FBI Director Louis Freeh.[20]

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15 Diane Gorman, Assistant Deputy Minister of Health Canada, HHS Task Force on Drug Importation, U.S. Department of Health and Human Services, December 2004, https://safedr.ug/2H2QN6d.

16 Alliance for Safe Online Pharmacies, Key Data About Controlled Substances Sold Online, ASOP Global, February 2020, https://buysaferx.pharmacy/for-the-media/key-data-about-controlled-substances-sold-online/

17 USPS Office of Inspector General Management Alert. September 21, 2016. https://www.uspsoig.gov/sites/default/files/document-library-files/2016/MS-MT-16-003.pdf

18 FDA News Release, February 18, 2020, "Takes Action with Indian Government to Protect Consumers From Illicit Medical Products." https://www.fda.gov/news-events/press-announcements/fda-takes-action-indian-government-protect-consumers-illicit-medical-products?utm_campaign=021820_PR_FDA%20Launches%20First%20Bilateral%20Operation%20to%20Prevent%20Import%20of%20Illicit%20Medical%20Products&utm_medium=email&utm_source=Eloqua

19 *Ibid.*

20 2 Freeh, Sporkin, and Sullivan LLP and Freeh Group International Solutions, LLC, Report on the Potential Impact of Drug Importation Proposals on U.S.

3. WHOLESALE DRUG IMPORTATION WILL NOT RESULT IN "SIGNIFICANT COST SAVINGS"

The weight of the evidence shows that wholesale drug importation will not result in significant cost savings for American consumers and, as such, the rule should fail. The NPRM puts the burden on states to establish significant cost savings. Current law requires that any importation plan result in "significant savings" in the cost to consumers, yet the NPRM fails to define what would constitute "significant savings." Even FDAs' own impact analysis states "*We are unable to estimate the cost savings from this proposed rule, as we lack information about the likely size and scope of SIP programs, the specific drug products that may become eligible for importation, the degree to which imported drugs would be less expensive than non-imported drugs available in the U.S., and which SIP eligible products are produced by U.S. drug manufacturers"* (See NPRM, pages 101-103).[21] Without a quantifiable metric for evaluation of state importation plans, it will be nearly impossible to determine whether this requirement is being met.

A June 2019 working paper[22] by Dr. Kristina M. L. Acri nee Lybecker at Colorado College studied the cost implications of state drug importation proposals by analyzing the cost of testing and the cost of treating an adverse medical event. This entailed examining 40 drugs, documenting the costs, presumed cost savings from two unregulated suppliers (Canadian online supplier and a brick-and-mortar Canadian pharmacy), the medical consequences of treatment failure, and the expense of treating such adverse events.[23] The results indicate that the true costs of pharmaceutical importation outweigh any anticipated cost savings.[24]

According to George Karavetsos, the former head of the FDA's Office of Criminal Investigation, the implementation costs of state importation programs would be significant. In April 2019, he noted that "our drug supply is safe because of efforts in the area of licensing and enforcement of the FDA. Just the enforcement division alone, which [he] ran, has an annual budget of over $75 million dollars. The division of the FDA that conducts inspections and quality initiatives has a budget of at least three times that."[25] Granted, these figures finance a national program.[26] Nevertheless, a state program will necessarily have to duplicate many of the federal functions and the costs will be in accordance with that.[27] When all potential risks and costs are accounted for, it is difficult to justify moving outside of the U.S. supply chain for medicines.

The Congressional Budget Office has also concluded that allowing importation would reduce prescription drug spending by only about 1 percent and that importation from Canada would result in a "negligible reduction in drug spending."[28] If the NPRM does not achieve significant cost reductions, then any importation plan would be illegal under the current statutory authority.

Even if the initial U.S. buyer (the importer) were to purchase Canadian medicine at a lower price than available in the U.S., there is no way to ensure that significant savings get consistently passed on to the American consumer. It is more likely that the U.S. importer would markup the medicine and pocket the difference. The rule

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Law Enforcement, June 2017, https://safedr.ug/FreehReport

21 Department of Health and Human Services, Food and Drug Administration, Importation of Prescription Drugs, Docket No. FDA-2019-N-5711, December 2019, https://www.fda.gov/media/133553/download

22 Kristina M.L. Acri née Lybecker, Department of Economics and Business, State Pharmaceutical Importation Programs: An Analysis of the Cost Effectiveness, SSRN, June 2019, https://ssrn.com/abstract=3402784

23 *Ibid.*

24 *Ibid.*

25 The Partnership for Safe Medicines, Risking Safety at All Costs: How Drug Importation is Dangerous Policy, National Press Club, April 2017, https://www.youtube.com/watch?v=103f2WYL9mk

26 *Ibid.*

27 *Ibid.*

28 Congressional Budget Office: Would Prescription Drug Importation Reduce U.S. Drug Spending, April 2004. https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf

itself does nothing to prevent the enrichment of middle-men other than shift the burden to the states. With lesser authorities and resources for oversight, states are not best positioned to solve this cost-shifting problem. They are, however, motivated in the short-run to show their constituents that they took action on drug pricing, even if the long-term savings never materialize. This is bad politics, and even worse policy.

The proposed rule also does little to change the fundamental economics of the prescription drug industry as it exists in the U.S. today. The reasons Americans pay more are rooted both in philosophical and practical differences in the way the U.S. health system provides comprehensive benefits to its citizens. The U.S. does not regulate or negotiate the prices of new prescription drugs when they come onto market. However, most developed countries regulate prescription drug prices with national price controls, short-circuiting the U.S. system and leaving American taxpayers to unfairly carry the burden. The debate about importing drugs is therefore not about importing medications but rather about importing another country's drug price controls. Importing "Canadian" drugs doesn't change that simple economic and systemic reality.

CONCLUSION

While ASOP Global applauds policymakers desire to increase patient access to safe, affordable medicines, prescription drug importation isn't the answer. The debate about importing drugs isn't about importing medications, but rather it's about importing another country's drug price controls and socialized approach to health care – which can't be done under the current U.S. health care system and places consumers at greater risk of unknowingly relying upon substandard or falsified products for potentially life-saving purposes. The fundamental reality is that the NPRM seeks to secure medicines at prices regulated and determined by a foreign government. Economists and health care experts overwhelmingly agree that importing drugs from countries that control their prices would do little to solve the problem of expensive drugs in the United States.

Canadian regulators, patient-advocacy groups and health care professionals have been vocal in their disapproval of U.S. importation bills. Canada already faces shortages for a range of medicines to treat diabetes, cancer, arthritis, epilepsy and other chronic conditions. The NPRM would surely deepen Canada's ongoing drug shortage crisis. Canada, a country with a population of just 37 million people, cannot supply the U.S. which is ten times its size. Canada will – and has in the past – proposed a ban on Canadian commercial exports of prescription drugs to protect their pharmaceutical supply.

ASOP Global also has significant concerns about the risks of the NPRM and the dangers posed by counterfeit medicines online. The proposed rule puts the health of Americans in foreign hands by undermining the safety and security of U.S. supply chains, it doesn't save patients money, and it doesn't work. ASOP Global does not stand alone[29] in our opposition to allowing wholesale drug importation. The healthcare and law enforcement communities oppose it and past importation schemes in states like Illinois, Maine, Minnesota and Vermont have failed.

29 Alliance for Safe Online Policy, Drug Importation Position Statements, ASOP Global, February 2020, https://buysaferx.pharmacy/public-awareness-campaigns/drug-importation/position-statements/

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2. GOVERNMENT OF CANADA

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a. U.S. Senate, Permanent Subcommittee on Investigations, Staff Report, "Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail." *(January 2018)*

ASOP GLOBAL STATEMENT ON HHS DRUG IMPORTATION ANNOUNCEMENT

WASHINGTON – December 18, 2019 – In response to today's announcement by Health and Human Services Secretary Alex Azar on the White House's plan to allow U.S. consumers to import drugs from Canada, the Alliance for Safe Online Pharmacies (ASOP Global), issued the following statement:

> While ASOP Global appreciates and supports efforts to find new ways to increase patient access to safe, affordable prescription medicines, the proposed importation policy does not directly address the core issue of domestic prices and overlooks the significant risks to patient safety associated with sourcing drugs from outside the highly regulated U.S. supply chain.
>
> Today's NPRM proposes that stakeholders may submit proposals to "import Health-Canada approved drugs." However, fearing drug shortages and higher prices of their own, Canadian government officials, patient-advocacy groups and healthcare professionals have been vocal in their disapproval of drug importation bills. *See video here.*
>
> Canada simply does not have a sufficient quantity of drugs to fill America's needs. Canada's current pharmaceutical supply system, the subject of national price negotiation and regulation, is designed to serve the Canadian population of 36 million people. In contrast, the four states that have passed importation legislation - Florida, Vermont, Maine and Colorado combined have a population of 29 million people- more than 80% of Canada's total population.
>
> Moreover, drug importation from Canada is unrealistic in practice. The ongoing and widely reported drug shortage issues in Canada threaten the nation's health care system. To protect the Canadian drug supply, Health Canada may – and has in the past – revoked the license to operate from wholesalers that agree to export Health Canada-approved prescription drugs. Before the Trump Administration moves forward with a final rule and implementation, policymakers should seek counsel from Canadian regulators such as Health Canada, the Foreign Affairs Consular at the Canadian Embassy in Washington, D.C., the Canadian Pharmacist Association and others. ASOP Global's Canada Chapter members stand ready to provide perspective on the issues as they impact Canadian safety and drug supply.
>
> Even before today's importation schemes are implemented, Americans may be put at risk. ASOP Global appreciates and applauds the FDA's acknowledgment of the dangers of rogue online pharmacies "often run by sophisticated criminal networks that knowingly and unlawfully cause the importation of adulterated, counterfeit, misbranded and unapproved drugs into the United States." *See* NPRM discussion, pages 18-19.
>
> Despite that warning, we fear that news of today's actions may lead consumers to go online looking for "import Canadian medicines," as Americans are so accustomed these days to buying nearly everything online. When they do, Americans will find dozens if not hundreds of sellers offering promises of safe Canadian products. We urge consumers to not believe the hype. As the draft FDA rule states, "Consumers go to these websites believing they are buying safe and effective medications, but often they are being deceived and put at risk by individuals who put financial gain above patient safety." *Id.*
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> It is widely known that the open internet is awash with illegal online pharmacies posing as "Canadian" and claiming to be selling safe U.S. Food and Drug Administration (FDA)- or Health Canada-approved
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> medicines. *Id*. At any given time, there are up to 35,000 active online pharmacy websites operating on the open web, of which about 94.8% are operating out of compliance with U.S. state and federal law and relevant pharmacy practice standards. U.S. consumers buying medications from alleged 'Canadian online pharmacies'

rarely, if ever, receive the same regulator-approved products provided to Canadian consumers. Indeed, FDA has found that 85% of the drugs being promoted as "Canadian" came from 27 other countries around the globe.

And let us not forget the CanadaDrugs case, where a licensed Canadian wholesaler was indicted and plead guilty to making millions selling misbranded and/or counterfeit cancer medications to Americans. While the NPRM seeks to distinguish this case from what is being proposed (*Id),* ASOP Global fears the draft regulation opens the door to copy-cat criminals following this business model, getting rich while skirting safety laws and endangering Americans.

Additionally, major loopholes in the U.S. Postal System allow mass quantities of counterfeit pills – many of which have been laced with deadly fentanyl and other synthetic opioids – from foreign sources to slip into the U.S. illegally through International Mail Facilities (IMFs). If drug importation is authorized at the state level, the inevitable increased volume of drugs from other countries would stress an already overburdened postal safety system.

ASOP Global is not alone in its concerns. Republican and Democrat, for two decades HHS Secretaries and FDA Commissioners for have opposed importation proposals for many of these same reasons– including President Trump's former FDA Commissioner Scott Gottlieb.

Finally, it is important to remember that past importation efforts in states like Illinois, Maine, Minnesota and Vermont have failed.

While ASOP Global applauds all efforts to increase patient access to safe, affordable medicines, importation remains an implausible answer. ASOP Global welcomes the opportunity to provide data and insights showing why importation is not the solution and offer alternatives for keeping Americans safe when looking for medicines online.

###

ABOUT ASOP GLOBAL

The Alliance for Safe Online Pharmacies (ASOP Global) is a 501(c)(4) non-profit organization headquartered in Washington, D.C. with activities in U.S., Canada, Europe, India, Latin America and Asia. ASOP Global is dedicated to protecting consumers around the world, ensuring safe access to medications, and combating illegal online drug sellers. ASOP Global has an expansive membership including non-profit public health organizations, international members, pharmacy members, as well as pharmaceutical manufacturers.

BAD ACTORS USE ONLINE PLATFORMS TO

SELL OPIOIDS AND COUNTERFEIT MEDICINES ILLEGALLY

KEY FACTS AND FIGURES: OPIOIDS AND ILLEGAL ONLINE WEBSITES

From sex trafficking to illicit drug sales, Congress and the American people are increasingly alarmed about dangerous, illegal, and criminal activity manifesting online. For most consumers, finding a safe online pharmacy website can be like finding a needle in a haystack.

35,000 SITES

At any given time, there are up to 35,000 active online 'pharmacy' websites operating on the surface web.

96% ILLEGAL

96% of online 'pharmacy' websites are illegal and unsafe, selling counterfeit or otherwise illegal medicines, peddling prescription medicines without a prescription, and/or operating without a pharmacy license.[1]

600 EACH MONTH

Approximately 600 new online pharmacy websites launch each month.

3,400 SELL OPIOIDS

Approximately 3,400 sites at any one time sell controlled substances like opioids, often without a prescription. [2]

NON-PRESCRIPTION

31% of newly reviewed websites offered controlled substances with 99% not requiring a prescription.[1]

45,000 TWEETS

In a two-week period, there were over45,000 tweets that promoted the purchase and nonmedical use of prescription drugs through an actively marketed illegal online pharmacy.[3]

OVER 40 STATES

A 2018 Senate Permanent Subcommittee on Investigations (PSI) report identified hundreds of illegal online drug transactions in over 40 states, adding up to $230,000worth of fentanyl – with a street value of over$750 million – from just six online sellers.[4]

FOUND EVERYWHERE

In the US, counterfeit drugs have been found across all therapeutic areas and indications. These fake versions include often include varying amounts of or altogether different active pharmaceutical ingredients, heavy metals, poisons, toxins, salt or sugar pills, and recently, fentanyl.

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[1] Rogue RX Activity Report. National Association of Boards of Pharmacy. November 2019. https://cutt.ly/lrSJDnO

[2] National Association of Boards of Pharmacy, Internet Drug Outlet Identification Program Progress Report. July 2016. https://nabp.pharmacy/wp-content/uploads/2016/09/idoi_report_july_2016.pdf

[3] Detection of Illicit Online Sales of Fentanyls via Twitter [version 1; peer review: 3 approved]. Tim K Macey and Janani Kalyanam. F1000Research 2017. https://cutt.ly/arSJSh3

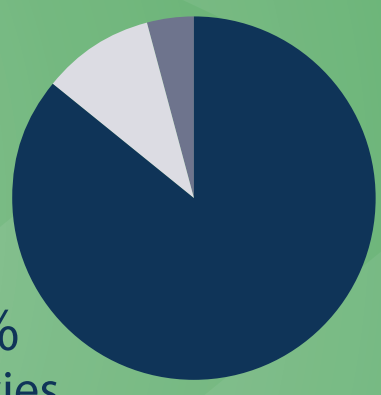
[4] Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail. United States Senate Permanent Subcommittee on Investigation, Committee on Homeland Security and Governmental Affairs. January 2018. https://cutt.ly/prSJFap

U.S. Consumers and Canadian Online Pharmacies: What You Need to Know

U.S. consumers buying medications from Canadian online pharmacies rarely, if ever, receive the same Health Canada-approved products provided to Canadian consumers.

95% of products advertised on Canadian pharmacy websites are non-U.S. FDA approved medicines meant for other countries like India or Turkey.

600 new illegal pharmacy websites launch each month to sell often counterfeit medicines to U.S. consumers.



More than 96% of online pharmacies are operating illegally and nearly 3,400 of these sites illegally sell controlled substances that are only available in the U.S. with a valid prescription.

Since 2010 there have been more than 200 felony counts against networks operating 400,000 pharmacy websites affiliated with Canadian online pharmacies.

FDA studies have shown that upwards of 85% of drugs claiming to be from Canada actually come from other countries.

Visit www.BuySafeRx.pharmacy to learn more and verify your online pharmacy is safe and legal before you buy. Need help paying for your prescription medications? Visit NeedyMeds.org.

ASOP Global | Alliance for Safe Online Pharmacies

BuySafeRx

ASOP GLOBAL | ALLIANCE FOR SAFE ONLINE PHARMACIES

Online Pharmacy Behavior and Perception Survey Results

The Alliance for Safe Online Pharmacies (ASOP Global)

September 2017

Online Pharmacy Behavior and Perception Survey Results

TABLE OF CONTENTS

Introduction and Executive Summary

In May 2017, the Alliance for Safe Online Pharmacies (ASOP Global) commissioned a national polling firm to evaluate consumer behavior and perception of online pharmacies. The study sought to measure awareness and perceptions of online pharmacy websites, including Canadian online pharmacies, and to gauge the impact facts have on consumers' views of these websites.

The survey results are particularly timely, as millions of Americans face the prospect of changes in their healthcare coverage should Congress repeal or replace the Affordable Care Act, or legalize prescription drug importation from Canada and elsewhere. As policymakers, industry and consumers continue to look to potential paths to lower prescription drug prices, consumers may turn to the internet to access prescription drugs in the meantime.

The survey provided new information on consumer perception and behavior related to purchasing medicines from online pharmacies, including answering the following questions:

- **a.** Who uses online pharmacies?
- **b.** What do patients discuss with their healthcare providers?
- **c.** How consumers find online pharmacies?
- **d.** Why consumers buy prescription medicine online?
- **e.** What medicines would consumers buy from online pharmacies?
- **f.** What makes consumers avoid online pharmacies?
- **g.** What consumers think about Canadian online pharmacies?
- **h.** What risks are consumers willing to take to buy medicines online?

The survey revealed that a majority of consumers are unaware of risks associated with online pharmacies amidst one-third of the participants having previously purchasing medications from an online pharmacy for themselves or a family member in the past. **While only 27% of consumers are very familiar with online pharmacies, a majority (55%) of survey respondents said they have or would consider buying medication online**. Although a majority of consumers are likely to use the internet as a potential source for prescription medicines**, less than 5% of consumers are aware of tools available to help them find safe online pharmacies**, such as the National Association of Boards of Pharmacy's .Pharmacy program and LegitScript's URL checker. Further, should the federal government publish a list of safe online pharmacy websites, less than 5% of survey respondents said they would use such resources.

The U.S. Food and Drug Administration (FDA) has reported that 85% of medicines that are sold to Americans by Canadian online pharmacies are not Canadian.[i] Since 2010, there have been more than 200 felony counts against networks operating 400,000 sites affiliated with Canadian online pharmacies.[ii] Furthermore, as we'll discuss later in this report, many of these illegal online pharmacies sell and distribute controlled substances, such as prescription opioids, without a prescription. This would provide access to individuals that misuse, abuse or divert these products outside of the necessary healthcare provider oversight and interaction with prescription drug monitoring programs.[iii]

There is, however, room for optimism: when presented with facts about the dangers of purchasing medicines from Canadian online pharmacies and other unverified websites, consumers' likelihood to buy online, tolerate

associated risks, and their utilization of Canadian online pharmacies changes dramatically; 59% of consumers who have been presented with the facts oppose prescription drug importation.

See below for more key findings from the survey.

Survey Key Findings:

- **Key Finding #1:** There is a generalized lack of awareness about online pharmacies. Just over a quarter of respondents (27%) are very familiar with online pharmacies, while one-third are not familiar. Only one in twenty respondents were familiar with available Internet resources to identify safe online pharmacies.
- **Key Finding #2:** One-third of respondents have used an online pharmacy to purchase medications for themselves, a family member or someone under their care. Those most likely to use online pharmacies are young, have higher incomes, purchase products online, are willing to take more risk and take more prescription drugs.
- **Key Finding #3:** Two out of five consumers mention price as a reason for using online pharmacies, and another third mention something about their insurance, totaling 76%. Two in five consumers do not use online pharmacies because they like their pharmacy, while a quarter of consumers do not think it is a good idea to purchase medicines from online pharmacies.
- **Key Finding #4:** A majority of respondents (55%) have or would consider purchasing at least one type of prescription or over-the-counter medication online, including classes such as drugs for the management of chronic diseases, cough, cold or allergy medications, as well as specialty medications such as fertility or cancer therapies.
- **Key Finding #5:** Consumers have very little interest in using a government website to find safe online pharmacy websites.
- **Key Finding #6:** 11% of consumers are likely to use a Canadian online pharmacy.
- **Key Finding #7:** Initially, a majority of respondents favor legalizing the use of Canadian online pharmacies. After respondents are informed that it can lead to worsening the opioid epidemic, a majority are opposed to legalizing the use of Canadian online pharmacies.
- **Key Finding #8:** Half of respondents (51%) are only willing to accept lower levels of risk when purchasing prescription drugs online or from a Canadian online pharmacy, indicating it is important they understand what the risks are. Another 35% would accept moderate or high risk, which indicates the importance of protecting consumers from certain risks.
- **Key Finding #9:** Initially only 13% of survey participants responded that they believe Canadian online pharmacies are very risky, but after learning more about the risk, 53% responded that they believe they are very risky.

Survey Rationale, Methodology and Demographics

ASOP Global commissioned this survey to obtain a better understanding of motivations behind consumer decisions on purchasing prescription medicines online. The survey provides new insights into U.S. consumer behavior and perceptions of these websites.

SURVEY METHODOLOGY AND DEMOGRAPHICS

Over a period of five days in May 2017, ASOP Global conducted a poll of 500 voters in Indiana through polling firm Baselice & Associates, Inc. Of the 500 interviews, 33% were conducted via an online panel, 37% through landline phone and 30% on a mobile phone. The age distribution, race/ethnicity and partisanship of the respondents is representative of voters in Indiana. A total of 500 individuals were included in the survey (48% male / 52% female) and the age of survey participants reflects national averages. Approximately 66% of all survey respondents were active social media users and 76% of survey participants or a member of their household were taking a prescription medicine.

Since Indiana is a Republican leaning state, the survey was consistent with state demographics in that responders included more Republicans than Democrats (48.8% to 32.2%). This differs from the national average (42.4% to 45.4%). However, when weighing responses against political affiliation, the results were similar. Responses from survey participants that identified as Republicans, Independents, or Democrats did not greatly differ to the point that they were not considered statistically significant.

BACKGROUND ON THE ONLINE PHARMACY MARKET

There are approximately 35,000 active online pharmacies operating worldwide[iv] and 100% of Internet searches for 'buy medicine online' lead consumers to dangerous pharmacy websites, increasing their chances of receiving counterfeit medications from unknown sources. In addition, 96% of online pharmacies do not comply with U.S. federal and state laws and pharmacy standards.[v] More than 12% of illegal online pharmacies (roughly 3,400 sites) sell controlled substances like opioids,[vi] and 600 illegal online pharmacy websites are launched each month.[vii] 100% of search results for "buy medicine online" lead consumers to illegal and unsafe websites.[viii]

AN EDUCATED CONSUMER IS A SAFE CONSUMER

Consumer education related to online pharmacies is important, since, as the survey results point out, a majority of consumers are not aware of the risks posed by illegal online drug sellers. **The survey results reveal, however, that educating consumers will impact consumers' behaviors.**

An educated consumer can also help mitigate the opioid epidemic, since consumers currently can purchase opioids from illegal Canadian online pharmacies. When searching for an online pharmacy, one in five previous online pharmacy users said they simply typed the name of their medication into a search engine and chose a website at random, rather than ordering from a pharmacy site associated with their local pharmacy, such as CVS.com, utilizing an approved site offered by their insurance plan, or searching the list of pre-approved sites made available through the National Association of Boards of Pharmacy.

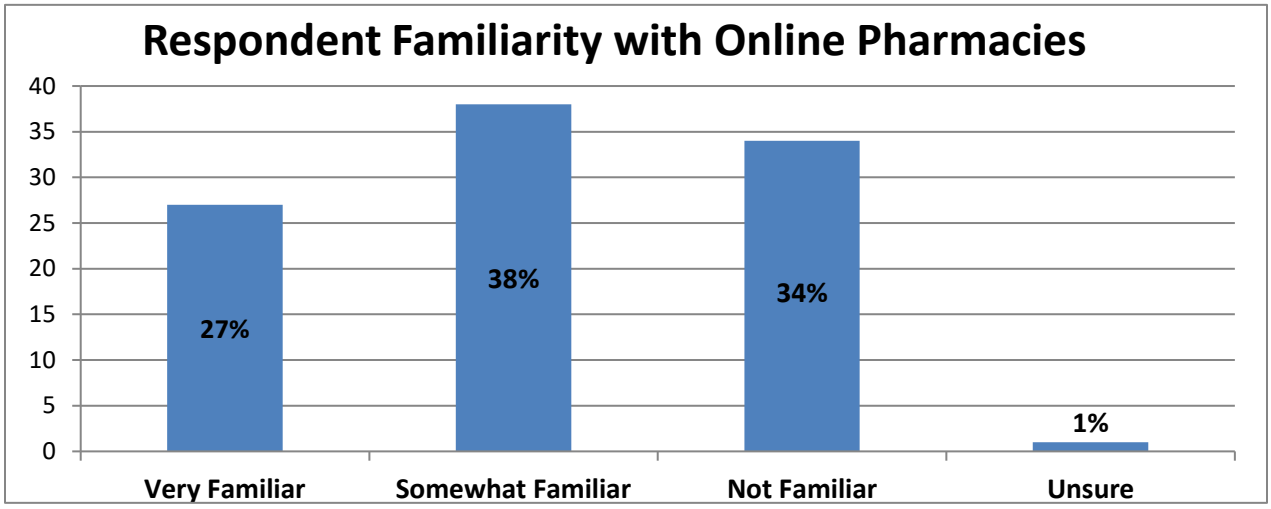
Further, **Purdue University's research[ix] found that even licensed pharmacists typically cannot differentiate legitimate from illegal online pharmacies just by looking at a website**. The average consumer is all the more susceptible to illegal pharmacy websites that offer 'too good to be true' prices, claims of selling 'genuine Canadian medicines', and other tactics that put patients at risk.

SURVEY RESULTS

Facts and Findings

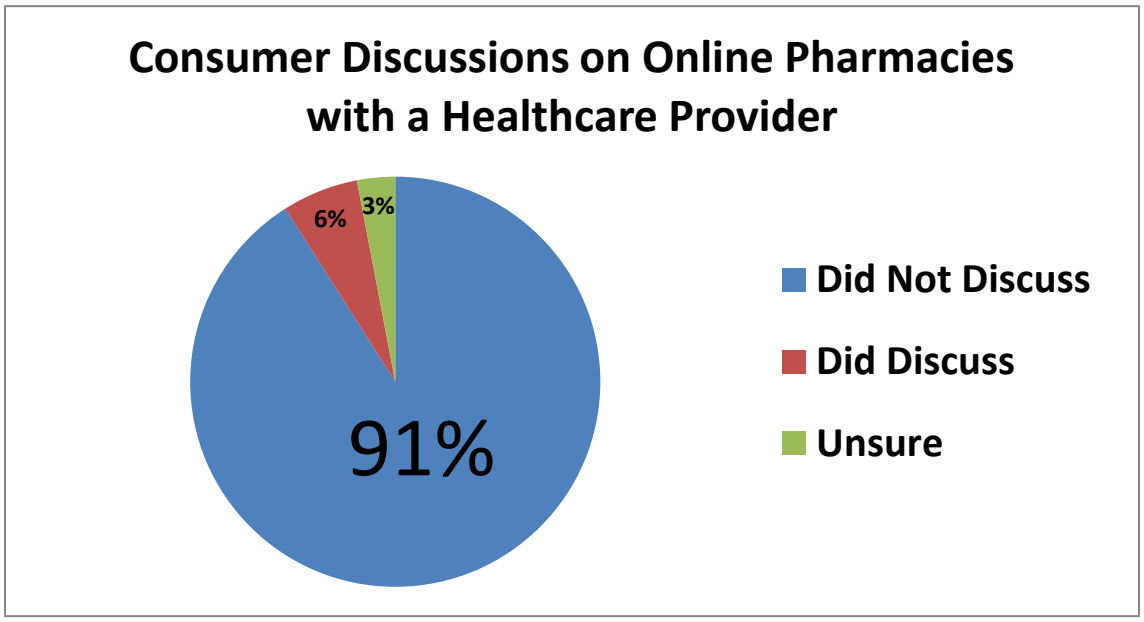
WHO USES ONLINE PHARMACIES?

There is very little awareness about online pharmacies and only about 1 in 4 consumers responded that they were very familiar with online pharmacies. Those most likely to consider purchasing medications online are those who are younger, have higher incomes (above $80,000 annual income per household), and purchase other items online. The clear majority (74%) of consumers who have purchased prescription medicines from an online pharmacy in the past would do it again.



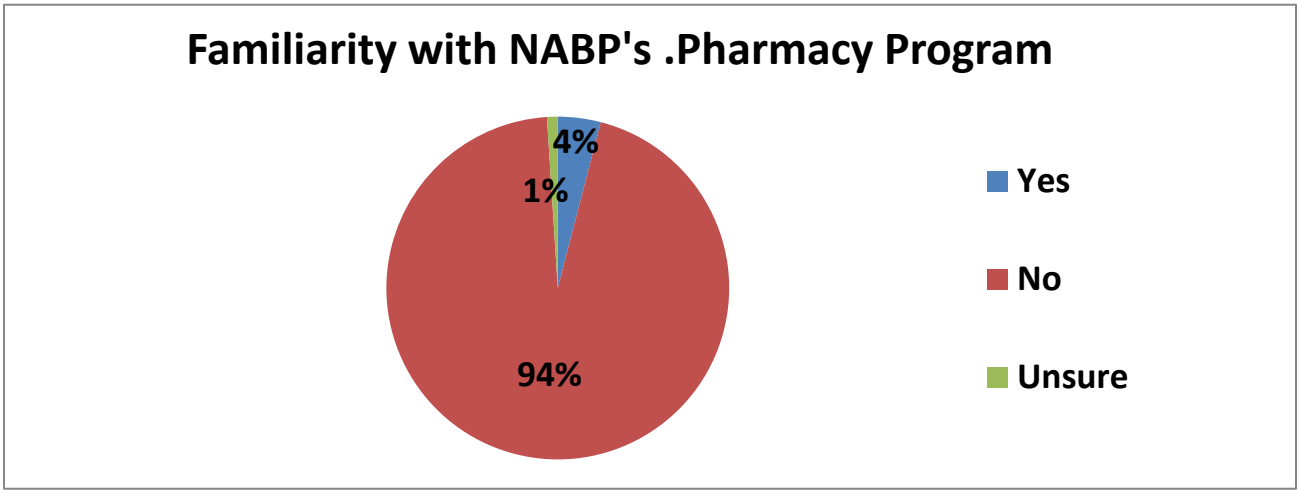
WHAT DO PATIENTS DISCUSS WITH THEIR HEALTHCARE PROVIDERS?

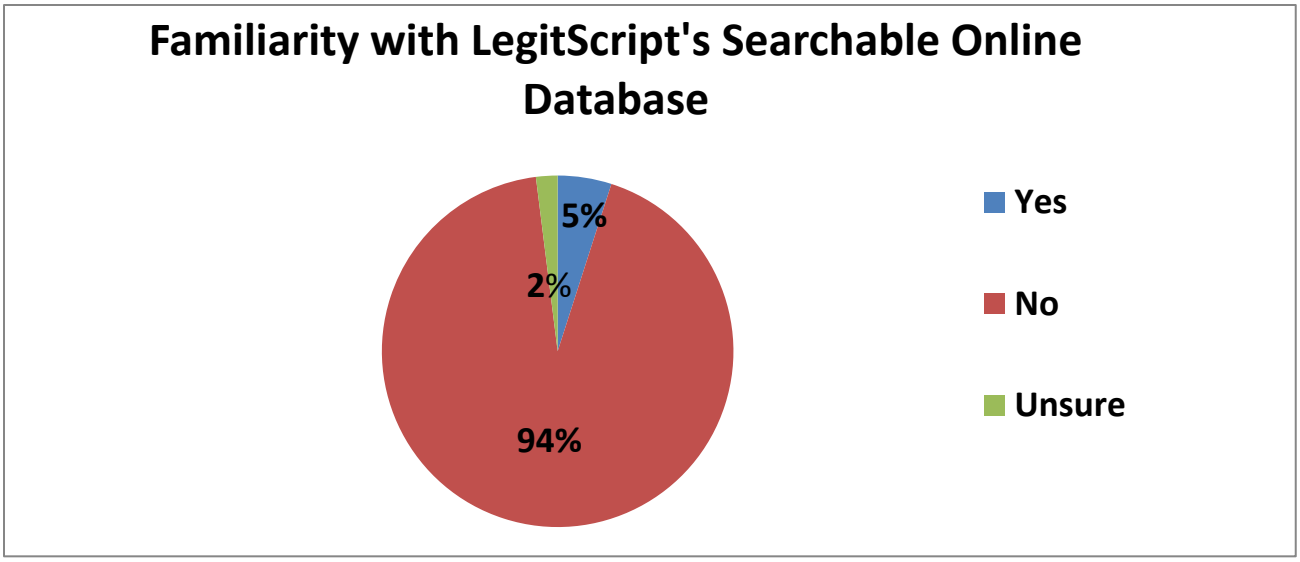
91% of consumers have not discussed online pharmacies with their healthcare provider. If healthcare providers were more aware of the risks associated with online medicine purchases and discussed the risks with their patients, consumers would be less likely to purchase online medicines.


Consumer Discussions on Online Pharmacies with a Healthcare Provider
6%
3%
91%
Did Not Discuss
Did Discuss
Unsure

HOW DO CONSUMERS FIND ONLINE PHARMACIES?

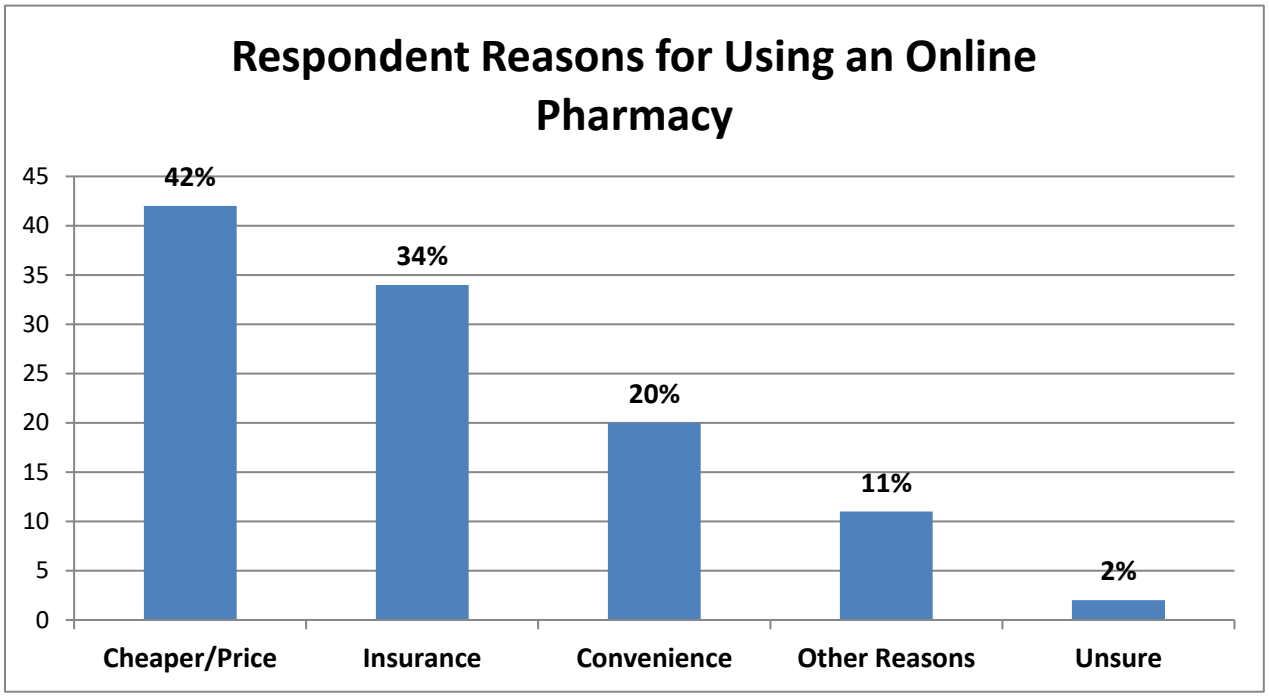
One-in-five online pharmacy users find online pharmacies through a web search alone. Lists of safe sites don't work. Less than 5% of consumers report they would use a government list of safe online pharmacies. Less than 5% of consumers are aware of tools available to help them find safe online pharmacies, such as the National Association of Boards of Pharmacy's .Pharmacy program and LegitScript's URL checker. Just over half (51%) of the aforementioned online pharmacy consumers used a site that was not affiliated with their local brick-and-mortar pharmacy. Of consumers who have used an online pharmacy: 9% bought from a Canadian online pharmacy, 5% bought from another foreign online pharmacy, 3% reported not knowing the location of the online pharmacy.





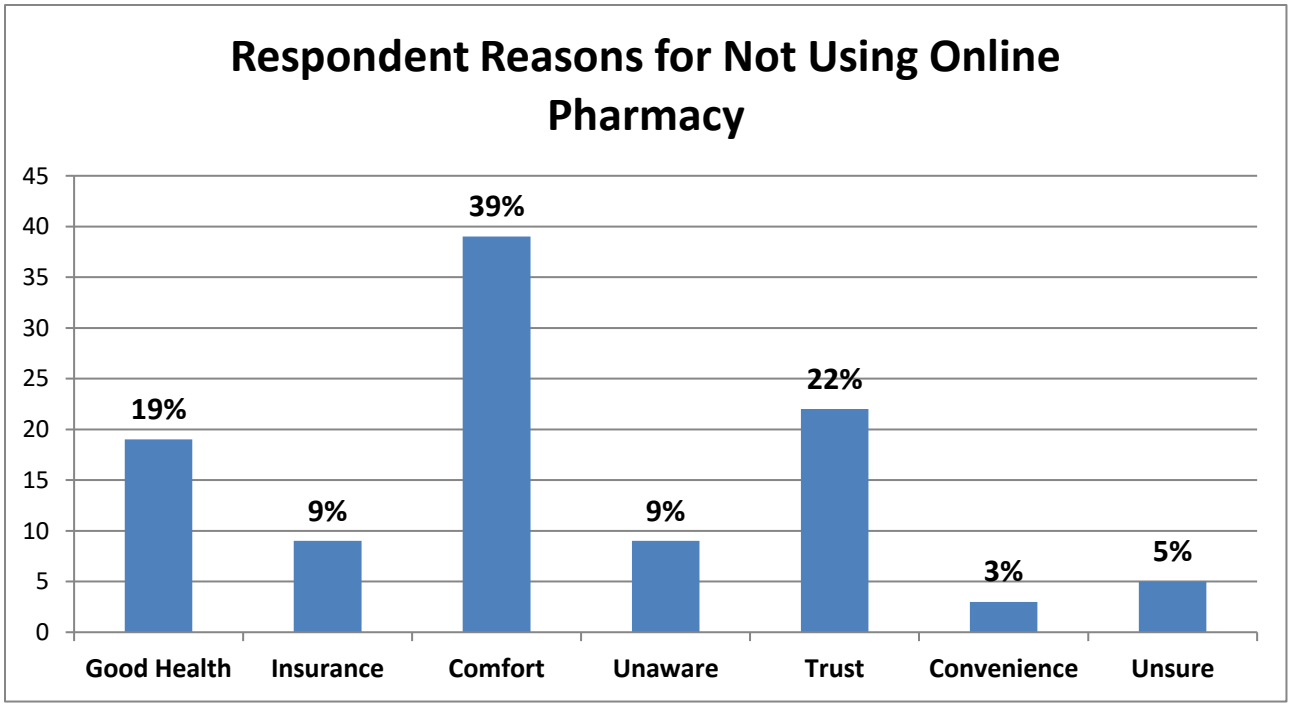
WHY DO CONSUMERS BUY PRESCRIPTION MEDICINES ONLINE?

For people who reported to have previously used an online pharmacy, 42% of consumers responded that they did so to purchase medicines for cheaper prices. 34% cited discounts offered through their insurance plans (e.g. to get a 90-day supply), suggesting that these respondents may have believed their pharmacy benefit managers' website was an online pharmacy. One-in-five respondents utilize online pharmacies for speed and/or convenience of the process. When told that medicines are cheaper with Canadian online pharmacies, consumers increased their likelihood to use Canadian online pharmacies by 9 points.



WHAT MAKES CONSUMERS AVOID ONLINE PHARMACIES?

Survey respondents that indicated they avoid using online pharmacies cited a variety of reasons, including comfort, good health, convenience and trust. See the below chart for additional details. In addition, consumers have privacy concerns with purchasing medicines online. 57% of consumers believe their privacy and/or identity theft is at risk when using online pharmacies. 39% of people who have not purchased prescription drugs online (non-purchasers) note their comfort with their current process of dealing with a brick-and-mortar pharmacy. 22% of non-purchasers report they are not comfortable and/or do not trust online pharmacies.



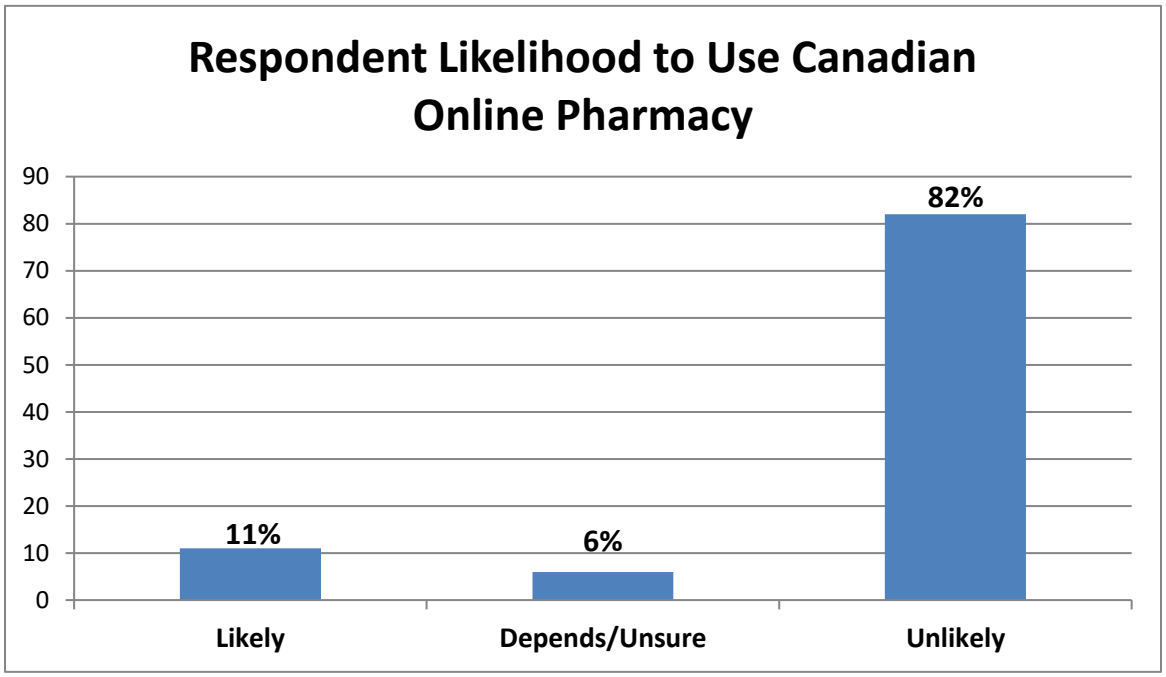
WHAT MEDICINES WOULD CONSUMERS BUY FROM ONLINE PHARMACIES?

The survey results provide important information concerning the types of medications that consumers have or would purchase from an online pharmacy website. **More than half of the respondents (55%) have or would consider buying at least one type of medication online, including**:

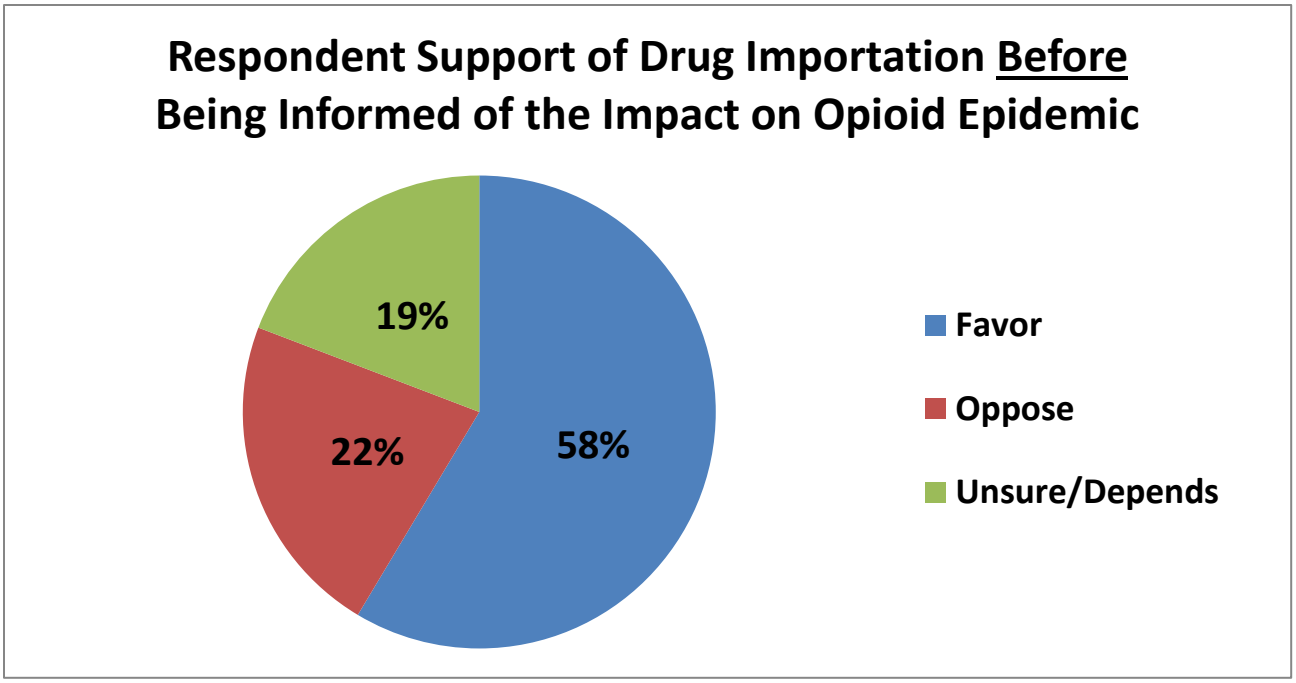
- **42%** – for chronic on-going conditions such as blood pressure and cholesterol;
- **34%** – for over-the-counter medicines such as cough, cold, allergy or pain reducers;
- **23%** – for medicines for acute, short-term issues such as infections and insomnia; and
- **21%** – for specialty medications, such as for cancer treatment and hormone replacement therapy.

WHAT DO CONSUMERS THINK ABOUT CANADIAN ONLINE PHARMACIES?

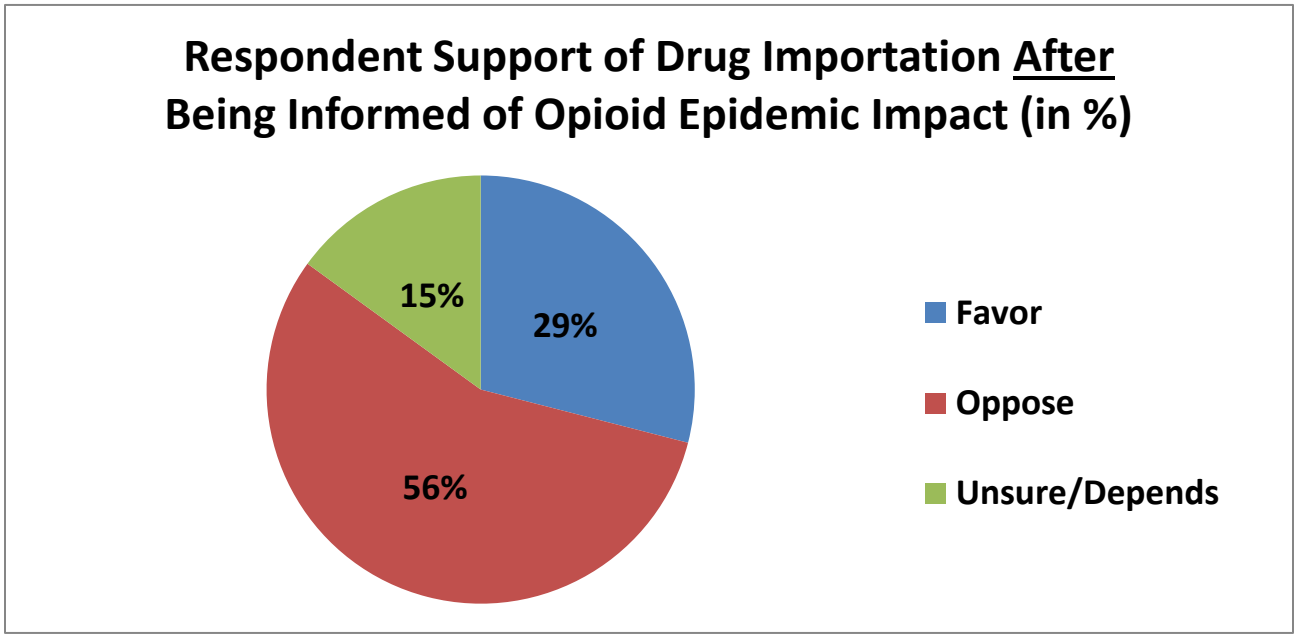
These survey findings demonstrate that consumers are not aware of the risks associated with purchasing medicines from Canadian Online pharmacies. 11% of consumers are likely to use a Canadian online pharmacy. 20% of consumers are likely to use a Canadian online pharmacy when told the medicines are cheaper. 47% of consumers do not perceive Canadian online pharmacies as risky and 46% perceive Canadian online pharmacies as offering cheaper medicines. 37% of consumers who would consider using a Canadian online pharmacy are not willing to accept much risk with an online pharmacy. Consumers who view Canadian online pharmacies as not risky are twice as likely to use them as those who view them as risky (15% to 8%, respectively).



While it is estimated that millions of Americans purchase prescription medication from Canadian online pharmacies, it is currently illegal to do so. **When consumers were asked if they favor or oppose legislation that would allow Americans to legally purchase prescription medication from Canadian online pharmacies 58% were in favor; 19% responded it depends and 22% responded they oppose**.



When presented with the fact that many foreign and Canadian online pharmacies do not require prescriptions for controlled substances and the potential to exacerbate the current opioid epidemic, 56% oppose allowing Americans to legally purchase prescription medications from Canadian online pharmacies, 29% favor and 15% said it depends.

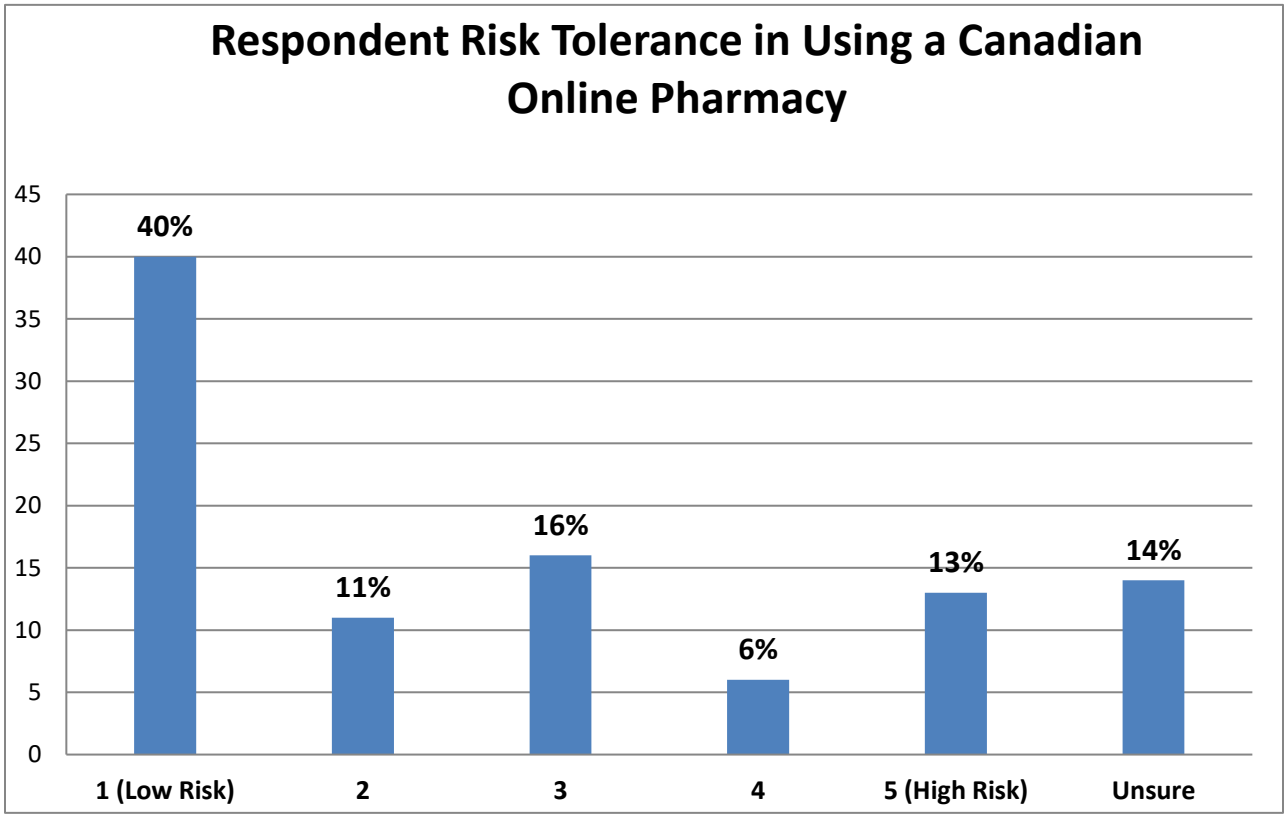


WHAT RISKS ARE CONSUMERS WILLING TO TAKE TO BUY MEDICINES ONLINE?

Initially only 13% of respondents thought Canadian online pharmacies were very risky, but after hearing the facts cited below, 53% said they are very risky. **Facts changed consumers' risk perception about Canadian online pharmacies by 40 points.**

Nearly one-in-five consumers who would consider purchasing medicines online would be willing to accept a moderate-to-high amount of risk when purchasing from a Canadian online pharmacy. People with lower incomes are willing to take more risk. Consumers willing to accept moderate-to-high amounts of risk to buy medicines online: 41% of people with income below $40,000, 38% of people with income between $40,000 - $79,000, 29% of people with income between $80,000 - $124,999, 24% of people with income above $125,000.

When asked on a scale of one to five, with one being the lowest risk and five being the highest risk, how much risk consumers are willing to accept in exchange for the convenience and savings with using prescription medications purchased from Canadian online pharmacy, respondents produced the following results:



Compelling Facts about Canadian Online Pharmacies

When educated, a majority of Americans oppose drug importation from Canada and believe that Canadian online pharmacies are "very risky." Here are the facts that impact consumers' perception:

1. Many foreign and Canadian online pharmacies do not require prescriptions for medication, making it easier for addicts to evade law enforcement and get drugs, and potentially exacerbating our country's opioid epidemic.[x]
2. Since 2010 there have been more than 200 felony counts against networks operating 400,000 websites affiliated with Canadian online pharmacies.[xi]
3. While the Canadian government requires Canadian online pharmacies to sell Canadian approved drugs to their own citizen, they cannot ensure Americans will receive Canadian medicines. In fact, according to the US FDA, 85% of medicines that are sold to Americans by Canadian online pharmacies are NOT Canadian.[xii]
4. Currently, as a U.S. consumer, there are legal remedies you can choose to pursue if you are harmed by the purchase of medicines from a U.S. online pharmacy. However, U.S. courts have no ability to enforce against Canadian online pharmacies.
5. There are thousands of illegal foreign websites – many of them passing themselves off as Canadian online pharmacies – and it is impossible to tell the real ones from the fake ones. Americans who buy from Canadian online pharmacies cannot be sure what they are getting.
6. There is a 50% chance of receiving a counterfeit medicine from a foreign online pharmacy, for which many of these drugs can worsen symptoms if not cause irreparable harm or even death.[xiii]

In addition, there are other facts about prescription drug importation that were used in the survey to help further educate consumers on the potential risks associated with online pharmacy websites. These *inconvenient* facts that some consumers and importation advocates don't want to hear include:

1. PharmacyChecker, a known site for vetting Canadian online pharmacies, had an executive indicted for his involvement in an international drug smuggling conspiracy involved with shipping counterfeit and other illegal drugs to U.S. consumers.[xiv]
2. Buying prescription medicines from illegal online pharmacies increases your risk of credit card fraud or identity theft.[xv]
3. Foreign online pharmacies have been found to sell products tainted with lead, paint, and other materials that could be potentially deadly to a consumer.[xvi]
4. The US FDA and Department of Health and Human Services has the ability to certify the importation of drugs from Canada as safe but has never chosen to do so.[xvii]

Conclusions

In summary, this survey shows:

1. **More consumer education is needed**. Lists of safe sites do not work, and less than 5% of consumers report that they would use a government list of safe online pharmacies. Less than 5% of consumers are aware of tools available to help them find safe online pharmacies, such as the National Association of Boards of Pharmacy's .Pharmacy program and LegitScript's URL checker.

2. **More healthcare provider education is needed**. 91% of patients never talk to their doctor about where they buy medicine, and 89% of people who have bought medicine online never discussed the risks with their healthcare provider.

3. **A majority of consumers oppose drug importation**. While a majority of consumers were initially in favor of legislation that allow the legal purchase of prescription medications from Canadian online pharmacies, over one third of consumers now opposed legislation, joining the one-in-five that stayed opposed, when made aware of the risks for this legislation to exacerbate the opioid epidemic. 56% of consumers opposed legislation when presented with this fact.

4. **Canadian online pharmacies are perceived as "very risky" by consumers who are educated on the issue.** Initially, only 13% of consumers felt that Canadian online pharmacies were "very risky", but after learning more about it, 53% felt they were very risky. Only 12% of consumers now felt that there was little to no risk associated with Canadian online pharmacies in comparison to 47% of consumers prior to being informed.

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i Hearing on the Nomination of Dr. Robert Califf to Serve as FDA Commissioner – Questions for the Record. Senate Committee on Health, Education, Labor and Pensions. November 2015.
ii ASOP Global and LegitScript, *see* Infographic, 2017
iii Internet Drug Outlet Identification Program, National Association of Boards of Pharmacy, March 2017
iv Internet Drug Outlet Identification Program, National Association of Boards of Pharmacy, August 2016
v Internet Drug Outlet Identification Program, National Association of Boards of Pharmacy, March 2017
vi Internet Drug Outlet Identification Program, National Association of Boards of Pharmacy, March 2017
vii The Internet Pharmacy Market in 2016, LegitScript and the Center for Safe Internet Pharmacies, January 2016
viii LegitScript, 2017
ix http://buysaferx.pharmacy/wp-content/uploads/2017/05/CMSA_whitepaper_rphonlinelegitimacy.pdf
x *Id.*
xi *Id.*
xii *Id.*
xiii Substandard, Spurious, Falsely Labelled, Falsified and Counterfeit Medical Products, World Health Organization
xiv U.S. vs. CanadaDrugs.com LTD Partnership, et al. Indictment, June 2015.
xv What You Need to Know Before You Buy Prescription Medications Online, Pinnacle Care – Disease Management, 2015
xvi Poisons Found in Counterfeit Medicines, Partnership for Safe Medicines, 2012
xvii Ex-FDA Commissioner Letter on Importation, March 2017

C-83

First Session, Thirty-eighth Parliament,
53-54 Elizabeth II, 2004-2005

HOUSE OF COMMONS OF CANADA

BILL C-83

An Act to amend the Food and Drugs Act (drug export restrictions)

FIRST READING, NOVEMBER 25, 2005

THE MINISTER OF HEALTH

C-83

Première session, trente-huitième législature,
53-54 Elizabeth II, 2004-2005

CHAMBRE DES COMMUNES DU CANADA

PROJET DE LOI C-83

Loi modifiant la Loi sur les aliments et drogues (restrictions visant l'exportation de drogues)

PREMIÈRE LECTURE LE 25 NOVEMBRE 2005

LE MINISTRE DE LA SANTÉ

90361

SUMMARY

The purpose of this enactment is to protect an adequate supply of safe and affordable drugs for Canadians. The enactment amends the *Food and Drugs Act* to

(*a*) enable the Minister of Health to prohibit, by order, the export of a drug or class of drugs if the Minister is of the opinion that there is a shortage or likely shortage of a drug or class of drugs and an order is necessary to protect human health;

(*b*) enable the Minister to compel manufacturers, importers, exporters and sellers to provide information that the Minister may require for the purpose of exercising the Minister's power to prohibit exports;

(*c*) provide increased enforcement powers; and

(*d*) increase the maximum penalties available under that Act.

SOMMAIRE

Le texte a pour objet d'assurer la protection d'un approvisionnement suffisant de drogues sécuritaires et abordables pour les Canadiens. Il modifie la *Loi sur les aliments et drogues* pour :

a) permettre au ministre de la Santé d'interdire, par arrêté, l'exportation de toute drogue ou catégorie de drogues s'il est d'avis que la protection de la santé humaine l'exige et qu'il existe une pénurie, effective ou probable, de la drogue ou catégorie de drogues;

b) permettre au ministre d'exiger des fabricants, des importateurs, des exporteurs et des vendeurs la fourniture des renseignements qu'il peut exiger afin d'exercer son pouvoir d'interdiction des exportations;

c) fournir des pouvoirs accrus de mise en application de la loi;

d) augmenter les amendes maximales prévues à la loi.

1st Session, 38th Parliament,
53-54 Elizabeth II, 2004-2005

HOUSE OF COMMONS OF CANADA

BILL C-83

An Act to amend the Food and Drugs Act (drug export restrictions)

R.S., c. F-27

Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

1. Section 2 of the *Food and Drugs Act* is amended by adding the following in alphabetical order:

"record" «*registre*»

"record" includes any material on which data are recorded, marked or stored and which is capable of being read or understood by a person or a computer system or other device.

2. The Act is amended by adding the following after section 21:

PART I.1

EXPORT RESTRICTION

Order

21.1 (1) If, in the opinion of the Minister, there is a shortage or there is likely to be a shortage of a drug or class of drugs, the Minister may, by order, prohibit any or all of the following if, in the opinion of the Minister, it is necessary in order to protect human health:

(*a*) the sale for export from Canada, on a retail basis, of the drug or class of drugs;

(*b*) the sale for export from Canada, on a wholesale basis, of the drug or class of drugs;

(*c*) the export from Canada of the drug or class of drugs; and

1re session, 38e législature,
53-54 Elizabeth II, 2004-2005

CHAMBRE DES COMMUNES DU CANADA

PROJET DE LOI C-83

Loi modifiant la Loi sur les aliments et drogues (restrictions visant l'exportation de drogues)

L.R., ch. F-27

Sa Majesté, sur l'avis et avec le consentement du Sénat et de la Chambre des communes du Canada, édicte :

1. L'article 2 de la *Loi sur les aliments et drogues* est modifié par adjonction, selon l'ordre alphabétique, de ce qui suit :

« registre » "*record*"

« registre » Tout support sur lequel des données sont enregistrées, inscrites ou emmagasinées et qui peut être lu ou compris par une personne ou par un système informatique ou un autre dispositif.

2. La même loi est modifiée par adjonction, après l'article 21, de ce qui suit :

PARTIE I.1

RESTRICTION — EXPORTATION

Arrêté d'interdiction

21.1 (1) S'il est d'avis que la protection de la santé humaine l'exige et qu'il existe une pénurie, effective ou probable, de toute drogue ou catégorie de drogues, le ministre peut, par arrêté, en interdire :

a) la vente au détail aux fins d'exportation;

b) la vente en gros aux fins d'exportation;

c) l'exportation;

d) la publicité aux fins d'exportation, par vente au détail ou en gros.

(*d*) the advertising for export from Canada, on a retail or wholesale basis, of the drug or class of drugs.

Drugs or class of drugs

(2) An order made under subsection (1) may only be made in respect of a drug or class of drugs that

(*a*) is manufactured, imported or sold for consumption in Canada; and

(*b*) is prescribed under paragraph 30(1)(*d.1*).

Additional measures

(3) If the Minister is of the opinion that an order or orders under subsection (1) may not be sufficient to protect human health in the event of a shortage or a likely shortage of a drug or class of drugs, the Minister may, by order, suspend the application of subsection 37(1) with respect to any drug or class of drugs and prohibit either or both of the following:

(*a*) the export from Canada, on any basis, of the drug or class of drugs; and

(*b*) the advertising for export from Canada of the drug or class of drugs.

Subsection 37(2)

(4) An order made under subsection (1) or (3) does not apply with respect to any supply of a drug manufactured for the purpose of being exported in accordance with subsection 37(2).

Renewal

(5) The Minister may, by order, renew an order for a further period or periods of no more than 90 days each if, in the opinion of the Minister, the shortage or the likelihood of a shortage of a drug or class of drugs continues to exist and the renewal of the order is necessary in order to protect human health.

Duration

(6) An order made under this section has effect from the time it is made but ceases to have effect on the earliest of

(*a*) 14 days after it is made, unless it is approved by the Governor in Council,

(*b*) the day on which it is repealed,

(*c*) in the case of an order made under subsection (1) or (3), 180 days after it is made or any shorter period that may be specified in it, and

(*d*) in the case of an order made under subsection (5), 90 days after it is made or any shorter period that may be specified in it.

Drogue ou catégorie de drogues

(2) L'arrêté ne peut être pris qu'à l'égard d'une drogue ou catégorie de drogues :

a) qui est fabriquée, importée ou vendue pour consommation au Canada;

b) qui fait l'objet de la désignation prévue à l'alinéa 30(1)*d.1*).

Mesures supplémentaires

(3) S'il est d'avis qu'un arrêté pris en vertu du paragraphe (1) ne serait pas suffisant pour la protection de la santé humaine dans le cas d'une pénurie, effective ou probable, de toute drogue ou catégorie de drogues, le ministre peut, par arrêté, suspendre l'application du paragraphe 37(1) à l'égard de la drogue ou catégorie de drogues et en interdire :

a) l'exportation, quelle qu'en soit la nature;

b) la publicité aux fins d'exportation.

Paragraphe 37(2)

(4) L'arrêté ne s'applique pas à l'approvisionnement d'une drogue fabriquée en vue de son exportation conformément au paragraphe 37(2).

Renouvellement

(5) S'il est d'avis que la pénurie, effective ou probable, persiste et que la protection de la santé humaine l'exige, le ministre peut, par arrêté, renouveler l'arrêté pour une ou plusieurs périodes maximales de quatre-vingt-dix jours.

Période de validité

(6) L'arrêté pris en vertu du présent article prend effet dès sa prise et cesse d'avoir effet :

a) soit quatorze jours plus tard, sauf agrément du gouverneur en conseil;

b) soit le jour de son abrogation;

c) soit, dans le cas d'un arrêté pris en vertu des paragraphes (1) ou (3), au plus tard cent quatre-vingts jours — ou la période plus courte qui y est précisée — après sa prise;

d) soit, dans le cas d'un arrêté pris en vertu du paragraphe (5), au plus tard quatre-vingt-dix jours — ou la période plus courte qui y est précisée — après sa prise.

Exemption from *Statutory Instruments Act*

21.2 (1) An order made under section 21.1

(*a*) is exempt from the application of sections 3, 5 and 11 of the *Statutory Instruments Act*; and

(*b*) shall be published in the *Canada Gazette* as soon as possible but in any case not later than 23 days after it is made.

Dérogation à la *Loi sur les textes réglementaires*

21.2 (1) L'arrêté pris en vertu de l'article 21.1 est soustrait à l'application des articles 3, 5 et 11 de la *Loi sur les textes réglementaires* mais est publié dans la *Gazette du Canada* dès que possible mais au plus tard vingt-trois jours après sa prise.

Contravention of unpublished order

(2) No person shall be convicted of an offence consisting of a contravention of an order that, at the time of the alleged contravention, had not been published in the *Canada Gazette* unless it is proved that, at the time of the alleged contravention, the person had been notified of the order or reasonable steps had been taken to bring the purport of the order to the notice of those persons likely to be affected by it.

Violation d'un arrêté non publié

(2) Nul ne peut être condamné pour violation d'un arrêté qui, à la date du fait reproché, n'avait pas été publié dans la *Gazette du Canada*, sauf s'il est établi qu'à cette date l'arrêté avait été porté à sa connaissance ou des mesures raisonnables avaient été prises pour que les intéressés soient informés de sa teneur.

Tabling of order

(3) A copy of each order must be tabled in each House of Parliament within 15 days after it is made.

Dépôt devant les chambres du Parlement

(3) Une copie de l'arrêté est déposée devant chaque chambre du Parlement dans les quinze jours suivant sa prise.

House not sitting

(4) In order to comply with subsection (3), the order may be sent to the Clerk of the House if the House is not sitting.

Communication au greffier

(4) Il suffit, pour se conformer au paragraphe (3), de remettre la copie de l'arrêté au greffier de la chambre dans le cas où celle-ci ne siège pas.

Request for reconsideration

21.3 (1) Any person may request that an order made under section 21.1 be reconsidered by submitting a request in writing to the Minister within 60 days after the day on which the order is published in the *Canada Gazette.*

Demande de révision

21.3 (1) Toute personne peut, dans les soixante jours suivant la publication dans la *Gazette du Canada* d'un arrêté pris en vertu de l'article 21.1, demander au ministre par écrit de le réviser.

Documentary evidence

(2) A request for reconsideration must include documentary evidence in support of the request and must comply with any prescribed requirements.

Documents

(2) La demande est accompagnée de preuves documentaires à l'appui et doit être conforme à toute exigence réglementaire.

Minister's response

(3) Unless the order in respect of which the request is made is repealed or expires within 30 days after the receipt of the request, the Minister shall, within that period, respond in writing to the person who made the request.

Réponse du ministre

(3) Le ministre doit, dans les trente jours suivant la réception de la demande, fournir à son auteur une réponse écrite, à moins que l'arrêté n'ait été abrogé ou n'ait expiré au cours de cette période.

Information

21.4 A person who manufactures, sells, imports or exports a drug that has been prescribed under paragraph 30(1)(*d.1*) shall provide to the Minister, on the Minister's request, any information that the Minister may require for the purposes of section 21.1 that is in the person's possession or is reasonably available to them.

Renseignements

21.4 Quiconque fabrique, vend, importe ou exporte une drogue désignée en vertu de l'alinéa 30(1)*d.1*) fournit au ministre, sur demande, tout renseignement en sa possession ou à sa disposition et dont le ministre pourrait avoir besoin dans le cadre de l'article 21.1.

Prohibitions

21.5 (1) No person shall export or sell a drug for export from Canada, or advertise a drug for export from Canada, in contravention of an order made under subsection 21.1(1), (3) or (5).

Exception

(2) Subsection (1) does not apply in respect of the export of a drug by, or the sale of a drug to,

(*a*) a Canadian citizen or permanent resident within the meaning of subsection 2(1) of the *Immigration and Refugee Protection Act* if the drug is for their use or the use of a dependant and the quantity of drug sold or exported, as the case may be, does not exceed the quantity required for a 90-day period;

(*b*) an officer or a servant of Her Majesty in right of Canada or a member of the Canadian Forces if the drug is for their use or the use of an accompanying dependant and the officer, servant or member will be absent from Canada in the course of their duties; or

(*c*) any other individual in Canada if the drug is for the use of the individual or an accompanying dependant and the quantity of drug sold or exported, as the case may be, does not exceed the quantity required for a 90-day period.

Sentencing

(3) If a person is convicted, or discharged under section 730 of the *Criminal Code*, of contravening this section, the court sentencing or discharging the person shall, in addition to considering any other relevant factors, consider the amount of any profit that was made or would have been made as a result of the commission of the offence.

Interdiction

21.5 (1) Il est interdit d'exporter une drogue, ou d'en vendre ou d'en faire la publicité aux fins d'exportation en contravention d'un arrêté pris en vertu des paragraphes 21.1(1), (3) ou (5).

Exemption

(2) Le paragraphe (1) ne s'applique pas à l'exportation d'une drogue par les personnes ci-après ni à la vente d'une drogue à celles-ci :

a) tout citoyen canadien ou résident permanent au sens du paragraphe 2(1) de la *Loi sur l'immigration et la protection des réfugiés*, pour sa propre utilisation ou celle d'une personne à sa charge, si la quantité exportée ou vendue n'excède pas un approvisionnement de quatre-vingt-dix jours;

b) un fonctionnaire ou préposé de Sa Majesté du chef du Canada ou un membre des Forces canadiennes, pour sa propre utilisation ou celle d'une personne à sa charge l'accompagnant, dans l'exercice de ses fonctions à l'étranger;

c) toute autre personne au Canada, pour sa propre utilisation ou celle d'une personne à sa charge l'accompagnant, si la quantité exportée ou vendue n'excède pas un approvisionnement de quatre-vingt-dix jours.

Détermination de la peine

(3) Lorsqu'un contrevenant est reconnu coupable d'une infraction au présent article ou en est absous sous le régime de l'article 730 du *Code criminel*, le tribunal saisi prend en considération, en plus de tout autre élément pertinent, le profit que la commission de l'infraction a ou aurait permis de réaliser.

R.S., c. 31 (1st Supp.), s. 11(1)

3. (1) The portion of subsection 23(1) of the Act before paragraph (*a.1*) is replaced by the following:

Powers of inspectors

23. (1) Subject to subsection (1.1), an inspector may at any reasonable time enter any place where the inspector believes on reasonable grounds any article to which this Act or the regulations apply is manufactured, prepared, preserved, packaged, sold, imported, exported or stored, and may

(*a*) examine any such article and take samples of it, and examine anything that the inspector believes on reasonable grounds is

L.R., ch. 31 (1er suppl.), par. 11(1)

3. (1) Le passage du paragraphe 23(1) de la même loi précédant l'alinéa *a.1*) est remplacé par ce qui suit :

Pouvoirs de l'inspecteur

23. (1) Sous réserve du paragraphe (1.1), l'inspecteur peut, à toute heure convenable, procéder à la visite de tout lieu où il a des motifs raisonnables de croire que sont fabriqués, préparés, conservés, emballés, vendus, importés, exportés ou emmagasinés des articles visés par la présente loi ou ses règlements. Il peut en outre :

used or capable of being used for that manufacture, preparation, preservation, packaging, selling, importing, exporting or storing;

a) examiner ces articles et en prélever des échantillons, et examiner tout objet dont il a des motifs raisonnables de croire qu'il est utilisé — ou susceptible de l'être — pour la fabrication, la préparation, la conservation, l'emballage, la vente, l'importation, l'exportation ou l'emmagasinage de tels articles;

(2) Paragraphs 23(1)(*c*) and (*d*) of the Act are replaced by the following:

(*c*) examine and make copies of, or extracts from, any record found in any place referred to in this subsection that the inspector believes on reasonable grounds contains any information relevant to the enforcement of this Act with respect to any article to which this Act or the regulations apply;

(*d*) seize and detain for any time that may be necessary any article or record by means of or in relation to which the inspector believes on reasonable grounds any provision of this Act or the regulations has been contravened;

(2) Les alinéas 23(1)*c*) et *d*) de la même loi sont remplacés par ce qui suit :

c) examiner tout registre qui est trouvé sur les lieux visés au présent paragraphe et dont il a des motifs raisonnables de croire qu'il contient des renseignements utiles à l'application de la présente loi à l'égard d'un article visé par celle-ci ou ses règlements, et en faire la reproduction totale ou partielle;

d) saisir et retenir aussi longtemps que nécessaire tout article ou registre dont il a des motifs raisonnables de croire qu'il a servi ou donné lieu à une infraction à la présente loi ou à ses règlements;

(*e*) use or cause to be used any computer or data processing system at the place to examine any data contained in or available to the computer or data processing system;

(*f*) reproduce any record or cause it to be reproduced from the data in the form of a printout or other intelligible output;

(*g*) take a printout or other output for examination or copying; and

(*h*) use or cause to be used any copying equipment at the place to make copies of the record.

e) utiliser ou faire utiliser tout ordinateur ou système informatique se trouvant sur les lieux pour prendre connaissance des données qu'il contient ou auxquelles il donne accès;

f) à partir de ces données, reproduire ou faire reproduire le registre sous forme d'imprimé ou toute autre forme intelligible;

g) emporter tout imprimé ou sortie de données pour examen ou reproduction;

h) utiliser ou faire utiliser le matériel de reproduction pour faire des copies du registre.

(3) Paragraph 23(2)(*b*) of the Act is replaced by the following:

(*b*) anything used for the manufacture, preparation, preservation, packaging, selling, importing, exporting or storing of a food, drug, cosmetic or device; and

(3) L'alinéa 23(2)*b*) de la même loi est remplacé par ce qui suit :

b) les objets utilisés pour la fabrication, la préparation, la conservation, l'emballage, la vente, l'importation, l'exportation ou l'emmagasinage des articles visés à l'alinéa *a*);

(4) Section 23 of the Act is amended by adding the following after subsection (3):

(4) L'article 23 de la même loi est modifié par adjonction, après le paragraphe (3), de ce qui suit :

Duties of persons required to maintain records

(4) A person who is required under the regulations to maintain records shall

(4) La personne à qui il incombe de tenir des registres conformément aux règlements doit :

Obligations pour les personnes devant tenir des registres

(*a*) on the request of an inspector, provide or make those records available to the inspector or another inspector;

(*b*) give an inspector all reasonable assistance and furnish the inspector with any information the inspector may reasonably require;

(*c*) keep those records at the person's place of business or residence in Canada or at any other place that may be designated by the Minister; and

(*d*) not falsify or unlawfully alter, destroy, erase or obliterate those records.

a) sur demande, les fournir ou les mettre à la disposition de tout inspecteur;

b) donner à l'inspecteur toute l'assistance voulue et lui fournir tout renseignement dont il peut valablement avoir besoin;

c) conserver les registres à son établissement ou sa résidence au Canada ou en un autre lieu désigné par le ministre;

d) s'abstenir de les falsifier ou de les modifier, les détruire, les supprimer ou les masquer illégalement.

Inspector may require measures

(5) If an inspector has reasonable grounds to believe that a person has contravened or will contravene this Act or the regulations, the inspector may require the person to

(*a*) refrain from doing anything in contravention of this Act or the regulations, or do anything to comply with this Act or the regulations;

(*b*) cease the operation of any activity or any part of a work, undertaking or thing until the inspector is satisfied that the activity, work, undertaking or thing will be operated in accordance with this Act and the regulations; and

(*c*) take any other measures that the inspector considers necessary to prevent further contravention of this Act or the regulations.

Mesures requises par l'inspecteur

(5) S'il a des motifs raisonnables de croire qu'il y a eu ou qu'il y aura contravention de la présente loi ou de ses règlements, l'inspecteur peut imposer au contrevenant tout ou partie des obligations suivantes :

a) mettre fin à la contravention ou, au contraire, faire le nécessaire pour s'y conformer;

b) cesser l'exercice de toute activité ou l'exploitation de toute partie d'un ouvrage ou d'une entreprise jusqu'à ce que l'inspecteur soit convaincu qu'ils sont conformes à la présente loi et à ses règlements;

c) prendre les correctifs qui, de l'avis de l'inspecteur, sont nécessaires pour prévenir toute récidive.

Duration of requirement

(6) A requirement under subsection (5) may apply for a specified period or until the inspector is satisfied that no further contravention is likely to take place.

Période de validité

(6) L'ordre reste exécutoire pendant la période fixée ou jusqu'à ce que l'inspecteur soit convaincu qu'il n'y a plus de risque de récidive.

Notice

(7) A requirement under subsection (5) shall be communicated by delivering a written notice to the person referred to in that subsection and the notice must be accompanied by a statement of the reasons for the requirement.

Avis

(7) L'ordre est remis au contrevenant sous forme d'avis écrit motivé.

Prosecutions

(8) A requirement under subsection (5) may be imposed whether or not the person has been charged with an offence relating to the contravention, but if the person is charged, the requirement may be confirmed, varied or rescinded by the court that tries the offence.

Poursuites

(8) L'ordre peut être donné même si aucune inculpation n'a été formulée contre le contrevenant. En cas d'inculpation, le tribunal saisi peut le confirmer, le modifier ou l'annuler.

4. (1) Subsection 30(1) of the Act is amended by adding the following after paragraph (*d*):

(*d.1*) prescribing any drug or class of drug for the purpose of subsection 21.1(2);

(2) Paragraph 30(1)(*f*) of the Act is replaced by the following:

(*f*) requiring persons who sell food, drugs, cosmetics or devices to maintain the records that the Governor in Council considers necessary for the proper enforcement and administration of this Act and the regulations;

(*f.1*) requiring persons who sell drugs to provide to the Minister, on the Minister's request, any record that they are required to maintain under this Act or the regulations;

(3) Section 30 of the Act is amended by adding the following after subsection (2):

Regulations re Part I.1

(2.1) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part of it for carrying into effect the purposes and provisions of this Act or any Part, the Governor in Council may make any regulations that the Governor in Council considers necessary for the purpose of carrying the purposes and provisions of Part I.1 into effect.

5. Paragraphs 31(*a*) and (*b*) of the Act are replaced by the following:

(*a*) on summary conviction for a first offence to a fine not exceeding $100,000 or to imprisonment for a term not exceeding six months or to both and, for a subsequent offence, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding 18 months or to both; and

(*b*) on conviction on indictment to a fine in the discretion of the court or to imprisonment for a term not exceeding three years or to both.

6. The Act is amended by adding the following after section 31.1:

4. (1) Le paragraphe 30(1) de la même loi est modifié par adjonction, après l'alinéa *d*), de ce qui suit :

d.1) désigner toute drogue ou catégorie de drogues pour l'application du paragraphe 21.1(2);

(2) L'alinéa 30(1)*f*) de la même loi est remplacé par ce qui suit :

f) enjoindre aux personnes qui vendent des aliments, des drogues, des cosmétiques ou des instruments de tenir les registres qu'il juge nécessaires pour l'application et l'administration judicieuses de la présente loi et de ses règlements;

f.1) enjoindre aux personnes qui vendent des drogues de fournir au ministre, sur demande, les registres qu'elles doivent tenir en vertu de la présente loi et de ses règlements;

(3) L'article 30 de la même loi est modifié par adjonction, après le paragraphe (2), de ce qui suit :

Règlements — partie I.1

(2.1) Sans que soit limité le pouvoir conféré par toute autre disposition de la présente loi de prendre des règlements d'application de la présente loi ou d'une partie de celle-ci, le gouverneur en conseil peut prendre les règlements qu'il estime nécessaires à l'application de la partie I.1.

5. Les alinéas 31*a*) et *b*) de la même loi sont remplacés par ce qui suit :

a) par procédure sommaire, pour une première infraction, une amende maximale de 100 000 $ et un emprisonnement maximal de six mois, ou l'une de ces peines et, en cas de récidive, une amende maximale de 250 000 $ et un emprisonnement maximal de dix-huit mois, ou l'une de ces peines;

b) par mise en accusation, une amende laissée à la discrétion du tribunal et un emprisonnement maximal de trois ans, ou l'une de ces peines.

6. La même loi est modifiée par adjonction, après l'article 31.1, de ce qui suit :

Continuing offences

31.2 A person who commits or continues an offence on more than one day is liable to be convicted for a separate offence for each day on which the offence is committed or continued.

31.2 Il est compté une infraction distincte pour chacun des jours au cours desquels se commet ou se continue l'infraction.

Infraction continue

1993, c. 34, s. 73

7. Subsection 37(1) of the Act is replaced by the following:

7. Le paragraphe 37(1) de la même loi est remplacé par ce qui suit :

1993, ch. 34, art. 73

Conditions under which exports exempt

37. (1) Subject to an order made under subsection 21.1(3), this Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export" or "Exportation" and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.

37. (1) Sous réserve d'un arrêté pris en vertu du paragraphe 21.1(3), la présente loi ne s'applique pas aux aliments, drogues, cosmétiques ou instruments emballés qui sont fabriqués et vendus pour consommation à l'étranger si l'emballage porte clairement en surimpression le mot « Exportation » ou « Export » et qu'il y a eu délivrance d'un certificat réglementaire attestant que l'emballage et son contenu n'enfreignent aucune règle de droit connue du pays auquel il est expédié ou destiné.

Exemption

Coming into force

8. This Act comes into force on a day to be fixed by order of the Governor in Council.

8. La présente loi entre en vigueur à la date fixée par décret.

Entrée en vigueur

Published under authority of the Speaker of the House of Commons

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WORKING PAPER

State Pharmaceutical Importation Programs: An Analysis of the Cost Effectiveness

By
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Colorado College Working Paper 2019-02
June 2019

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State Pharmaceutical Importation Programs: An Analysis of the Cost Effectiveness

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Word count: 17,871

18 June 2019

ABSTRACT

Recently proposed legislation in Colorado, Connecticut, Florida, Maine, Missouri, Oklahoma, Oregon, Utah, Vermont and West Virginia aims to reduce spending on pharmaceuticals by importing them from Canada. To examine the cost effectiveness of importation, this study analyzes 24 drugs obtained from both an online Canadian supplier and a brick-and-mortar Canadian pharmacy, accounting for the cost savings, the cost of testing, the medical consequences of treatment failure, and the cost of treating an adverse medical event. For a "Representative State", given an adverse medical event, the presumed savings from an online Canadian supplier are exhausted in the treatment of only one patient in the case of Nexium, to 24,318 adverse events for patients in the case of Advair. The analysis shows the cost of testing (99.999% confidence level with 99.999% reliability) exceeds the presumed cost savings in all cases. Pharmaceutical importation plans are politically attractive, but the numbers demonstrate that they fail to deliver cost savings.

KEY WORDS: pharmaceutical importation, drug prices, Canadian pharmacy, cost effectiveness

[♂] The author is grateful to the Partnership for Safe Medicine for their financial support of this work.

EXECUTIVE SUMMARY

Recently proposed legislation in Colorado, Connecticut, Florida, Maine, Missouri, Oklahoma, Oregon, Utah, Vermont and West Virginia aims to reduce spending on pharmaceuticals by importing them from Canada. To examine the cost effectiveness of importation, this study analyzes 24 drugs obtained from both an online Canadian supplier and a brick-and-mortar Canadian pharmacy, accounting for the cost savings, the cost of testing, the medical consequences of treatment failure, and the cost of treating an adverse medical event.

This study analyzes the cost effectiveness of pharmaceutical importation through three lenses.

- Per Patient: calculations for an individual patient, comparing the presumed cost savings to the cost of treating an adverse medical event.
- For a "Representative State" relative to an Adverse Medical Event: calculations for a "Representative State" comparing the presumed costs savings from importation to the cost of treating an adverse medical event.
- For a "Representative State" relative to the Cost of Testing into Safety: calculations for a "Representative State" comparing the presumed cost savings from importation to the expense of testing drugs into safety.

The analysis is based on a number of assumptions. While assumptions are unavoidable in any analysis, the assumptions made in this study are deliberately biased against a finding of the exhaustion of the presumed savings from importation. That is, the study is rigorously structured to estimate the greatest savings possible from pharmaceutical importation. Accordingly, the study's findings – that ***importation is not cost effective*** in the majority of cases – are all the more striking.

For an Individual Patient, regardless of whether one's drugs are obtained from a Canadian online supplier or a brick-and-mortar Canadian pharmacy, in three out of four cases, the annual presumed savings fails to cover the costs of an adverse medical event. For these drugs, patients would need to acquire the cost savings over a period of up to 111 years to cover the costs of one adverse event. Not surprisingly, for the few drugs for which the savings exceed the cost of treating an adverse medical event, the expense of an adverse medical event is modest (less than $50,000). For the majority of drugs, the cost of treating an adverse event will significantly exceed $50,000 and may reach more than $800,000.

For a "Representative State", regardless of whether one's drugs are obtained from a Canadian online supplier or a brick-and-mortar Canadian pharmacy, in three out of four cases, the annual presumed savings for a "Representative State" fails to cover the costs of an adverse medical event. Again, for the few drugs for which the savings exceed the cost of treating an adverse medical event, the expense of an adverse medical event is modest (less than $50,000 per patient), while, for the majority of drugs, the cost of treating an adverse event will significantly exceed $50,000 and may reach more than $800,000. In the analysis of a "Representative State", given an adverse medical event, the presumed savings from an online Canadian supplier are exhausted in the treatment of only one patient in the case of Nexium, and for 24,318 adverse events for patients in the case of Advair. Importantly, for this selection of 24 drugs, the cost savings will

be completely eliminated if a mere 3.2% of imported drugs are counterfeit for a brick-and-mortar pharmacy or 3.5% from a Canadian online supplier.

For a "Representative State", regardless of whether one's drugs are obtained from a Canadian online supplier or a brick-and-mortar Canadian pharmacy, in all cases, the annual presumed savings for a "Representative State" fails to cover the costs of testing a drug into safety with 99.999% confidence and 99.999% reliability. In the case of a lower level of quality assurance, there are a few drugs for which the presumed savings would exceed the cost of testing. If one is willing to accept the risk of a 90% confidence level with 90% reliability, then the presumed savings will (in all but one case) exceed the cost of testing for both online suppliers and brick-and-mortar Canadian pharmacies. Fundamentally, the presumed cost savings may be accrued only when a significant level of risk is present and the dangers of counterfeit drugs is deemed an acceptable gamble.

Quite simply, pharmaceutical importation plans are politically attractive, but the numbers demonstrate that they fail to deliver cost savings and instead may pose a serious threat to patients.

"Given the rapid growth in the prevalence of sophisticated counterfeit drugs, no politician will approve a drug importation scheme without implementing a reasonable measure of regulatory oversight. There are simply too many channels for fake drugs to enter any importation scheme to forgo some meaningful controls. . . Providing a reasonable measure of oversight to reduce the number of counterfeits coming through an importation scheme is complex and costly. It's very hard to 'inspect in' safety after a drug is manufactured. There's no question that a drug importation scheme will increase the flow of counterfeits in the U.S. supply chain. Policy makers would have to weigh that cost against any perceived benefits."

FDA Commissioner Scott Gottlieb
4 March 2016

I. INTRODUCTION

Drug importation schemes are again being propositioned as a remedy to high U.S. drug prices. Recently proposed legislation in Colorado, Connecticut, Florida, Maine, Missouri, Oklahoma, Oregon, Utah, Vermont and West Virginia aim to reduce spending on pharmaceuticals by importing them from Canada. Advocates reason that American patients can lower their drug costs by importing cheaper drugs from countries with lower pharmaceutical prices. What escapes their attention is the need for, and cost of, testing to ensure the safety of those imports. Fundamentally, it has not been established whether it is cost effective to import medicine from a source from which regulatory compliance cannot be assured, and then test it into safety.

In reality, it is very expensive to test suspect medication to the same level of expected safety as FDA-approved medicines made in FDA-monitored factories. The tremendous cost of testing must be taken into account when calculating the cost savings or dissavings associated with buying medicines from a suspicious source. Beyond the costs of testing drugs into safety, it is essential to recognize the cost of potential adverse medical events. Purchasing pharmaceuticals outside of the highly-regulated U.S. supply chain exposes patients to the risks of counterfeit, fraudulent and substandard drugs which may be dangerous or toxic, resulting in serious patient harm.

In order to examine the cost effectiveness of pharmaceutical importation, this study analyzes the cost savings, the cost of testing and the cost of treating an adverse medical event. This entails initially examining 40 drugs, documenting the costs, presumed cost savings from two unregulated suppliers (Canadian online supplier and a brick-and-mortar Canadian pharmacy), the medical consequences of treatment failure, and the expense of treating such adverse events. The results indicate that the true costs of pharmaceutical importation outweigh the anticipated cost savings. When all potential risks and costs are accounted for, it is difficult to justify moving outside of the U.S. supply chain for medicines.

II. DRUGS SELECTED FOR EXAMINATION

This study begins with a list of 40 drugs and due to lack of information and availability ultimately examines approximately two dozen drugs. The initial set of 40 drugs identified for inclusion were selected based on several criteria:

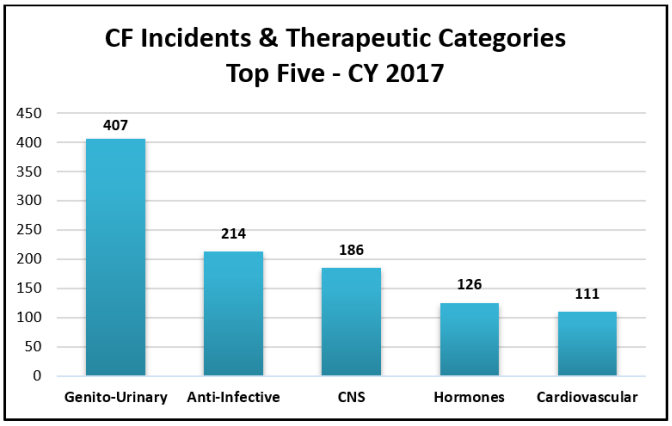
- The selection should include drugs from a wide variety of therapeutic classes, and treatments for a variety of diseases and medical conditions
- The selection should include drugs that are known to be widely counterfeited.
- The selection should include drugs that consumers readily seek to purchase outside the legitimate supply chain.
- The selection should include drugs mentioned in news and media reports that speak to consumers purchasing drugs abroad. Specifically, the Utah Tiajuana Thirteen List (Roe, 2018) (link here), the list promoted by Senator Bernie Sanders (IsraelPharm 2017) (link here), and the list promoted by the National Academy for State Health Policy (NASHP 2017) (link here).
- The selection should draw upon recommendations from experts.

Finally, the specific drugs considered as well as the number of drugs studied was also determined by data availability.

Forty drugs were initially selected for inclusion. The list included the thirteen drugs from the Utah Tijuana Thirteen List, the ten drugs cited by Senator Bernie Sanders, and the ten drugs promoted for importation by the NASHP[1]. In addition, the list reflects drug classes that are known to be widely counterfeited. Drawing on data from the Pharmaceutical Security Institute (PSI), the list includes drugs from each of the top five therapeutic categories. These categories are presented in Figure 1, below. Finally, several drugs were included based on the recommendations of board members of the Partnership for Safe Medicines. The full list of drugs and the source of their inclusion are included in Table 1.

[1] The drug included on the NASHP list was Tracleer. No Canadian sources were found for this drug, so Letairis is listed instead. Letairis is a more popular drug in the same class as Tracleer.

Figure 1: Top Counterfeiting Incidents and Therapeutic Categories



(Pharmaceutical Security Institute, webpost, 2018 (link here))

Combining all of these sources resulted in a list of 40 drugs. Of these, there are six that are not available for online purchase from online Canadian pharmacies. This may be because the drug is a controlled substance (Lyrica) or because the drug is an injectable that requires refrigeration during shipping (Avonex, Copaxone, Forteo, Humira, Stelara). With the elimination of these six drugs, the final list of drugs available from online Canadian pharmacies includes 34 drugs.

In addition to documenting the prices of these drugs from online Canadian pharmacies, the prices were also collected for a local neighborhood (brick-and-mortar) pharmacy in Vancouver, BC, Canada. From the list of 40 drugs, four drugs are not available. These are: Aubagio, Eliquis, Letaris, and Lyrica. The elimination of these four drugs results in a final list of 36 drugs available from a brick-and-mortar Canadian pharmacy.

Finally, there are eight drugs for which no potential adverse event is listed: Augmentin, Celebrex, Cialis, Lyrica, Stendra, Strattera, Synthroid, and Triumeq. For each of these drugs it was either impossible to identify the cost of a worsening condition (infection, rheumatoid arthritis, fibromyalgia, HIV/AIDS, hypothyroidism), or it was impossible to quantify the cost of the potential adverse event (erectile dysfunction, ADHA).

Combining the three lists results in 16 drugs for which all pieces of information are not available: Aubagio, Augmentin, Avonex, Celebrex, Cialis, Copaxone, Eliquis, Forteo, Humira, Letaris, Lyrica, Stelara, Stendra, Strattera, Synthroid, and Triumeq. The remaining 24 drugs were selected for extensive analysis: identification of the drug's indication, description of potential medical adverse events, calculation of cost of treating said adverse events, estimation of the cost of testing the quality, safety and efficacy of the drug. These drugs are highlighted in green Table 1, below.

Table 1: List of Drugs

	Drug	Utah Tiajuana Thirteen List	Bernie Sanders List	NASHP List	PMS Board Member Recommendation	Popular Drug in PSI Drug Class	No Online Canadian Source: controlled	No Online Canadian Source: injectable	No B-&-M Canadian Source	No Quantifiable Adverse Event
1	Abilify		X							
2	Actos				X					
3	Advair		X	X						
4	Albenza					X				
5	Ampyra	X								
6	Aubagio	X							X	
7	Augmentin					X				X
8	Avonex	X						X		
9	Celebrex		X							X
10	Cialis				X					X
11	Copaxone	X						X		
12	Crestor		X		X	X				
13	Eliquis			X		X			X	
14	Enbrel	X								
15	EpiPen		X							
16	Forteo	X						X		
17	Gilenya	X								
18	Harvoni			X	X					
19	Humira	X						X		
20	Januvia		X		X					
21	Letairis			X*					X	
22	Lipitor									
23	Lyrica			X			X		X	X
24	Nexium		X							
25	Orencia	X								
26	Otezla	X								
27	Premarin		X			X				
28	Revatio					X				
29	Sovaldi				X					
30	Stelara	X						X		
31	Stendra					X				X
32	Strattera			X						X
33	Synthroid		X							X
34	Tecfidera	X								
35	Tresiba				X					
36	Triumeq			X	X					X
37	Truvada				X					
38	Xarelto			X						
39	Zetia		X							
40	Zytiga	X								

III. DATA COLLECTION AND METHODOLOGY

Following the selection of the drugs included in this study, several pieces of information were collected for each drug. These included: the US cost of the drug, the cost from a brick-and-mortar Canadian pharmacy, the cost of the drug from an online Canadian supplier, the medical consequences of a treatment failure, the cost of addressing said treatment failure, and the cost of testing the quality of a drug sample.

US cost of the drug through the legitimate supply chain

The lowest available prices were collected for the four most populous cities in the United States: New York, Los Angeles, Chicago, and Houston. In addition to representing the most populous cities in the country, the four cities also represent four distinct geographic regions: East Coast, West Coast, Midwest, and South. These prices were gathered from the GoodRX.com website between January 2, 2019 and January 10, 2019. The average price per unit was then calculated.

Pharmaceutical prices are tremendously variable across regions, pharmacies and individuals. In order to find a U.S. cost that could be used in this analysis, this average US cost is assumed to be a workable proxy for the actual cost paid by patients in the US.

Importantly, the use of the GoodRX.com prices biases the study against a finding of the elimination of all cost savings. It is reasonable to assume that prices negotiated by state entities would be lower than the GoodRX.com prices, reducing the cost savings that are estimated here and more quickly eliminating the cost savings. Moreover, sites such as GoodRX.com offer coupons to consumers that would lower their actual out-of-pocket costs. Failure to include any coupon savings again biases the study against a finding of the elimination of cost savings.

Cost from Brick-and-Mortar Canadian Pharmacy

Canadian pricing data were collected from a "brick and mortar" pharmacy in Vancouver, BC. Marks Marine Pharmacy is located inside Main and Marine Medical Clinic, at 235 SE Marine Dr, Vancouver, BC V5X 2S4, Canada. The pricing data were collected on May 14, 2019. If proponents argue that they will obtain drugs from the Canadian drug supply, from a Canadian pharmacy, these prices provide that information.

Cost from an unregulated Canadian Supplier

The price of each drug was then collected from several (when possible) Canadian online pharmacies. These values were used to calculate the lowest available Canadian price per unit. The following online websites were consulted:

- DiscountDrugsFromCanada.com
- FillerSupplies.com

- CanadianPharmacyWorld.com
- PricePro Pharmacy.com
- InsulinOnline.com
- PlanetDrugsDirect.com
- CanadaDrugsOnline.com

Utilizing the lowest possible Canadian online price available will generate results that provide the largest possible savings. Notably, the study uses the lowest Canadian online price, rather than the average Canadian price. Again, this biases the analysis against a finding of eliminating the cost savings. In essence, this works to understate the extent to which the cost savings is eliminated.

While the online Canadian suppliers deliver the lowest prices, it is important to realize that these suppliers are not safe outlets for U.S. patients. Online suppliers are not regulated and pose significant risks to patients from counterfeit and substandard drugs.

Cost of testing samples

Four laboratories were contacted to obtain this information. Several are unable to provide a quote for the cost of testing samples. The testing cost information utilized in this study was provided by NMS Labs. Four tests are utilized to establish quality, depending on the type of drug, the dosage and the method of administration. These are: Assay, Content Uniformity, Dissolution Rate, and Sterility. For the 24 drugs included in this study, the cost of testing a single sample ranges from $2,500 to $4,100. Table 2, below provides a summary of this information. The full quote may be found in Appendix B.

Table 2: Cost of Testing a Single Sample

Drug	Assay	Dissolution Rate	Content Uniformity	Sterility	Total Cost of Testing
Abilify	$600	$1,200	$1,200	$1,000	$4,000
Actos	$500	$1,000	$1,000		$2,500
Advair	$1,100		$2,000	$1,000	$4,100
Albenza	$500	$1,000	$1,000		$2,500
Ampyra	$500	$1,000	$1,000		$2,500
Crestor	$500	$1,000	$1,000		$2,500
Enbrel	$600		$1,200	$1,000	$2,800
EpiPen	$600		$1,200	$1,000	$2,800
Gilenya	$500	$1,000	$1,000		$2,500
Harvoni	$500	$1,000	$1,000		$2,500
Januvia	$500	$1,000	$1,000		$2,500
Lipitor	$500	$1,000	$1,000		$2,500
Nexium	$600	$1,200	$1,200		$3,000
Orencia	$600		$1,200	$1,000	$2,800
Otezla	$500	$1,000	$1,000		$2,500
Premarin	$600	$1,000	$1,000		$2,600
Revatio	$600	$1,000	$1,000	$1,000	$3,600
Sovaldi	$500	$1,000	$1,000		$2,500
Tecfidera	$500	$1,000	$1,000		$2,500
Tresiba	$600		$1,200	$1,000	$2,800
Truvada	$500	$1,000	$1,000		$2,500
Xarelto	$500	$1,000	$1,000		$2,500
Zetia	$500	$1,000	$1,000		$2,500
Zytiga	$500	$1,000	$1,000		$2,500

Source: NMS Labs.

Determination of Sample Size

The sample size necessary for testing is dependent on the desired confidence level and reliability one would like to have.[2] For example, in order to provide 90% confidence in the quality of the

[2] The number of samples required will depend upon whether one uses Attribute Sampling or Variables Sampling.

- Attribute Sampling: Determine the sample size for a categorical response that classifies each unit as Good or Bad (or, perhaps, In-spec or Out-of-spec).
- Variables Sampling: Determine the sample size for a continuous measurement that follows a Normal distribution.

This endeavor requires the use of Attribute Sampling, a sampling plan that ensures zero defects in the sample, or C=0. The basic formula for sample size based on the desired Confidence level and Reliability is:

$$n = [\ln(1-\text{Confidence})]/[\ln(\text{Reliability})].$$

For example, this formula provides the sample size required to make a 99% confidence statement about the probability an item will be in-spec when your sample of size n has zero defects with 95% confidence. For a test with 99% confidence and 95% reliability, a sample size of 90 would be necessary. Once a sample of a representative drug is collected, each sample will go through a lab test that will determine whether the pill "passes" or "fails". In a

imported drugs, with a 90% reliability, 22 samples must be tested. In order to increase this confidence level to 99.99%, with a 99.99% reliability, 92,099 samples must be tested. In order to increase this confidence level to 99.999%, with a 99.999% reliability, 1,151,287 samples must be tested. Table 3, below, provides the required sample size for combinations of confidence levels (ranging from 0.9 to 0.99999) and reliability (ranging from 0.9 to 0.99999). Accordingly, these testing sample sizes may then be used to estimate the cost of "testing drugs into safety". The table presents the highest ($4,100) and lowest ($2,500) costs of testing the requisite number of samples for each of these combinations of confidence level and reliability.

scenario like this, to demonstrate with confidence level C that at least p% of all pills are of good quality, then there should be n>=ln(1-C)/ln(p) consecutive "passes" for the test. In reliability theory, this is called the "success run theorem". Sources: Westpack.com (link here) and Mintab.com (link here). The author is grateful to Dr. Flavia Sancier-Barbosa for her assistance in determining the appropriate sample size.

Table 3: Sample Size as a Function of Confidence and Reliability

Confidence level (% as decimal)	Reliability (% as decimal)	Sample Size Required: Ln(1-Confidence)/Ln(Reliability)	Cost of Testing Sample at $2500	Cost of Testing Sample at $4100
0.9	0.9	22	$55,000.00	$90,200.00
0.9	0.9	22	$55,000.00	$90,200.00
0.99	0.9	44	$110,000.00	$180,400.00
0.999	0.9	66	$165,000.00	$270,600.00
0.9999	0.9	87	$217,500.00	$356,700.00
0.99999	0.9	109	$272,500.00	$446,900.00
0.9	0.99	229	$572,500.00	$938,900.00
0.99	0.99	458	$1,145,000.00	$1,877,800.00
0.999	0.99	687	$1,717,500.00	$2,816,700.00
0.9999	0.99	916	$2,290,000.00	$3,755,600.00
0.99999	0.99	1146	$2,865,000.00	$4,698,600.00
0.9	0.999	2301	$5,752,500.00	$9,434,100.00
0.99	0.999	4603	$11,507,500.00	$18,872,300.00
0.999	0.999	6904	$17,260,000.00	$28,306,400.00
0.9999	0.999	9206	$23,015,000.00	$37,744,600.00
0.99999	0.999	11507	$28,767,500.00	$47,178,700.00
0.9	0.9999	23025	$57,562,500.00	$94,402,500.00
0.99	0.9999	46049	$115,122,500.00	$188,800,900.00
0.999	0.9999	69074	$172,685,000.00	$283,203,400.00
0.9999	0.9999	92099	$230,247,500.00	$377,605,900.00
0.99999	0.9999	115123	$2,878,217,500.00	$4,720,276,700.00
0.9	0.99999	230257	$575,642,500.00	$944,053,700.00
0.99	0.99999	460515	$1,151,287,500.00	$1,888,111,500.00
0.999	0.99999	690772	$1,726,930,000.00	$2,832,165,200.00
0.9999	0.99999	921029	$2,302,572,500.00	$3,776,218,900.00
0.99999	0.99999	1151287	$2,853,217,500.00	$4,679,276,700.00

Source: Author's calculations.

Determination of Treatment Failure

The author of this study worked with Dr. Peter H. Rheinstein, M.D., J.D., M.S., President, Severn Health Solutions in order to establish the indications for each drug and the consequences of receiving an ineffective dose. The assumption made in compiling this data was that the drug taken was ineffective. In reality, many poor quality medicines are not only ineffective, but they contain dangerous or toxic ingredients that may result in more severe and significant adverse health effects. The complete review of each drug is provided in Appendix A.

Table 4, below, identifies the consequences of ineffective treatment, the potential adverse medical event. While the table includes the complete list of 40 drugs, there are eight drugs for which no potential adverse event is listed: Augmentin, Celebrex, Cialis, Lyrica, Stendra, Strattera, Synthroid, and Triumeq. For each of these drugs it was either impossible to identify the cost of a worsening condition (infection, rheumatoid arthritis, fibromyalgia, HIV/AIDS, hypothyroidism), or it was impossible to quantify the cost of the potential adverse event (erectile dysfunction, ADHA).

Medical consequences of treatment failure

The medical consequences of getting a counterfeit version can vary from no effect to death from a toxic substance.[3] This analysis assumes that the counterfeit version is a placebo, containing no active ingredient, and no harmful ingredients. That is, the treatment is ineffective. Accordingly, the treatment failure is simply the result of taking a drug that does not contain the active pharmaceutical ingredient. Obviously, if a counterfeit drug contains substantial impurities or toxins the adverse effects of ingestion may be significantly more consequential. The consequences of taking a counterfeit drug containing harmful ingredients will be far worse, potentially resulting in death, and more costly to treat. Again, this will bias the analysis against the finding of the elimination of any cost savings.

[3] The Partnership for Safe Medicine (2019) documents the harms of counterfeit drugs and the individuals harmed by them. Dozens of their stories may be found on their website: https://www.safemedicines.org/victim-tragedies

Table 4: Potential Adverse Event

	Drug	Potential Adverse Event
1	Abilify	Suicide attempt
2	Actos	Diabetic ketoacidosis
3	Advair	COPD
4	Albenza	Neurocysticercosis
5	Ampyra	Worsening MS
6	Aubagio	Worsening MS
7	Augmentin	
8	Avonex	Worsening MS
9	Celebrex	
10	Cialis	
11	Copaxone	Worsening MS
12	Crestor	Stroke
13	Eliquis	Stroke
14	Enbrel	Worsening Psoriatic Arthritis
15	EpiPen	Anaphylaxis
16	Forteo	Fracture due to Osteoporosis
17	Gilenya	Worsening MS
18	Harvoni	Liver failure requiring transplant
19	Humira	Worsening Psoriatic Arthritis
20	Januvia	Diabetic Ketoacidosis
21	Letairis	PAH
22	Lipitor	Stroke
23	Lyrica	
24	Nexium	Esophageal Cancer
25	Orencia	Worsening Psoriatic Arthritis
26	Otezla	Worsening Psoriatic Arthritis
27	Premarin	Fracture due to Osteoporosis
28	Revatio	PAH
29	Sovaldi	Liver failure requiring transplant
30	Stelara	Worsening Psoriatic Arthritis
31	Stendra	
32	Strattera	
33	Synthroid	
34	Tecfidera	Worsening MS
35	Tresiba	Diabetic Ketoacidosis
36	Triumeq	
37	Truvada	New HIV-1 infection
38	Xarelto	Stroke
39	Zetia	Stroke
40	Zytiga	Prostate Cancer

Expense of treating such adverse events

Healthcare costs are uniquely difficult to measure. Across the United States costs vary significantly. Moreover, costs may vary significantly across hospitals in the same city or even across patients in the same hospital. Insurance status and the details of a particular plan further complicate measurement of such expenses.

The data on the expense of treating an adverse event was gathered from medical journals and institutional sources. Given the difficulty of specifying medical costs, Appendix C details the sources and methodology used for each calculation used in the analysis. Additional details for each calculation may be found in the original source material.

Table 5 provides the cost of treatment (in 2019 dollars) for the 14 unique adverse medical events found in Table 4. The costs presented here are estimated for the treatment of a patient for one year or a single adverse event. Given that the cost savings from buying Canadian drugs is estimated for a single year, the treatment of an adverse event is also estimated for a single year. Notably, in many cases, the cost of treatment failure will extend over many years and may present a lifelong burden. Again, this assumption biases the results against the finding of eliminating all cost savings.

Table 5: Cost of Treatment for Potential Adverse Medical Events

Potential Adverse Medical Event	Cost in 2019 dollars[4]	Details
Anaphylaxis	$5,958	$4719 annual cost in 2007 dollars
CABG	$165,822	$151,785 in 2014 dollars
COPD	$3,958	$3356 annual cost in 2010 dollars
Diabetic ketoacidosis	$29,023	$26,566 in 2014 dollars
Esophageal Cancer	$93,966	$79,677 initial year in 2010 dollars
New HIV-1 infection	$447,758	$379,668 lifetime cost in 2010 dollars
Liver transplant	$855,022	$812,500 in 2017 dollars
Multiple Sclerosis	$48,893	$42,134 annual cost in 2011 dollars
Neurocysticercosis	$55,085	$48,859 in 2012 dollars
Osteoporosis Fracture	$12,409	$8,600 in 2002 dollars
Prostate Cancer	$23,243	$19,710 initial year in 2010 dollars
Psoriatic Arthritis	$6,699	$6,126 annual cost in 2015 dollars
Pulmonary Arterial Hypertension	$41,617	$32,964 annual cost in 2007 dollars
Schizophrenia: Suicide Attempt	$64,729	$46,024 annual cost in 2003 dollars

Source: Author's calculations using data from medical journals included in Appendix C.

[4] Cost in 2019 dollars was calculated using the Bureau of Labor Statistics' CPI Inflation Calculator (link here).

Number of Patients in a "Representative State"

According to the U.S. Census Bureau (link here), the population of the United State is approximately 328 million and dividing by 50, a representative state would have a population of 6,560,000 people. The Medicaid website (link here) indicates that Medicaid and CHIP now cover nearly 70 million people, or one in every five people in the country. Using 20% of the population as a conservative estimate of the share of people who would utilize a state-importation program, the annual presumed savings may be calculated. Assuming 20% of that population utilizes the state-importation program, this equates to 1,312,000 persons in the representative state. Admittedly, this may be an overestimation of the number of patients. If so, this again biases the analysis against a finding of the elimination of cost savings.

Disease Prevalence

The analysis presented to this point considers only the costs and savings available to an individual patient. Given that the importation programs under consideration would extend to larger populations, by state, it is important to calculate the costs and savings available to a state program, as well as the consequences of such programs.

In the cases of the 14 unique adverse events listed above the calculations have been extended to provide estimates for a "representative state". The disease prevalence was determined for the entire United States. This number was then divided by 50 to calculate the number of patients for a "representative state". Table 6, below, presents the number of patients for each of the 14 unique adverse events. The calculations and sources for these estimates may be found in Appendix D.

Table 6: Number of Patients in a Representative US State for Potential Adverse Medical Events

Potential Adverse Medical Event	Number of Patients in Representative US State
Anaphylaxis	131,200
High Cholesterol: CABG	860,000
COPD	392,400
Diabetic ketoacidosis	606,000
Esophageal Cancer	300
New HIV-1 infection	22,000
Liver transplant	48,000
Multiple Sclerosis	20,000
Neurocysticercosis	41
Osteoporosis Fracture	204,000
Prostate Cancer	3,671
Psoriatic Arthritis	3,490
Pulmonary Arterial Hypertension	4,000
Schizophrenia: Suicide Attempt	29,192

Source: Author's calculations using data from medical journals included in Appendix D.

IV. ANALYSIS

This analysis presents the calculations for an individual patient (Tables 7-9), comparing the presumed cost savings to the cost of treating an adverse medical event. It also presents the calculations for a "Representative State" (Tables 10-13), comparing the presumed cost savings to the costs of treating an adverse medical event and to the costs of testing the imported medicines into safety.

Calculation of presumed cost savings

Utilizing the average US price per unit and the lowest Canadian price per unit (for both the brick-and-mortar pharmacy and the online supplier), the average cost savings per unit was calculated for the 24 drugs for which extensive analysis is possible. For drugs taken for a chronic condition, this number was multiplied by the number of doses prescribed per month to calculate the presumed monthly savings, which was then multiplied by 12 to calculate the presumed annual savings. For drugs taken for an acute condition, the average per unit cost savings was multiplied by the number of doses needed for treatment to calculate the savings per episode per patient. These calculations are presented in Table 7, below.

Table 7: Presumed Cost Savings Per Patient from Online Canadian Supplier and Brick-and-Mortar Canadian Pharmacy

Drugs	Online Canadian savings per patient: yearly	Online Canadian savings per patient: monthly	Online Canadian savings per patient: per episode	US Price less online Canadian Price	B&M Canadian savings per patient: yearly	B&M Canadian savings per patient: monthly	B&M Canadian savings per patient: per episode	US Price less B&M Canadian Price	Average US price per unit♦	Lowest Online Canadian price per unit	Lowest B&M Canadian price per unit
Abilify	$10,270.54	$855.88		$28.53	$9,004.23	$750.35		$25.01	$30.01	$1.48	$5.00
Actos	$6,931.29	$577.61		$19.25	$5,722.84	$476.90		$15.90	$20.08	$0.82	$4.18
Advair	$3,978.57	$331.55		$331.55	$3,438.61	$286.55		$286.55	$396.55	$65.00	$110.00
Albenza			$50,450.40	$209.09			$50,021.87	$208.42	$210.21	$1.13	$1.79
Ampyra	$23,560.40	$1,963.37		$32.72	$23,367.67	$1,947.31		$32.46	$44.95	$12.23	$12.50
Crestor	$1,580.07	$131.67		$4.39	$1,494.40	$124.53		$4.15	$5.82	$1.43	$1.67
Enbrel	$37,823.70	$3,151.98		$787.99	$34,379.70	$2,864.98		$716.24	$1,217.99	$430.00	$501.75
EpiPen			$171.53	$171.53			$168.54	$168.54	$308.53	$137.00	$139.99
Gilenya	$55,650.44	$4,637.54		$154.58	$58,222.00	$4,851.83		$161.73	$261.73	$107.14	$100.00
Harvoni			$34,864.52	$387.38			$17,604.88	$195.61	$1,124.18	$736.80	$928.57
Januvia	$4,777.35	$398.11		$13.27	$3,731.76	$310.98		$10.37	$14.70	$1.43	$4.33
Lipitor	$4,708.92	$392.41		$13.08	$4,808.96	$400.75		$13.36	$14.25	$1.17	$0.89
Nexium	$1,655.49	$137.96		$4.60	$922.76	$76.90		$2.56	$5.60	$1.00	$3.04
Orencia	$32,467.60	$2,705.63		$676.41	$18,260.08	$1,521.67		$380.42	$1,080.41	$404.00	$699.99
Otezla	$24,933.99	$2,077.83		$34.63	$22,343.41	$1,861.95		$31.03	$56.03	$21.40	$25.00
Premarin	$1,540.51	$128.38		$4.28	$1,540.55	$128.38		$4.28	$5.05	$0.77	$0.77
Revatio	$18,707.61	$1,558.97		$17.32	$16,055.72	$1,337.98		$14.87	$23.87	$6.54	$9.00
Sovaldi			$16,843.18	$187.15			$28,662.91	$318.48	$997.05	$809.90	$678.57
Tecfidera	$63,857.73	$5,321.48		$88.69	$65,233.44	$5,436.12		$90.60	$126.10	$37.41	$35.50
Tresiba	$1,852.70	$154.39		$154.39	$1,826.32	$152.19		$152.19	$192.19	$37.80	$40.00
Truvada	$18,702.39	$1,558.53		$51.95	$7,854.39	$654.53		$21.82	$56.12	$4.17	$34.30
Xarelto	$4,495.76	$374.65		$12.49	$3,797.23	$316.44		$10.55	$14.21	$1.73	$3.67
Zetia	$3,382.19	$281.85		$9.39	$3,230.80	$269.23		$8.97	$11.42	$2.02	$2.44
Zytiga	$74,685.00	$6,223.75		$51.86	$72,093.12	$6,007.76		$50.06	$85.19	$33.33	$35.12

Source: Author's calculations, May 2019.

♦Note that the US Price is the average obtained from GoodRX.com.

Ratio of the Expense of Treating an Adverse Event to Presumed Cost Savings <u>Per Patient</u>

Given that cost savings is the primary motivation for pharmaceutical importation, it is essential to consider whether patients actually save money. This section compares the presumed cost savings that will accrue to a patient and compares it to the cost of treating an adverse medical event. Simply stated, if a patient receives a counterfeit version of the imported drug and they suffer the health consequences, will they save any money?

Again, utilizing the average US price per unit and the lowest Canadian price per unit for both online suppliers and brick-and-mortar pharmacies, the average cost savings per unit was calculated. For drugs taken for a chronic condition, this number was multiplied by the number of doses prescribed per month to calculate the presumed monthly savings, which was then multiplied by 12 to calculate the presumed annual savings. For drugs taken for an acute condition, the average per unit cost savings was multiplied by the number of doses needed for treatment to calculate the savings per episode per patient.

As described in Section III above, the data on the expense of treating an adverse event were gathered from medical journals and institutional sources. These expenses are then compared to the presumed cost savings. Tables 8 and 9, below, presents the ratio of treatment expenses to the presumed cost savings for both online Canadian suppliers and brick-and-mortar Canadian pharmacies. The dollar values highlighted in green correspond to the greatest amount of savings across online Canadian suppliers and brick-and-mortar Canadian pharmacies.

Online Suppliers In the case of online suppliers, the annual presumed savings fails to cover the treatment of an adverse event for 18 of the 24 drugs (75%). The calculations indicate that these ratios range from 0.01 for Crestor to 5.65 for Enbrel. That is, for Crestor, the annual savings covers less than 1% of the cost of treating an adverse medical event, such that patients would require 105 years of presumed cost savings to cover the treatment of an adverse medical event. For Enbrel, patients would require 66 days of presumed cost savings to cover the treatment of an adverse medical event. For Crestor, the cost of treating an adverse event is more than 10,500% of the presumed cost savings. Of the 14 adverse medical events considered, the presumed cost savings exceeds the cost of treatment for only 3 conditions (21%). These are: Multiple Sclerosis (Gilenya, Tecfidera), Psoriatic Arthritis (Enbrel, Orencia, Otezla) and Prostate Cancer (Zytiga). For ten of the 24 drugs analyzed, the annual presumed savings is less than 5% the cost of treating an adverse medical event. On average, patients would need to accumulate 24 years of the presumed cost savings to cover the treatment for an adverse medical event.

Brick-and-Mortar Pharmacies In the case of brick-and-mortar suppliers, the annual presumed savings fails to cover the treatment of an adverse event for 18 of the 24 drugs (75%). The calculations indicate that these ratios range from 0.01 for Crestor to 5.13 for Enbrel. That is, for Crestor, the annual savings covers less than 1% of the cost of treating an adverse medical event, such that patients would require 111 years of presumed cost savings to cover the treatment of an adverse medical event. For Crestor, the cost of treating an adverse event is more than 11,100% of the presumed cost savings. For Enbrel, patients would require 71 days of presumed cost savings to cover the treatment of an adverse medical event. Again, of the 14 adverse medical events considered, the presumed cost savings exceeds the cost of treatment for only 3 conditions

(21%): Multiple Sclerosis (Gilenya, Tecfidera), Psoriatic Arthritis (Enbrel, Orencia, Otezla) and Prostate Cancer (Zytiga). For ten of the 24 drugs analyzed, the annual presumed savings is less than 5% the cost of treating an adverse medical event. On average, patients would need to accumulate 20 years of the presumed cost savings to cover the treatment for an adverse medical event.

It is essential to recognize the true danger posed to U.S. patients from drugs that are obtained outside of the highly regulated U.S. supply chain. This is a case in which an attempt to save money ends up leading to even greater expenses in the end. In a relatable situation, at least a dozen U.S. patients have traveled to Mexico for surgical procedures that were less expensive in Tijuana and contracted a rare and potentially deadly strain of bacteria resistant to virtually all antibiotics. Treatment of the deadly superbug has resulted in medical expenses that far outstrip the initial savings (Sun, 2019) (link here). Also, consider two instances in which Canada Drugs, through its subsidiary River East Supplies, distributed counterfeit cancer drugs Avastin and Altuzan (the Turkish version of the drug) in the United States. According to the U.S. FDA, testing of vials of the drugs recovered from these shipments revealed that both contained no active ingredient. In April 2018 the Canadian firm admitted to widespread illegal sales of misbranded and counterfeit prescription drugs in the United States (U.S. FDA, 2018) (link here). Again, the cost savings are eliminated in the face of complete treatment failure.

Per Patient Takeaway Regardless of whether one's drugs are obtained from a Canadian online supplier or a brick-and-mortar Canadian pharmacy, in three out of four cases, the annual presumed savings fails to cover the costs of an adverse medical event. For these drugs, patients would need to acquire the cost savings over a period of up to 111 years to cover the costs of one adverse event. Not surprisingly, for the few drugs for which the savings exceed the cost of treating an adverse medical event, the expense of an adverse medical event is modest (less than $50,000). For the majority of drugs, the cost of treating an adverse event will significantly exceed $50,000 and may reach more than $800,000.

Table 8: Presumed Cost Savings Per Patient from an Online Supplier Relative to the Cost of Treating an Adverse Event

Drugs	Online savings per patient: yearly	Online savings per patient: monthly	Online savings per patient: per episode	US Price less online Canadian Price	Cost of Treating Adverse Event per Patient	Number of Years of Savings needed to cover Adverse Event	Percent of Adverse Event Treatment Covered by Annual Savings
Abilify	$10,270.54	$855.88		$28.53	$64,729	6.30	0.16
Actos	$6,931.29	$577.61		$19.25	$165,822	23.92	0.04
Advair	$3,978.57	$331.55		$331.55	$11,097	2.79	0.36
Albenza			$50,450.40	$209.09	$55,085	1.09	0.92
Ampyra	$23,560.40	$1,963.37		$32.72	$48,893	2.08	0.48
Crestor	$1,580.07	$131.67		$4.39	$165,822	104.95	0.01
Enbrel	$37,823.70	$3,151.98		$787.99	$6,699	0.18	5.65
EpiPen			$171.53	$171.53	$4,719	27.51	0.04
Gilenya	$55,650.44	$4,637.54		$154.58	$48,893	0.88	1.14
Harvoni			$34,864.52	$387.38	$812,500	23.30	0.04
Januvia	$4,777.35	$398.11		$13.27	$29,023	6.08	0.16
Lipitor	$4,708.92	$392.41		$13.08	$165,822	35.21	0.03
Nexium	$1,655.49	$137.96		$4.60	$93,966	56.76	0.02
Orencia	$32,467.60	$2,705.63		$676.41	$6,699	0.21	4.85
Otezla	$24,933.99	$2,077.83		$34.63	$6,699	0.27	3.72
Premarin	$1,540.51	$128.38		$4.28	$12,409	8.06	0.12
Revatio	$18,707.61	$1,558.97		$17.32	$41,617	2.22	0.45
Sovaldi			$16,843.18	$187.15	$812,500	48.24	0.02
Tecfidera	$63,857.73	$5,321.48		$88.69	$48,893	0.77	1.31
Tresiba	$1,852.70	$154.39		$154.39	$29,023	15.67	0.06
Truvada	$18,702.39	$1,558.53		$51.95	$447,758	23.94	0.04
Xarelto	$4,495.76	$374.65		$12.49	$165,822	36.88	0.03
Zetia	$3,382.19	$281.85		$9.39	$165,822	49.03	0.02
Zytiga	$74,685.00	$6,223.75		$51.86	$23,243	0.31	3.21

Source: Author's calculations.

Table 9: Presumed Cost Per Patient Savings from a Brick-and-Mortar Canadian Pharmacy Relative to the Cost of Treating an Adverse Event

Drugs	B&M savings per patient: yearly	B&M savings per patient: monthly	B&M savings per patient: per episode	US Price less B&M Canadian Price (per unit)	Cost of Treating Adverse Event per Patient	Number of Years of Savings needed to cover Adverse Event	Percent of Adverse Event Treatment Covered by Annual Savings
Abilify	$9,004.23	$750.35		$25.01	$64,729	7.19	0.14
Actos	$5,722.84	$476.90		$15.90	$165,822	28.98	0.03
Advair	$3,438.61	$286.55		$286.55	$11,097	3.23	0.31
Albenza			$50,021.87	$208.42	$55,085	1.10	0.91
Ampyra	$23,367.67	$1,947.31		$32.46	$42,134	2.09	0.48
Crestor	$1,494.40	$124.53		$4.15	$165,822	110.96	0.01
Enbrel	$34,379.70	$2,864.98		$716.24	$6,699	0.19	5.13
EpiPen			$168.54	$168.54	$4719	28.00	0.04
Gilenya	$58,222.00	$4,851.83		$161.73	$42,134	0.84	1.19
Harvoni			$17,604.88	$195.61	$812,500	46.15	0.02
Januvia	$3,731.76	$310.98		$10.37	$29,023	7.78	0.13
Lipitor	$4,808.96	$400.75		$13.36	$165,822	34.48	0.03
Nexium	$922.76	$76.90		$2.56	$93,966	101.83	0.01
Orencia	$18,260.08	$1,521.67		$380.42	$6,699	0.37	2.73
Otezla	$22,343.41	$1,861.95		$31.03	$6,699	0.30	3.34
Premarin	$1,540.55	$128.38		$4.28	$12,409	8.05	0.12
Revatio	$16,055.72	$1,337.98		$14.87	$41,617	2.59	0.39
Sovaldi			$28,662.91	$318.48	$812,500	28.35	0.04
Tecfidera	$65,233.44	$5,436.12		$90.60	$42,134	0.75	1.33
Tresiba	$1,826.32	$152.19		$152.19	$29,023	15.89	0.06
Truvada	$7,854.39	$654.53		$21.82	$447,758	57.01	0.02
Xarelto	$3,797.23	$316.44		$10.55	$165,822	43.67	0.02
Zetia	$3,230.80	$269.23		$8.97	$165,822	51.33	0.02
Zytiga	$72,093.12	$6,007.76		$50.06	$23,243	0.32	3.10

Source: Author's calculations.

Presumed Cost Savings for a "Representative State"

Given that the majority of importation proposals are presented at the state level, it is worthwhile to consider the financial implications for a "Representative State". Recognizing that this "Representative State" correlates to 1/50th of the population of the United States and that some states will be larger and others smaller, it is still illustrative to consider the implications. The cost-versus-savings calculations for a "Representative State" are presented in Tables 10 and 11, below. Table 10 depicts the presumed savings from Online Suppliers, while Table 11 depicts the presumed savings from a Brick-and-Mortar Pharmacy.

Number of Patients The population of a "representative state" is assumed to be 1/50th of the population of the United States, approximately 6,540,000 people. The number of patients for each condition considered here is assumed to be 1/50th of the U.S. patient population suffering from the named condition.

Covered Patients In order to estimate the number of "covered patients" in a "representative state", it is assumed that 20% of the impacted patient population will enroll in the state program. This fraction was utilized because approximately one in five individuals in the U.S. is currently covered by Medicaid.[5]

Total Presumed Cost Savings The total amount of presumed cost savings is calculated by multiplying the number of covered patients by the presumed cost savings (either per year or per episode). Again, this number may be an overestimation which again biases the analysis against a finding of the elimination of all cost savings.

Cost of Treating an Adverse Medical Event Estimates of the cost of treating an adverse medical event were gleaned from medical journals and government sources. These are presented and detailed in Appendix C.

Number of Adverse Events Covered by Presumed Savings This number corresponds to the maximum number of adverse events that could be covered through by the expenditure of the presumed cost savings. It is calculated by dividing the total presumed savings by the cost of treating an adverse event. That is, this number represents the number of patients that would be covered by the State's presumed savings, in the case of an adverse event. These numbers range from a low of 0.59 adverse events for patients in the case of Nexium, to 24,318 adverse events for patients in the case of Advair. That is, the State's cost savings would be exhausted before treating one adverse medical event in the case of Nexium, and after more than 24,000 patients in the case of Advair.

Adverse Events would exhaust presumed savings after covering this share of Covered Patients If the presumed cost savings were exhausted covering adverse events, it is important to know not only how many patients could be covered, but the share of patients enrolled in the plan taking a particular drug. This share is calculated by dividing the number of adverse events covered by presumed savings by the number of covered patients. In the case of Online Suppliers, this

[5] This fraction can easily be changed if other assumptions are more defensible or appropriate for this calculation. In addition, if needed, it should be possible to make the calculations for a specific state.

number ranges from 0.95% (Crestor) to 564% (Enbrel). In the case of a Brick-and-Mortar Pharmacy, this number ranges from 0.90% (Crestor) to 513% (Enbrel). From both sources, if an adverse medical event affected less than 1% of all patients taking Crestor, the entire presumed cost savings would be wiped out. Alternatively, one can think of this as the share of counterfeit drugs that would wipe out all cost savings from an importation program.

Cost of treating an Adverse Event in 100% of Covered Patients The cost of treating an adverse medical event in 100% of covered patients taking a particular drug is calculated by multiplying the cost of treating an adverse event by the total number of covered patients. This number ranges from approximately $452,000 to more than $28.5 billion dollars.

Losses from treating adverse events in 100% of Covered Patients less Presumed Cost Savings Finally, the extent to which the cost of treating an adverse event in 100% of covered patients exceeds the presumed cost savings is calculated. The overage between the cost of treating an adverse medical event in 100% of the covered population and the presumed cost savings comes from subtracting the presumed cost savings from the cost of treating an adverse event in 100% of covered patients. In all but six cases (for three conditions) the cost of treatment far exceeds the presumed cost savings. The presumed savings is dwarfed by the potential cost of treating adverse medical events. These estimates range from savings of $60 million to losses of $28 billion.

Losses from treating adverse events in 10% of Covered Patients beyond Presumed Cost Savings Fortunately, it is highly unlikely that 100% of covered patients will experience an adverse medical event. Assuming that only 10% of drugs are counterfeit and result in an adverse event, approximately half of the 24 drugs will result in a situation in which the presumed savings is eliminated by the cost of treating an adverse event. However, these are the drugs in which the losses greatly exceed the potential savings.

All of these calculations are presented in Table 10 (online suppliers) and Table 11 (brick-and-mortar), below. The calculations are included for the subset of 24 drugs for which all information is available.

Online Suppliers In the case of online suppliers, the annual presumed savings fails to cover the treatment of an adverse event for 18 of the 24 drugs (75%). The calculations indicate that these ratios range from 0.01 for Crestor to 5.65 for Enbrel.

Brick-and-Mortar Pharmacies In the case of online suppliers, the annual presumed savings fails to cover the treatment of an adverse event for 18 of the 24 drugs (75%). The calculations indicate that these ratios range from 0.01 for Crestor to 5.13 for Enbrel.

"Representative State" Adverse Medical Events Takeaway Regardless of whether one's drugs are obtained from a Canadian online supplier or a brick-and-mortar Canadian pharmacy, in three out of four cases, the annual presumed savings for a "Representative State" fails to cover the costs of an adverse medical event. Again, for the few drugs for which the savings exceed the cost of treating an adverse medical event, the expense of an adverse medical event is modest (less than $50,000 per patient), while, for the majority of drugs, the cost of treating an adverse

event will significantly exceed $50,000 and may reach more than $800,000. Importantly, for this selection of 24 drugs, the cost savings will be completely eliminated if a mere 3.2% of imported drugs are counterfeit for a brick-and-mortar pharmacy or 3.5% from a Canadian online supplier.

Table 10: Presumed Online Cost Savings for a "Representative State" relative to Cost of an Adverse Medical Event

Drugs	Savings per year	Savings per episode	Number of Patients *	Covered Patients ♠	Total Presumed Savings ♦	Cost of Treating an Adverse Event per patient	Number of Adverse Events Covered by Presumed Savings⅀	Adverse Events would exhaust presumed savings after covering this share of Covered Patients ⍿	Cost of treating an Adverse Event in 100% of Covered Patients Δ	Losses from treating adverse events in 100% of Covered Patients beyond Presumed Cost Savings ☋	Losses from treating adverse events in 10% of Covered Patients beyond Presumed Cost Savings
Abilify	$10,270.54		29,192	5838	$59,963,520.74	$64,729	926.38	15.87%	$377,913,793.60	($317,950,272.86)	$22,172,141.38
Actos	$6,931.29		606,000	121200	$840,072,348.00	$165,822	5066.11	4.18%	$20,097,626,400.00	($19,257,554,052.00)	($1,169,690,292.00)
Advair	$3,978.57		392,400	78480	$312,238,173.60	$11,097	28137.17	35.85%	$870,892,560.00	($558,654,386.40)	$225,148,917.60
Albenza		$50,450.40	41	8	$413,693.28	$55,085	7.51	91.59%	$451,697.00	($38,003.72)	$368,523.58
Ampyra	$23,560.40		20,000	4000	$94,241,600.00	$48,893	1927.51	48.19%	$195,572,000.00	($101,330,400.00)	$74,684,400.00
Crestor	$1,580.07		860,000	172000	$271,772,040.00	$165,822	1638.94	0.95%	$28,521,384,000.00	($28,249,611,960.00)	($2,580,366,360.00)
Enbrel	$37,823.70		3,490	698	$26,400,942.60	$6,699	3941.03	564.62%	$4,675,902.00	$21,725,040.60	$25,933,352.40
EpiPen		$171.53	131,200	26240	$4,500,947.20	$4,719	953.79	3.63%	$123,826,560.00	($119,325,612.80)	($7,881,708.80)
Gilenya	$55,650.44		20,000	4000	$222,601,760.00	$48,893	4552.83	113.82%	$195,572,000.00	$27,029,760.00	$203,044,560.00
Harvoni		$34,864.52	48,000	9600	$334,699,392.00	$812,500	411.94	4.29%	$7,800,000,000.00	($7,465,300,608.00)	($445,300,608.00)
Januvia	$4,777.35		606,000	121200	$579,014,820.00	$29,023	19950.21	16.46%	$3,517,587,600.00	($2,938,572,780.00)	$227,256,060.00
Lipitor	$4,708.92		860,000	172000	$809,934,240.00	$165,822	4884.36	2.84%	$28,521,384,000.00	($27,711,449,760.00)	($2,042,204,160.00)
Nexium	$1,655.49		300	60	$99,329.40	$93,966	1.06	1.76%	$5,637,960.00	($5,538,630.60)	($464,466.60)
Orencia	$32,467.60		3,490	698	$22,662,384.80	$6,699	3382.95	484.66%	$4,675,902.00	$17,986,482.80	$22,194,794.60
Otezla	$24,933.99		3,490	698	$17,403,925.02	$6,699	2597.99	372.20%	$4,675,902.00	$12,728,023.02	$16,936,334.82
Premarin	$1,540.51		204,000	40800	$62,852,808.00	$12,409	5065.10	12.41%	$506,287,200.00	($443,434,392.00)	$12,224,088.00
Revatio	$18,707.61		4,000	800	$14,966,088.00	$41,617	359.61	44.95%	$33,293,600.00	($18,327,512.00)	$11,636,728.00
Sovaldi		$16,843.18	48,000	9600	$161,694,528.00	$812,500	199.01	2.07%	$7,800,000,000.00	($7,638,305,472.00)	($618,305,472.00)
Tecfidera	$63,857.73		20,000	4000	$255,430,920.00	$48,893	5224.28	130.61%	$195,572,000.00	$59,858,920.00	$235,873,720.00
Tresiba	$1,852.70		606,000	121200	$224,547,240.00	$29,023	7736.87	6.38%	$3,517,587,600.00	($3,293,040,360.00)	($127,211,520.00)
Truvada	$18,702.39		22,000	4400	$82,290,516.00	$447,758	183.78	4.18%	$1,970,135,200.00	($1,887,844,684.00)	($114,723,004.00)
Xarelto	$4,495.76		860,000	172000	$773,270,720.00	$165,822	4663.26	2.71%	$28,521,384,000.00	($27,748,113,280.00)	($2,078,867,680.00)
Zetia	$3,382.19		860,000	172000	$581,736,680.00	$165,822	3508.20	2.04%	$28,521,384,000.00	($27,939,647,320.00)	($2,270,401,720.00)
Zytiga	$74,685.00		3,671	734	$54,833,727.00	$23,243	2359.15	321.32%	$17,065,010.60	$37,768,716.40	$53,127,225.94

* The population of a "representative state" is assumed to be 1/50th of the population of the United States, approximately 6,540,000 people. The number of patients for each condition considered here is assumed to be 1/50th of the U.S. patient population.

♠ The number of "covered patients" is assumed to be 20% of the patient population in a "representative state". This fraction was utilized because approximately one in five individuals in the U.S. is covered by Medicaid.

♦ This number comes from multiplying the number of covered patients by the savings (either per year or per episode).

⅀ This number comes from dividing the total presumed savings by the cost of treating an adverse event.

⍿ This number comes from dividing the number of adverse events covered by presumed savings by the number of covered patients.

Δ This number comes from multiplying the cost of treating an adverse event by the total number of covered patients.

☋ This number comes from subtracting the presumed cost savings from the cost of treating an adverse event in 100% of covered patients.

Source: Author's calculations.

Table 11: Presumed Brick-&-Mortar Cost Savings for a "Representative State" relative to Cost of an Adverse Medical Event

Drugs	Savings per year	Savings per episode	Number of Patients *	Covered Patients ♠	Total Presumed Savings ♦	Cost of Treating an Adverse Event	Number of Adverse Events Covered by Presumed Savings⇟	Adverse Events would exhaust presumed savings after covering this share of Covered Patients⇣	Cost of treating an Adverse Event in 100% of Covered Patients Δ	Losses from treating adverse events in 100% of Covered Patients beyond Presumed Cost Savings ☋	Losses from treating adverse events in 10% of Covered Patients beyond Presumed Cost Savings
Abilify	$9,004.23		29,192	5838	$52,570,296.43	$64,729	812.16	13.91%	$377,913,793.60	($325,343,497.17)	$14,778,917.07
Actos	$5,722.84		606,000	121200	$693,608,208.00	$165,822	4182.85	3.45%	$20,097,626,400.00	($19,404,018,192.00)	($1,316,154,432.00)
Advair	$3,438.61		392,400	78480	$269,862,112.80	$11,097	24318.47	30.99%	$870,892,560.00	($601,030,447.20)	$182,772,856.80
Albenza		$50,021.87	41	8	$410,179.33	$55,085	7.45	90.81%	$451,697.00	($41,517.67)	$365,009.63
Ampyra	$23,367.67		20,000	4000	$93,470,680.00	$48,893	1911.74	47.79%	$195,572,000.00	($102,101,320.00)	$73,913,480.00
Crestor	$1,494.40		860,000	172000	$257,036,800.00	$165,822	1550.08	0.90%	$28,521,384,000.00	($28,264,347,200.00)	($2,595,101,600.00)
Enbrel	$34,379.70		3,490	698	$23,997,030.60	$6,699	3582.18	513.21%	$4,675,902.00	$19,321,128.60	$23,529,440.40
EpiPen		$168.54	131,200	26240	$4,422,489.60	$4,719	937.17	3.57%	$123,826,560.00	($119,404,070.40)	($7,960,166.40)
Gilenya	$58,222.00		20,000	4000	$232,888,000.00	$48,893	4763.22	119.08%	$195,572,000.00	$37,316,000.00	$213,330,800.00
Harvoni		$17,604.88	48,000	9600	$169,006,848.00	$812,500	208.01	2.17%	$7,800,000,000.00	($7,630,993,152.00)	($610,993,152.00)
Januvia	$3,731.76		606,000	121200	$452,289,312.00	$29,023	15583.82	12.86%	$3,517,587,600.00	($3,065,298,288.00)	$100,530,552.00
Lipitor	$4,808.96		860,000	172000	$827,141,120.00	$165,822	4988.13	2.90%	$28,521,384,000.00	($27,694,242,880.00)	($2,024,997,280.00)
Nexium	$922.76		300	60	$55,365.60	$93,966	0.59	0.98%	$5,637,960.00	($5,582,594.40)	($508,430.40)
Orencia	$18,260.08		3,490	698	$12,745,535.84	$6,699	1902.60	272.58%	$4,675,902.00	$8,069,633.84	$12,277,945.64
Otezla	$22,343.41		3,490	698	$15,595,700.18	$6,699	2328.06	333.53%	$4,675,902.00	$10,919,798.18	$15,128,109.98
Premarin	$1,540.55		204,000	40800	$62,854,440.00	$12,409	5065.23	12.41%	$506,287,200.00	($443,432,760.00)	$12,225,720.00
Revatio	$16,055.72		4,000	800	$12,844,576.00	$41,617	308.64	38.58%	$33,293,600.00	($20,449,024.00)	$9,515,216.00
Sovaldi		$28,662.91	48,000	9600	$275,163,936.00	$812,500	338.66	3.53%	$7,800,000,000.00	($7,524,836,064.00)	($504,836,064.00)
Tecfidera	$65,233.44		20,000	4000	$260,933,760.00	$48,893	5336.83	133.42%	$195,572,000.00	$65,361,760.00	$241,376,560.00
Tresiba	$1,826.32		606,000	121200	$221,349,984.00	$29,023	7626.71	6.29%	$3,517,587,600.00	($3,296,237,616.00)	($130,408,776.00)
Truvada	$7,854.39		22,000	4400	$34,559,316.00	$447,758	77.18	1.75%	$1,970,135,200.00	($1,935,575,884.00)	($162,454,204.00)
Xarelto	$3,797.23		860,000	172000	$653,123,560.00	$165,822	3938.70	2.29%	$28,521,384,000.00	($27,868,260,440.00)	($2,199,014,840.00)
Zetia	$3,230.80		860,000	172000	$555,697,600.00	$165,822	3351.17	1.95%	$28,521,384,000.00	($27,965,686,400.00)	($2,296,440,800.00)
Zytiga	$72,093.12		3,671	734	$52,930,768.70	$23,243	2277.28	310.17%	$17,065,010.60	$35,865,758.10	$51,224,267.64

* The population of a "representative state" is assumed to be 1/50th of the population of the United States, approximately 6,540,000 people. The number of patients for each condition considered here is assumed to be 1/50th of the U.S. patient population.

♠ The number of "covered patients" is assumed to be 20% of the patient population in a "representative state". This fraction was utilized because approximately one in five individuals in the U.S. is covered by Medicaid.

♦ This number comes from multiplying the number of covered patients by the savings (either per year or per episode).

⇟ This number comes from dividing the total presumed savings by the cost of treating an adverse event.

⇣ This number comes from dividing the number of adverse events covered by presumed savings by the number of covered patients.

Δ This number comes from multiplying the cost of treating an adverse event by the total number of covered patients.

☋ This number comes from subtracting the presumed cost savings from the cost of treating an adverse event in 100% of covered patients.

Source: Author's calculations.

Presumed Cost Savings for a "Representative State" relative to the Cost of "Testing into Safety"

The cost of testing the authenticity and quality of the imported medicine is based on the estimated cost provided by NMS Labs. As described earlier, Table 2 provides the cost of the different types of testing a single sample to ensure the quality of each drug. Utilizing this information to determine the savings or dissavings available to a "Representative State", the calculations are presented for 24 drugs in Tables 12 and 13, below, representing the online and brick-and-mortar estimates respectively.

It is important to recognize that the testing estimates provided here only include the cost of the tests. The cost of purchasing the requisite number of samples needed for testing is not included in these cost estimates. Again, this assumption biases the results against a finding of the elimination of the presumed cost savings.

Number of Samples that could be Tested, Exhausting the Presumed Savings The maximum number of doses that could be tested while exhausting the presumed cost savings is calculated by dividing the total presumed savings by the cost of testing a specific drug.

Presumed Savings Less the Cost of Testing with a 90% Confidence Level and 90% Reliability In order to ensure the quality of a particular drug with a 90% confidence level and 90% reliability, 22 samples must be tested. The difference in the cost of testing 22 samples of the imported drugs and the presumed cost savings available from importation is calculated by subtracting the presumed cost savings from the cost of testing all imported doses.

Presumed Savings Less the Cost of Testing with a 99.99% Confidence Level and 99.99% Reliability In order to ensure the quality of a particular drug with a 99.99% confidence level and 99.99% reliability, 92,099 samples must be tested. The difference in the cost of testing 92,099 samples of the imported drugs and the presumed cost savings available from importation is calculated by subtracting the presumed cost savings from the cost of testing all imported doses.

Presumed Savings Less the Cost of Testing with a 99.999% Confidence Level and 99.999% Reliability In order to ensure the quality of a particular drug with a 99.999% confidence level and 99.999% reliability, 1,151,287 samples must be tested. The difference in the cost of testing 1,151,287 samples of the imported drugs and the presumed cost savings available from importation is calculated by subtracting the presumed cost savings from the cost of testing all imported doses.

Online Suppliers In the case of online suppliers, to ensure the quality of a particular drug with a 90% confidence level and 90% reliability, 22 samples must be tested and the savings exceed the cost of testing for all 24 drugs. In order to ensure the quality of a particular drug with a 99.99% confidence level and 99.99% reliability, 92,099 samples must be tested and the savings exceeds the cost of testing for 8 drugs. In order to ensure the quality of a particular drug with a 99.999% confidence level and 99.999% reliability, 1,151,287 samples must be tested and presumed savings are dwarfed by the cost of testing for all drugs. The cost of testing ranges

from 2.43 times the presumed savings for Advair to 34,770 times the presumed savings for Orencia. That is, the cost of testing ranges from 243% the presumed savings (Advair) to 3,477,079% the presumed savings (Orencia).

Brick-and-Mortar Pharmacies In the case of brick-and-mortar pharmacies, to ensure the quality of a particular drug with a 90% confidence level and 90% reliability, 22 samples must be tested and the savings exceed the cost of testing for 23 of the 24 drugs. In order to ensure the quality of a particular drug with a 99.99% confidence level and 99.99% reliability, 92,099 samples must be tested and the savings exceeds the cost of testing for 9 drugs. In order to ensure the quality of a particular drug with a 99.999% confidence level and 99.999% reliability, 1,151,287 samples must be tested and presumed savings are dwarfed by the cost of testing for all drugs. The cost of testing ranges from 2.48 times the presumed savings for Nexium to 62,382 times the presumed savings for Orencia.

"Representative State" Testing into Safety Takeaway Regardless of whether one's drugs are obtained from a Canadian online supplier or a brick-and-mortar Canadian pharmacy, in all cases, the annual presumed savings for a "Representative State" fails to cover the costs of testing a drug into safety with 99.999% confidence and 99.999% reliability. In the case of a lower level of quality assurance, there are a few drugs for which the presumed savings would exceed the cost of testing. If one is willing to accept the risk of a 90% confidence level with 90% reliability, then the presumed savings will (in all but one case) exceed the cost of testing for both online suppliers and brick-and-mortar Canadian pharmacies.

Table 12: Presumed Online Cost Savings for a "Representative State" relative to the Cost of Testing

Drugs	Savings per year	Savings per episode	Number of Patients *	Covered Patients ♠	Total Presumed Savings ♦	Cost of Quality Testing (per sample)	Number of samples that could be tested, exhausting the Presumed Savings⁜	Online Presumed Savings Less Cost of Testing with 90% confidence and 90% reliability (22 samples)	Online Presumed Savings Less Cost of Testing with 99.99% confidence and 99.99% reliability (92,099 samples)	Online Presumed Savings Less Cost of Testing with 99.999% confidence and 99.999% reliability (1,151,287 samples)
Abilify	$9,004.23		29,192	5838	$59,963,520.74	$4,000	14991	$59,875,520.74	($308,432,479.26)	($4,545,184,479.26)
Actos	$5,722.84		606,000	121200	$840,072,348.00	$2,500	336029	$840,017,348.00	$609,824,848.00	($2,038,145,152.00)
Advair	$3,438.61		392,400	78480	$312,238,173.60	$4,100	76156	$312,147,973.60	($65,367,726.40)	($4,408,038,526.40)
Albenza		$50,021.87	41	8	$413,693.28	$2,500	165	$358,693.28	($229,833,806.72)	($2,877,803,806.72)
Ampyra	$23,367.67		20,000	4000	$94,241,600.00	$2,500	37697	$94,186,600.00	($136,005,900.00)	($2,783,975,900.00)
Crestor	$1,494.40		860,000	172000	$271,772,040.00	$2,500	108709	$271,717,040.00	$41,524,540.00	($2,606,445,460.00)
Enbrel	$34,379.70		3,490	698	$26,400,942.60	$2,800	9429	$26,339,342.60	($231,476,257.40)	($3,197,202,657.40)
EpiPen		$168.54	131,200	26240	$4,500,947.20	$2,800	1607	$4,439,347.20	($253,376,252.80)	($3,219,102,652.80)
Gilenya	$58,222.00		20,000	4000	$222,601,760.00	$2,500	89041	$222,546,760.00	($7,645,740.00)	($2,655,615,740.00)
Harvoni		$17,604.88	48,000	9600	$334,699,392.00	$2,500	133880	$334,644,392.00	$104,451,892.00	($2,543,518,108.00)
Januvia	$3,731.76		606,000	121200	$579,014,820.00	$2,500	231606	$578,959,820.00	$348,767,320.00	($2,299,202,680.00)
Lipitor	$4,808.96		860,000	172000	$809,934,240.00	$2,500	323974	$809,879,240.00	$579,686,740.00	($2,068,283,260.00)
Nexium	$922.76		300	60	$99,329.40	$3,000	33	$33,329.40	($276,197,670.60)	($3,453,761,670.60)
Orencia	$18,260.08		3,490	698	$22,662,384.80	$2,800	8094	$22,600,784.80	($235,214,815.20)	($3,200,941,215.20)
Otezla	$22,343.41		3,490	698	$17,403,925.02	$2,500	6962	$17,348,925.02	($212,843,574.98)	($2,860,813,574.98)
Premarin	$1,540.55		204,000	40800	$62,852,808.00	$2,600	24174	$62,795,608.00	($176,604,592.00)	($2,930,493,392.00)
Revatio	$16,055.72		4,000	800	$14,966,088.00	$3,600	4157	$14,886,888.00	($316,590,312.00)	($4,129,667,112.00)
Sovaldi		$28,662.91	48,000	9600	$161,694,528.00	$2,500	64678	$161,639,528.00	($68,552,972.00)	($2,716,522,972.00)
Tecfidera	$65,233.44		20,000	4000	$255,430,920.00	$2,500	102172	$255,375,920.00	$25,183,420.00	($2,622,786,580.00)
Tresiba	$1,826.32		606,000	121200	$224,547,240.00	$2,800	80195	$224,485,640.00	($33,329,960.00)	($2,999,056,360.00)
Truvada	$7,854.39		22,000	4400	$82,290,516.00	$2,500	32916	$82,235,516.00	($147,956,984.00)	($2,795,926,984.00)
Xarelto	$3,797.23		860,000	172000	$773,270,720.00	$2,500	309308	$773,215,720.00	$543,023,220.00	($2,104,946,780.00)
Zetia	$3,230.80		860,000	172000	$581,736,680.00	$2,500	232695	$581,681,680.00	$351,489,180.00	($2,296,480,820.00)
Zytiga	$72,093.12		3,671	734	$54,833,727.00	$2,500	21933	$54,778,727.00	($175,413,773.00)	($2,823,383,773.00)

⁜ This number is calculated by dividing the total presumed savings by the cost of testing.
⸸ This number is calculated by dividing the number of doses that could be tested (exhausting the presumed cost savings) by the total number of imported doses.
ↀ This number is calculated by multiplying the cost of testing by the total number of imported doses.
♦ This number is calculated by subtracting the presumed cost savings from the cost of testing all imported doses.
Source: Author's calculations.

Table 13: Presumed Brick-&-Mortar Cost Savings for a "Representative State" relative to the Cost of Testing

Drugs	Savings per year	Savings per episode	Number of Patients *	Covered Patients ♠	Total Presumed Savings ♦	Cost of Quality Testing (per sample)	Number of units (samples) that could be tested, exhausting the Presumed Savings⸸	B&M Presumed Savings Less Cost of Testing with 90% confidence and 90% reliability (22 samples)	B&M Presumed Savings Less Cost of Testing with 99.99% confidence and 99.99% reliability (92,099 samples)	B&M Presumed Savings Less Cost of Testing with 99.999% confidence and 99.999% reliability (1,151,287 samples)
Abilify	$10,270.54		29,192	5838	$59,963,520.74	$4,000	13143	$52,482,296.43	($315,825,703.57)	($4,552,577,703.57)
Actos	$6,931.29		606,000	121200	$840,072,348.00	$2,500	277443	$693,553,208.00	$463,360,708.00	($2,184,609,292.00)
Advair	$3,978.57		392,400	78480	$312,238,173.60	$4,100	65820	$269,771,912.80	($107,743,787.20)	($4,450,414,587.20)
Albenza		$50,450.40	41	8	$413,693.28	$2,500	164	$355,179.33	($229,837,320.67)	($2,877,807,320.67)
Ampyra	$23,560.40		20,000	4000	$94,241,600.00	$2,500	37388	$93,415,680.00	($136,776,820.00)	($2,784,746,820.00)
Crestor	$1,580.07		860,000	172000	$271,772,040.00	$2,500	102815	$256,981,800.00	$26,789,300.00	($2,621,180,700.00)
Enbrel	$37,823.70		3,490	698	$26,400,942.60	$2,800	8570	$23,935,430.60	($233,880,169.40)	($3,199,606,569.40)
EpiPen		$171.53	131,200	26240	$4,500,947.20	$2,800	1579	$4,360,889.60	($253,454,710.40)	($3,219,181,110.40)
Gilenya	$55,650.44		20,000	4000	$222,601,760.00	$2,500	93155	$232,833,000.00	$2,640,500.00	($2,645,329,500.00)
Harvoni		$34,864.52	48,000	9600	$334,699,392.00	$2,500	67603	$168,951,848.00	($61,240,652.00)	($2,709,210,652.00)
Januvia	$4,777.35		606,000	121200	$579,014,820.00	$2,500	180916	$452,234,312.00	$222,041,812.00	($2,425,928,188.00)
Lipitor	$4,708.92		860,000	172000	$809,934,240.00	$2,500	330856	$827,086,120.00	$596,893,620.00	($2,051,076,380.00)
Nexium	$1,655.49		300	60	$99,329.40	$3,000	18	($10,634.40)	($276,241,634.40)	($3,453,805,634.40)
Orencia	$32,467.60		3,490	698	$22,662,384.80	$2,800	4552	$12,683,935.84	($245,131,664.16)	($3,210,858,064.16)
Otezla	$24,933.99		3,490	698	$17,403,925.02	$2,500	6238	$15,540,700.18	($214,651,799.82)	($2,862,621,799.82)
Premarin	$1,540.51		204,000	40800	$62,852,808.00	$2,600	24175	$62,797,240.00	($176,602,960.00)	($2,930,491,760.00)
Revatio	$18,707.61		4,000	800	$14,966,088.00	$3,600	3568	$12,765,376.00	($318,711,824.00)	($4,131,788,624.00)
Sovaldi		$16,843.18	48,000	9600	$161,694,528.00	$2,500	110066	$275,108,936.00	$44,916,436.00	($2,603,053,564.00)
Tecfidera	$63,857.73		20,000	4000	$255,430,920.00	$2,500	104374	$260,878,760.00	$30,686,260.00	($2,617,283,740.00)
Tresiba	$1,852.70		606,000	121200	$224,547,240.00	$2,800	79054	$221,288,384.00	($36,527,216.00)	($3,002,253,616.00)
Truvada	$18,702.39		22,000	4400	$82,290,516.00	$2,500	13824	$34,504,316.00	($195,688,184.00)	($2,843,658,184.00)
Xarelto	$4,495.76		860,000	172000	$773,270,720.00	$2,500	261249	$653,068,560.00	$422,876,060.00	($2,225,093,940.00)
Zetia	$3,382.19		860,000	172000	$581,736,680.00	$2,500	222279	$555,642,600.00	$325,450,100.00	($2,322,519,900.00)
Zytiga	$74,685.00		3,671	734	$54,833,727.00	$2,500	21172	$52,875,768.70	($177,316,731.30)	($2,825,286,731.30)

⸸ This number is calculated by dividing the total presumed savings by the cost of testing.
⸸ This number is calculated by dividing the number of doses that could be tested (exhausting the presumed cost savings) by the total number of imported doses.
ᔓ This number is calculated by multiplying the cost of testing by the total number of imported doses.
♦ This number is calculated by subtracting the presumed cost savings from the cost of testing all imported doses.
Source: Author's calculations.

V. ISSUES AFFECTING COST NOT STUDIED

There are several issues that will certainly impact the cost of an importation program that are not included in this study. These issues are beyond the scope of this work, but will undoubtedly reduce the estimated cost savings. These include: shortages, quality controls, legal liability, post-sale pharmacovigilance, and the implementation cost. Each is briefly addressed here in turn.

Shortages

Importation schemes will be unable to supply the quantities of drugs demanded by U.S. consumers and shortages are virtually guaranteed to occur. Fundamentally, Canada does not have a sufficient supply of drugs to satisfy American demand. Canada's population is just one-ninth of the US population. That is, 37 million people, compared to 318 million in the United States. Annually, 627 million prescriptions are dispensed in Canada, while 4.4 billion are dispensed in the US. If 100% of US prescriptions were filled in Canada, the annual Canadian drug supply would be exhausted in just 52 days. (Shepherd, 2018) (link here)

In addition, it is important to recognize that drug shortages are already a significant problem in Canada (DrugShortagesCanada, 2019) (link here). Drug shortages have become a chronic problem for the Canadian healthcare system. In a single week in September 2018, 25 drugs were added to the drug shortage list (Crowe, 2018). "As Canada continues to grapple with a relentless stream of drug shortages, one in four adults in the country has either personally been affected in the last three years or knows someone who has, according to a survey commissioned by the Canadian Pharmacists Association." (Ireland, 2018) (link here)

The Canadian market receives a supply of medicines designed to meet the needs of Canada. There will not be sufficient quantities to export to the United States. Moreover, one can imagine backlash against such efforts as Canadians begin to experience shortages of drugs because the supply went to the U.S.

Quality Controls in a Foreign Country

The U.S. Food and Drug Administration expends tremendous resources in their efforts to maintain the safety and security of the pharmaceutical supply chain. It would be impossible for them, or a state entity, to enforce quality controls in Canada. They do not have the resources or the jurisdiction to do so. Moreover, given the global nature of the international pharmaceutical market, enforcing quality controls in Canada would be insufficient. The efforts would need to be global, extending to every country producing or transshipping drugs.

Legal Liability

Given the risks of obtaining a counterfeit drug and the associated medical consequences, states must consider their legal liability. Since the medicines are obtained outside of the regulated supply chain, the pharmaceutical manufacturer is unable to guarantee the quality of their products. Arguably, they may not be held responsible for the quality of imported drugs. If the legal liability rests with the state, the expense of insuring against adverse events must be incorporated into the cost of an importation program.

Post-Sale Pharmacovigilance

Post-sale pharmacovigilance is a critical element of safeguarding the pharmaceutical supply chain and ensuring that medicines are safe and effective. Given that the drugs are purchased outside of the legitimate supply chain the manufacturer has lost the ability to guarantee the quality or the responsibility for pharmacovigilance. The question remains "who is responsible for post-sale pharmacovigilance?" The costs associated with establishing such a program must be accounted for, and again, will reduce the estimated cost savings.

Implementation cost

The implementation costs of an importation program will increase the cost of the program and reduce the estimated savings. According to George Karavetsos, the former head of the FDA's Office of Criminal Investigation, the implementation costs of a state importation program will be significant. He notes that "our drug supply is safe because of efforts in the area of licensing and enforcement of the FDA. Just the enforcement division alone, which [he] ran, has an annual budget of over $75 million dollars. The division of the FDA that conducts inspections and quality initiatives has a budget of at least three times that." (Karavetsos, 2019) Granted, these figures finance a national program. Nevertheless, a state program will necessarily have to duplicate many of the federal functions and the costs will be in accordance with that.

VII. CONCLUSIONS

This study evaluates the cost savings generated by pharmaceutical importation programs. The focus here is on the potential savings resulting from the purchase of drugs from both an online Canadian supplier and a brick-and-mortar Canadian pharmacy. This analysis is done for a typical patient and also for a "Representative State". Importantly, the analysis incorporates the cost of an adverse medical event as well as the cost of "testing drugs into safety". These data establish that pharmaceutical importation does not ultimately result in cost savings when the expense of treatment failure and quality testing are included in the calculus.

In the case of an online Canadian supplier, for the 24 drugs analyzed, patients would need to acquire the cost savings over a period of up to 111 years to cover the costs of one adverse event. Not surprisingly, for the few drugs for which the savings exceed the cost of treating an adverse

medical event, the expense of an adverse medical event is modest (less than $50,000). For the majority of drugs, the cost of treating an adverse event will significantly exceed $50,000 and may reach more than $800,000. For a "Representative State", in the presence of an adverse medical event, the presumed savings from an online Canadian supplier are exhausted in the treatment of only one patient in the case of Nexium, to 24,318 adverse events for patients in the case of Advair. Further, the analysis shows that the cost of testing (99.999% confidence level with 99.999% reliability) exceeds the presumed cost savings in all cases, from more than two times the presumed costs savings to more than 34,000 times. Importantly, the assumptions underlying this analysis were biased against this finding, resulting in a likely underestimation of the true cost of pharmaceutical importation programs.

The analysis presented for a brick-and-mortar Canadian pharmacy mirrors the results for an online Canadian supplier. Again, the true savings of pharmaceutical importation is evaluated in multiple contexts: relative to the occurrence of an adverse medical event, relative to the cost of testing, on a per-patient basis and for a "Representative State". These data establish that pharmaceutical importation does not ultimately result in cost savings when the expense of treatment failure and quality testing are included in the calculus. For a "Representative State", in the presence of an adverse medical event, the presumed savings from a brick-and-mortar Canadian pharmacy are exhausted in the treatment of only one patient in the case of Nexium and after 28,137 adverse medical events in the case of Advair . Further, the analysis shows that the cost of testing (99.999% confidence level with 99.999% reliability) exceeds the presumed cost savings: testing costs range from 248% the presumed cost savings (Nexium) to 6,238,180% the presumed cost savings (Orencia).

Pharmaceutical importation plans are politically attractive, but realistically dangerous and expensive if implemented safely. The risks seem too great to justify the presumed cost savings that would quickly evaporate in the face of adverse medical events or a serious attempt to truly test the quality of the imported drugs. While purchasing price-controlled medicines from a Canadian supplier does deliver some cost savings, it also involves significant risk. Instead of lowering prices for patients these pharmaceutical importation schemes can be expected to both harm patients and cost them more than the presumed importation savings. Ultimately, the numbers demonstrate that pharmaceutical importation fails to deliver cost savings.

BIBLIOGRAPHY

American College of Rheumatology. "Statistics: Prevalence Statistics," webpost, 2019. Available at: https://www.rheumatology.org/Learning-Center/Statistics/Prevalence-Statistics

American Thoracic Society. "Pulmonary Hypertension," chapter 17 in Breathing in America: Diseases, Progress and Hope, online post, 2010. Available at: https://www.thoracic.org/patients/patient-resources/breathing-in-america/resources/chapter-17-pulmonary-hypertension.pdf

Bentley, T. Scott and Steven J. Phillips. "Milliman Research Report: 2017 U.S. organ and tissue transplant cost estimates and discussion," Milliman, August 2017. Available at: http://www.milliman.com/uploadedFiles/insight/2017/2017-Transplant-Report.pdf

Blume, S.W. and J.R. Curtis. "Medical costs of osteoporosis in the elderly Medicare population," Osteoporosis International, June 2011, vol.22, no 6, pp. 1835-1844. Available at: https://www.ncbi.nlm.nih.gov/pubmed/21165602

Burgos-Pol, R., J.M. Martinex-Sesmero, J.M. Ventura-Cerda, I.Elias, M.T. Caloto, and M.A. Casado. "The Cost of Psoriasis and Psoriatic Arthritis in 5 European countries: A Systematic Review, Actas dermo-sifiliográficas, September 2016, vol. 107, no.7, pp.577-590. Available at: https://www.ncbi.nlm.nih.gov/pubmed/27316590

Center for Disease Control and Prevention (CDC). "Atrial Fibrillation Fact Sheet," webpost, August 22, 2017. Available at: https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm

Centers for Disease Control and Prevention, (CDC). "Attention-Deficit/Hyperactivity Disorder," webpost, September 21, 2018. Available at: https://www.cdc.gov/ncbddd/adhd/data.html

Centers for Disease Control and Prevention (CDC). "Chronic Obstructive Pulmonary Disease (COPD)," webpost, June 5, 2018. Available at: https://www.cdc.gov/copd/data.html

Center for Disease Control and Prevention (CDC). "High Cholesterol Facts," webpost, December 6, 2018. Available at: https://www.cdc.gov/cholesterol/facts.htm

Center for Disease Control and Prevention (CDC). "HIV/AIDS," webpost, November 16, 2018. Available at: https://www.cdc.gov/hiv/statistics/overview/index.html

Center for Disease Control and Prevention (CDC). "HIV Cost-effectiveness," webpost, March 8, 2018. Available at: https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html

Centers for Disease Control and Prevention. (CDC, National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation). "National Diabetes Statistics Report, 2017: Estimates of Diabetes and Its Burden in the United States," webpost,

2017. Available at: https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

Center for Disease Control and Prevention (CDC). "United States Cancer Statistics: Data Visualizations," webpost, 2019. Available at: https://gis.cdc.gov/Cancer/USCS/DataViz.html

Center for Disease Control and Prevention (CDC). "Viral Hepatitis," webpost, April 30, 2018. Available at: https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm

Crowe, Kelly. "It's not just the EpiPen. Canada had 25 new drug shortages this week alone," CBC News, September 18, 2018. Available at: https://www.cbc.ca/news/health/second-opinion-drug-shortages180908-1.4815355

Desai, Dimpi, Dhruv Mehta, Priyanka Mathias, Gopal Menon, and Ulrich K. Schubart. "Health Care Utilization and Burden of Diabetic Ketoacidosis in the U.S. Over the Past Decade: A Nationwide Analysis," Diabetes Care, August 2018, no.41, no.8, pp.1631-1638. Available at: http://care.diabetesjournals.org/content/41/8/1631.long

DrugShortagesCanada.ca. Available at: https://www.drugshortagescanada.ca/

Ernstsson, Olivia, Hanna Gyllensten, Kristina Alexanderson, Petter Tinghog, Emille Friberg, and Anders Norfund. "Cost of Illness of Multiple Sclerosis – A Systematic Review," PLOS One, July 13, 2016. Available at: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0159129

Endocrine Society. "Endocrine Facts and Figures," webpost, 2019. Available at: http://endocrinefacts.org/health-conditions/thyroid/4-hyperthyroidism/

Fair Health Consumer. "Estimate your healthcare expenses," webpost, 2019. Available at: https://www.fairhealthconsumer.org/

Giacomino, Bria, Peter Cram, Mary Vaughan-Sarrazin and Saket Girotra. "Abstract 208: Association of Hospital Prices for Coronary Artery Bypass Graft Surgery with Hospital Quality and Reimbursement," Circulation: Cardiovascular Quality and Outcomes, May 1, 2015, vol.8, no. supplement 2, pg.8. Available at: https://www.ahajournals.org/doi/abs/10.1161/circoutcomes.8.suppl_2.208

GoodRX. Website providing drug pricing information, 2019. Available at: https://www.goodrx.com/

Gottlieb, Scott. "What Trump Should Have Said on Drug Prices," Forbes, webpost, March 4, 2016. Available at: https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/#a11a1d72e747

Guarascio, Anthony J., Shauntá M. Ray, Christopher K. Finch and Timothy H. Self. "The Clinical and Economic Burden of Chronic Obstructive Pulmonary Disease in the USA,"

ClinicoEconomics and Outcomes Research, 17 June 2013, vol. 5, pp.235-245. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3694800/

Harding, Anne. "A type of drug used by 50 million Americans has been linked to an increased risk of death," Business Insider, Reuters, webpost, July 5, 2017. Available at: https://www.businessinsider.com/r-heartburn-drugs-tied-to-greater-mortality-2017-7

Ireland, Nicole. "'Unprecedented' drug shortages affecting many Canadians, new survey suggests," webpost, CBC News, December 10, 2018. Available at: https://www.cbc.ca/news/health/canadian-pharmacists-association-drug-shortage-survey-1.4938557

IsraelPharm. "USA vs Canada vs Israel Drug Prices," webpost, 2017. Available at: http://www.israelpharm.com/blog/canada-vs-israel-drug-price-comparison/

Karavetsos, George. Testimony to the Colorado House of Representatives, Denver, Colorado, April 17, 2019.

Kirson, Noam Y., Howard G. Birnbaum, Jasmina I. Ivanova, Tracy Waldman, Matt Schiller, N. Joish Vijay, and Todd Williamson. "Pulmonary Arterial Hypertension (PAH): Direct Cost of Illness in the US Privately Insured Population, Chest Journal, October 2010, vol.138, no.4, Supplement, pp.376A. Available at: https://journal.chestnet.org/article/S0012-3692(16)42051-9/fulltext

Louie, Grant. "Psoriatic Arthritis," Johns Hopkins Arthritis Center, webpost, August 28, 2017. Available at: https://www.hopkinsarthritis.org/arthritis-info/psoriatic-arthritis/

Mariotto, A.B., K.R. Yabroff, Y. Shao, E.J. Feuer, and M.L. Brown. "Projections of the Cost of Cancer Care in the United States: 2010-2020," Journal of the National Cancer Institute, January 19, 2011, vol.103, no.2, pp.117-128. Available at: https://www.ncbi.nlm.nih.gov/pubmed/21228314

Marks Marine Pharmacy. Available at: https://rxcanada4less.com/

Medicaid.gov. "October 2018 Medicaid & CHIP Enrollment Data Highlights," webpost, 2019. Available at: https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html

Melly, Ludovic, Gianluca Torregrossa, Timothy Lee, Jean-Luc Jansens, and John D. Puskas. "Fifty years of coronary artery bypass grafting," Journal of Thoracic Disease, March 2018, vol.10, no.3, pp.1960-1967. Available here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5906252/

Minitab. "How Many Samples Do You Need to Be Confident Your Product Is Good?" webpost, July 12, 2017. Available at: https://blog.minitab.com/blog/the-statistical-mentor/how-many-samples-do-you-need-to-be-confident-your-product-is-good

National Academy for State Health Policy (NASHP). "Will States Save by Importing Drugs from Canada? Yes, Here's How," webpost, 2017. Available at: https://nashp.org/wp-content/uploads/2017/11/drug-infographic-2.pdf

National Cancer Institute. "Cancer Prevalence and Cost of Care Projections: Annualized Mean Net Costs of Care per Patient," 2011. Available at: https://costprojections.cancer.gov/annual.costs.html

National Institute of Mental Health. "Schizophrenia," webpost, May 2018. Available at: https://www.nimh.nih.gov/health/statistics/schizophrenia.shtml#part_154880

National Multiple Sclerosis Society. "MS Prevalence," webpost, 2019. Available at: https://www.nationalmssociety.org/About-the-Society/MS-Prevalence

National Osteoporosis Foundation. "NOF Releases Updated Data Detailing the Prevalence of Osteoporosis and Low Bone Mass in the U.S." webpost, June 2, 2014. Available at: https://www.nof.org/news/54-million-americans-affected-by-osteoporosis-and-low-bone-mass/

National Psoriasis Foundation "Statistics," webpost, 2018. Available at: https://www.psoriasis.org/content/statistics

NMS Labs. Available at: https://www.nmslabs.com/

O'Neal, Seth E. and Robert H. Flecker. "Hospitalization Frequency and Charges for Neurocysticercosis, United States, 2003-2012," Emerging Infectious Diseases, June 2015, vol.21, no.6. Available at: https://wwwnc.cdc.gov/eid/article/21/6/14-1324_article

Partnership for Safe Medicines. "Counterfeit Drugs Harm Real People. We're Collecting Their Stories," webpost, May 2019. Available at: https://www.safemedicines.org/victim-tragedies

Patel, D.A., D.A. Holdford, E. Edwards, and N.V. Carroll. "Estimating the Economic Burden of Food-Induced Allergic Reactions and Anaphylaxis in the United States," Journal of Allergy and Clinical Immunology, vol.128, no.1, July 2011, pp.110-115.e5. Available at: https://www.jacionline.org/article/S0091-6749(11)00431-3/pdf

Pharmaceutical Security Institute (PSI). "Counterfeiting Situation: Therapeutic Categories," webpost, 2019. Available at: http://www.psi-inc.org/therapeuticcategories.cfm

Reveille, John D. "Epidemiology of Spondyloarthritis in North America," American Journal of Medical Sciences, April 2011, vol.341, no.4, pp. 284–286. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0002962915313197?via%3Dihub

Rheinstein, Peter H. M.D., J.D., M.S., President, Severn Health Solutions, personal communication with author, February 2019.

Roe, Gina. "Utah insurer plans to send patients to Mexico for cheaper medicine," KUTV.com, webpost, October 29, 2018. Available at: https://kutv.com/news/local/utah-insurer-plans-to-send-patients-to-mexico-for-cheaper-medicine

Selvin, E., A.L. Burnett, and E.A. Platz. "Prevalence and risk factors for erectile dysfunction in the US," American Journal of Medicine, February 2007, vol.120, no.2, pp.151-157. Available at: https://www.ncbi.nlm.nih.gov/pubmed/17275456

Shepherd, Marv "U.S. Drug Importation: Impact on Canada's Prescription Drug Supply," Health Economics and Outcome Research: Open Access, vol.4, no.1, 2018. Available at: http://www.safemedicines.org/wp-content/uploads/2017/08/us-drug-importation-impact-on-canadas-prescription-drug-supply-2471-268X-1000146.pdf

Sun, Lena H. " They went to Mexico for surgery. They came back with a deadly superbug," The Seattle Times, January 23, 2019. Available at: https://www.seattletimes.com/nation-world/they-went-to-mexico-for-surgery-they-came-back-with-a-deadly-superbug/

U.S. Bureau of Labor Statistics. "CPI Inflation Calculator," webpost. Available at: https://www.bls.gov/data/inflation_calculator.htm

U.S. Census Bureau. U.S. and World Population Clock, website. Accessed March 2019. Available at: https://www.census.gov/popclock/

U.S. Food and Drug Administration Office of Criminal Investigations. "April 13, 2018: Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States," webpost, April 13, 2018. Available here: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/april-13-2018-canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs

Westpak. "Sample Size for Attributes When C=0," webpost. Accessed on May 28, 2019. Available at: https://www.westpak.com/page/resources/calculator/sample-size-for-attributes-when-c-is-zero

Whitehead, Nadia. "Why A Pill That's 4 Cents In Tanzania Costs Up To $400 In The U.S.," NPR.org, webpost, December 11, 2017. Available at: https://www.npr.org/sections/goatsandsoda/2017/12/11/567753423/why-a-pill-thats-4-cents-in-tanzania-costs-up-to-400-in-the-u-s

Wright, Nicole C., Anne C. Looker, Kenneth G. Saag, Jeffrey R. Curtis, Elizabeth S. Delzell, Susan Randall, and Bess Dawson-Hughes. "The Recent Prevalence of Osteoporosis and Low Bone Mass in the United States Based on Bone Mineral Density at the Femoral Neck or Lumbar Spine," Journal of Bone and Mineral Research, November 2014, vol.29, no.11, pp.2520-2526. Available at: https://onlinelibrary.wiley.com/doi/full/10.1002/jbmr.2269

Zhu, Baojin, Haya Ascher-Svanum, Doublas E. Faries, Xiaomei Peng, David Salkever, and Eric P. Slade. "Costs of treating patients with schizophrenia who have illness-related crisis events,"

BMC Psychiatry, 2008, vol.8, p.72. Available at:
https://bmcpsychiatry.biomedcentral.com/articles/10.1186/1471-244X-8-72

APPENDIX A

Description of the indications for each drug and the consequences of receiving an ineffective dose. Compiled by Dr. Peter H. Rheinstein, M.D., J.D., M.S., President, Severn Health Solutions.

	Drug	Generic Name	Dosage Form	Generic Available?	BLACK BOX	Indications	Consequences if Ineffective	Remarks
1	Abilify Oral Long Acting	aripiprazole	 Tablets Deep IM	 Yes No	Yes	Schizophrenia, Bipolar I	Recurrence of Symptoms, Rehospitalization, Suicide attempts in severely depressed	Abilify Maintena is once a month deep IM injection that allows some patients to be released from and stay out of institutions; Labeling states Deep IM injection s to be given by health care provide only.
2	Actos	pioglitazone	Tablets	Yes	Yes	Type 2 Diabetes Mellitus	Increased Blood Sugar may result in end organ damage without warning, Diabetic ketoacidosis may require hospitalization.	
3	Advair	fluticasone/ salmeterol inhalation	Metered aerosol Powder	 No One Only	No	Asthma, COPD	Increased shortness of breath may result in Emergency Room visits; Adrenal Insufficiency may be fatal	See warnings in Advair Patient Info regarding sudden discontinuation. First generic (Mylan) approved 1/30/2019
4	Albenza	albendazole	Oral Tablets	Yes	No	Neurocysticercosis (pork tapeworm) Cystic echinocccosis (Hydatid Disease, dog tapeworm)	Epilepsy (neurocysticercosis) Cysts in Liver and Lungs – Sometimes Fatal (hydatid disease)	Requires monthly blood test during treatment. Untreated tapeworm infestation also can be spread through human feces (https://www.who.int/taeniasis/transmission/en)
5	Ampyra	dalfampridine	Tablets	Yes	No	Improves walking speed in multiple sclerosis	Patients may be more disabled requiring more personal care	
6	Augmentin	amoxicillin/ clavulanate	Tablets Suspension	Yes	No	Antibacterial (lower respiratory tract, acute otitis media. sinus, skin, urinary)	Infection worsens – May lead to hospitalizations	One of the most frequently prescribed antibacterial agents.
7	Aubagio	teriflunomide	Tablets	No	Yes	Relapsing Multiple Sclerosis	Faster progression of multiple sclerosis and disability	
8	Avonex	interferon beta-1a	IM injection	No	No	Relapsing Multiple Sclerosis	More relapses with faster progression of disability	IM injection once weekly x 4, then once monthly
9	Celebrex	celecoxib	Oral capsules	Yes	Yes	OA, RA, JRA, ankylosing spondylitis, acute pain, primary dysmenorrhea	Symptoms not relieved	
10	Cialis	tadalafil	Tablets	No	No	Erectile Dysfunction benign prostatic hypertrophy	Erectile Failure, Anxiety Possible Acute Urinary Retention with ER visits and catheterization	Pharmacologic treatment of BPH has greatly reduced the need for prostate surgery
11	Copaxone	glatiramer	SQ Injection	Two only	No	Relapsing Multiple Sclerosis	Faster progression of multiple sclerosis and disability	Dose is 20 mg daily or 40 mg three times per weeks
12	Crestor	rosuvastatin	Tablets	Yes	No	Reduce high triglycerides and high cholesterol; slow progression of atherosclerosis; reduce risk of stroke, myocardial infarction, arterial revascularization procedures	Faster progression of atherosclerosis with increased incidence of stroke, myocardial infarction and revascularization surgery	Progression of disease may be insidious until irreversible damage has occurred.
13	Eliquis	apixaban	tablets	No	Yes	reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation;	Increased risk of thrombotic events (stroke, pulmonary embolus, systemic emboli); Recurrence of Deep Vein Thrombosis	Package insert explicitly states risk of sudden discontinuation (which would be the result of taking an ineffective

						prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery; treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy		counterfeit product). Permanent injury and disability could occur without warning
14	Enbrel	etanercept	SQ Injection	One biosimilar	Yes	Rheumatoid Arthritis (RA); Polyarticular Juvenile Idiopathic Arthritis (JIA); Psoriatic Arthritis (PsA); Ankylosing Spondylitis (AS); Plaque Psoriasis (PsO) in patients 4 years or older	Worsening of symptoms and disease progression.	SQ injection once weekly for most indications Enbrel is disease modifying so that an ineffective counterfeit medication may lead to actual; disease progression in addition to increased symptoms.
15	EpiPen	epinephrine	Autoinjector (SQ and/or IM)	One Only	No	Emergency treatment of anaphylaxis	Worsening tachycardia with fall in blood pressure, convulsions, wheezing, dyspnea, angioedema possibly fatal	Defective autoinjector may result in delay of administering lifesaving medication even if effective drug is present in counterfeit injector
16	Forteo	teriparatide	SQ injection	No	Yes	Postmenopausal osteoporosis in women; increase of bone mass in men with primary or hypogonadal osteoporosis; osteoporosis due to glucocorticoid therapy	Fractures of Hips, Back, Other Bones resulting in hospitalization and surgery; Irreversible progression of osteoporosis	Once daily injection from 28-day device; Progression of osteoporosis may not be apparent until fracture occurs. Hip fractures in older women are followed by death within one year in a significant percentage of patients.
17	Gilenya	fingolimod	Capsules	No	No	Relapsing Multiple Sclerosis	Faster progression of multiple sclerosis and disability	Label states "first dose of GILENYA in a setting in which resources to appropriately manage symptomatic bradycardia are available. Monitor all patients for 6 hours after the first dose for signs and symptoms of bradycardia with hourly pulse and blood pressure measurement."
18	Harvoni	ledipasvir/ sofosbuvir	Tablets	No	Yes	Treatment of Certain Patients with Hepatitis C	Progression of hepatitis C with need for liver transplant; may be fatal; primary (hepatocellular) liver cancer	Ineffective treatment may result in persistence of infection and spread of Hepatitis C to other individuals
19	Humira	adalimumab	SQ Injection	One biosimilar (not approved for all uses)	Yes	Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Adult Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis, Hidradenitis Suppurativa, Uveitis	Worsening of symptoms with faster progression of underlying disease.	SQ injection every other week in most patients, SQ injection once weekly in some RA patients. Humira is disease modifying so that an ineffective counterfeit medication may lead to actual; disease progression in addition to increased symptoms.
20	Januvia	sitagliptin	Tablets	No	No	Type 2 Diabetes Mellitus	Increased Blood Sugar may result in end organ damage without warning, Diabetic ketoacidosis may require hospitalization.	Also sold in combination with ertugliflozin (Steglujan) and metformin (Janumet)
21	Letairis	ambrisentan	Tablets	No	No	Pulmonary Arterial Hypertension (PAH)	Reduced exercise ability; Disease progression and hospitalization	Labeled indication is "reduce the risks of disease progression and

								hospitalization for worsening PAH, and to improve exercise ability."
22	Lipitor	atorvastatin	Tablets	Yes	No	Reduce the risk of MI, stroke, revascularization procedures in adult patients and in some patients age 10-17; Reduces elevated total-C, LDL Cholesterol, apo-B, and triglyceride levels	Increased risk of MI, stroke, revascularization procedures; progression of atherosclerosis; Patients with very high triglycerides may be at increased risk of pancreatitis	Prescribing information actually states that Lipitor reduces risk of MI, stroke, and revascularization procedures in addition to lowering cholesterol and triglycerides. These conditions may result in hospitalizations, permanent disability and/or death. Atorvastatin is also sold in combination with amlodipine (Caduet) and ezetimibe (formerly Liptruzet, now only generics).
23	Lyrica	pregabalin	Capsules; Controlled Release Tablets, Solution	No	No	Diabetic Peripheral Neuropathy; Post Herpetic Neuralgia; Partial Onset Seizures; Fibromyalgia; Neuropathic pain from Spinal Cord Injury	Return of pain from DPH, PHN, fibromyalgia, and spinal cord injury with disability and absence from work. Loss of control of partial onset seizures.	Unexpected recurrence of seizures may lead to motor vehicle and on-the-job accidents with injuries to the patient and to others.
24	Nexium	omeprazole	Tablets, Capsules, Suspension, IV	Yes No No No	No	GI Reflux Disease, Risk reduction of NSAID-associated gastric ulcer, H. pylori eradication to reduce risk of duodenal ulcer recurrence, pathological hypersecretory conditions including Zollinger-Ellison Syndrome; Nexium IV is used to reduce risk of rebleeding after endoscopic treatment for acute bleed gastric or duodenal ulcers	Formation or recurrence of gastric and duodenal ulcers with blood loss – sometimes requiring surgery and hospitalization. Untreated esophagitis can lead to changes in the structure of the esophagus increasing the risk of cancer. (https://www.mayoclinic.org/diseases-conditions/esophagitis/symptoms-causes/syc-20361224)	Tablets are also available OTC
25	Orencia	abatacept	IV injection SQ injection	No	No	Adult Rheumatoid Arthritis (RA); Juvenile Idiopathic Arthritis; Adult Psoriatic Arthritis (PsA)	Worsening of symptoms and disease progression.	Lyophilized powder for IV Prefilled syringes and autoinjector SQ Orencia is disease modifying so that an ineffective counterfeit medication may lead to actual; disease progression in addition to increased symptoms.
26	Otezla	apremilast	Tablets	No	No	Psoriatic Arthritis, Plaque Psoriasis	Worsening of tender and swollen joint counts; worsening or return of skin lesions	Twice daily with dosage titration in first week
27	Premarin	conjugated estrogens	Tablets IV Injection IM Injection Vaginal Cream	No	Yes	Tablets are used for Vasomotor Symptoms due to Menopause; Hypoestrogenism due to Hypogonadism, Castration or Primary Ovarian Failure; Palliation of Metastatic Disease; Prevention of Postmenopausal Osteoporosis IV is used for short term treatment of abnormal uterine bleeding Cream is used for symptoms of vulvar and vaginal atrophy due to menopause	Failure to relieve symptoms, progression of osteoporosis with fractures, hospitalization, surgery and disability; IV – failure to control uterine bleeding	Lyophilized powder is for injection Also sold in combination with medroxyprogesterone Progression of osteoporosis may be insidious until irreversible damage has occurred.
28	Revatio	sildenafil	Tablets Suspension	Yes No	No	Pulmonary Arterial Hypertension (PAH)	Reduced exercise ability; Disease progression and hospitalization	Labeled indication is "improve exercise ability and delay clinical worsening"

			IV Injection	One Only				IV injection is for patients "temporarily unable to take oral medication" Same active ingredient as Viagra.
29	Sovaldi	sofosbuvir	tablets	No	Yes	Treatment of Certain Patients with Hepatitis C	Progression of hepatitis C with need for liver transplant; may be fatal; primary (hepatocellular) liver cancer	Ineffective treatment may result in persistence of infection and spread of Hepatitis C to other individuals. Also sold in combination with ledipasvir Harvoni – see above), velpatasvir (Epclusa) and velpatasvir + voxilaprevir (vosevi).
30	Stelara	ustekinumab	IV Injection SQ Injection	No	No	Psoriasis (Ps), Psoriatic Arthritis (PsA); Crohn's Disease (CD)	Worsening of symptoms and disease progression.	Dosing: Psoriasis SQ to start, at 4 weeks, then q 12 weeks; Crohn's IV to start, then SQ q 8 weeks X
31	Stendra	avanafil	tablets	No	No	Erectile Dysfunction	Erectile Failure, Anxiety	
32	Strattera	atomoxetine	Capsules	Yes	No	ADHD	Behavioral Problems; Difficulties in School	
33	Synthroid	levothyroxine	tablets	Yes	Yes	Hypothyroidism; Adjunct in treatment of TSH dependent thyroid cancer	Recurrence of symptoms of hypothyroidism including depression, weight gain, infertility, heart failure; Progression of thyroid cancer	
34	Tecfidera	dimethyl fumarate	capsules	No	No	Relapsing multiple sclerosis	Faster progression of multiple sclerosis and disability	Delayed-release capsules are important for efficacy because half-life of active ingredient is short.
35	Tresiba	insulin degludec	SQ injection	No	No	Diabetes Mellitus (Type 1 or Type 2)	Increased Blood Sugar may result in end organ damage without warning, Diabetic ketoacidosis may require hospitalization	FlexTouch pen delivers prescribed amount Also sold in multiple-dose vial
36	Triumeq	abacavir/ dolutegravir/ lamivudine	tablets	No	Yes	Treatment of HIV-1 Infection	Progressions of AIDS with disability and death	Ineffective treatment may result in persistence of infection and spread of Human Immunodeficiency Virus to other individuals. Individual ingredient are sold separately, but there is no generic form of dolutegravir.
37	Truvada	Emtricitabine/ tenofovir disoproxil fumarate	Tablets	No – Only approved generic discontinued	Yes	Treatment of HIV-1 infection; HIV-1 Pre-Exposure Prophylaxis	Progressions of AIDS with disability and death; New HIV-1 infection in patients who believed themselves to be protected	Ineffective treatment may result in persistence of infection and spread of Human Immunodeficiency Virus to other individuals. Ineffective prophylaxis may result in patients who believed themselves protected contracting HIV,
38	Xarelto	rivaroxaban	tablets	No	Yes	reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery; treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy; Reduction of Risk of Major	Increased risk of thrombotic events (stroke, pulmonary embolus, systemic emboli); Recurrence of Deep Vein Thrombosis	Package insert explicitly states risk of sudden discontinuation (which would be the result of taking an ineffective counterfeit product). Permanent injury and disability could occur without warning.

						Cardiovascular Events in Patients with Chronic Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD)		
39	Zetia	ezetimibe	Tablets	Yes	No	Reduction of elevated cholesterol and lipids	Label states, "The effect of ZETIA on cardiovascular morbidity and mortality has not been determined." However, patients with elevated cholesterol and lipid are at increased risk of MI, stroke, revascularization procedures; progression of atherosclerosis; Patients with very high triglycerides may be at increased risk of pancreatitis	Permanent injury and disability could occur without warning. Also sold in combination with simvastatin.(Vytorin) and atorvastatin (formerly Liptruzet, now only generics)
40	Zytiga	abiraterone	Tablets	Yes 250 No 500	No	Metastatic prostate cancer	Earlier disease progression and shorter patient survival	

APPENDIX B

Quote for the cost of testing drug quality: Assay, Dissolution Rate, Content Uniformity, Sterility. Provided by NMS Labs.

Quote for Testing Drug Quality

Products				COSTS for testing by test for a single batch (multiple batches reduce price by -0.5% each additional batch)					
	Product Type/Delivery System	Dosages	Total # of all dosages	Assay	Dissolution Rate	Content Uniformity	Sterility	Price for Testing Each Dose	Price for all Doses Once
Abilify	Tablets and Oral Solution	2, 5, 10, 15, 20, 30mg +30mg/ml	7	$600	$1,200	$1,200	$1,000	$4,000	$28,000
Actos	Tablets	15, 30, 45mg	3	$500	$1,000	$1,000		$2,500	$7,500
Advair	Inhaled powder and aerosol	50, 100, 115, 125, 150, 200, 230,250, 500 mcg	9	$1,100		$2,000	$1,000	$4,100	$36,900
Albenza	Tablets	200, 400mg	2	$500	$1,000	$1,000		$2,500	$5,000
Augmentin	Tablets and Oral Solution	500, 875, 1000, 100, 150, 200mg	6	$600	$1,200	$1,200		$3,000	$18,000
Ampyra	Tablets	10mg	1	$500	$1,000	$1,000		$2,500	$2,500
Aubagio	Tablets	7, 14mg	2	$500	$1,000	$1,000		$2,500	$5,000
Celebrex	Tablets	50, 100, 200, 400mg	4	$500	$1,000	$1,000		$2,500	$10,000
Cialis	Tablets	2.5, 5, 10, 20, 40, 60mg	6	$500	$1,000	$1,000		$2,500	$15,000
Crestor	Tablets	5, 10, 20, 40mg	4	$500	$1,000	$1,000		$2,500	$10,000

Eliquis	Tablets	2.5, 5mg	2	$500	$1,000	$1,000		$2,500	$5,000
Enbrel	Injection Syrine	50mg/ml	1	$600		$1,200	$1,000	$2,800	$2,800
EpiPen	Injection Syringe	0.3, 0.15mg	2	$600		$1,200	$1,000	$2,800	$5,600
Gilenya	Tablets	0.5mg	1	$500	$1,000	$1,000		$2,500	$2,500
Harvoni	Tablets	400mg	1	$500	$1,000	$1,000		$2,500	$2,500
Januvia	Tablets	25, 50, 100mg	3	$500	$1,000	$1,000		$2,500	$7,500
Letairis	Tablets	5, 10, 20, 40mg	4	$500	$1,000	$1,000		$2,500	$10,000
Lipitor	Tablets	10, 20, 40, 80mg	4	$500	$1,000	$1,000		$2,500	$10,000
Nexium	Tablets and Oral Suspension	2.5, 5, 10, 20, 40mg	5	$600	$1,200	$1,200		$3,000	$15,000
Orencia	Injection Syringe	125mg/ml	1	$600		$1,200	$1,000	$2,800	$2,800
Otezla	Tablets	10, 20 30mg	2	$500	$1,000	$1,000		$2,500	$5,000
Premarin	Oral Tablet and Vaginal Cream	0.3, 0.625, 0.9, 1.25mg	4	$600	$1,000	$1,000		$2,600	$10,400
Revatio	Tablets and Injection Syringe	20, 50, 100mg	3	$600	$1,000	$1,000	$1,000	$3,600	$10,800
Sovaldi	Tablets	400mg	1	$500	$1,000	$1,000		$2,500	$2,500
Stendra	Tablets	100, 200mg	2	$500	$1,000	$1,000		$2,500	$5,000
Strattera	Tablets	10, 18, 25, 40, 60mg	5	$500	$1,000	$1,000		$2,500	$12,500
Synthroid	Tablets	25-200mcg	12	$500	$1,000	$1,000		$2,500	$30,000
Tecfidera	Tablets	120, 240mg	2	$500	$1,000	$1,000		$2,500	$5,000

Tresiba	Auto-injector	100u/ml	1	$600		$1,200	$1,000	$2,800	$2,800
Triumeq	Tablets	50, 300, 600mg	3	$500	$1,000	$1,000		$2,500	$7,500
Truvada	Tablets	150, 200, 300mg	3	$500	$1,000	$1,000		$2,500	$7,500
Xarelto	Tablets	15, 20mg	2	$500	$1,000	$1,000		$2,500	$5,000
Zetia	Tablets	10mg	1	$500	$1,000	$1,000		$2,500	$2,500
Zytiga	Tablets	250, 500mg	2	$500	$1,000	$1,000		$2,500	$5,000
							Totals	**$91,500**	**$313,100**

APPENDIX C

This Appendix details the sources and methodology used to calculate the expense of treating adverse events. Additional details for each calculation may be found in the original source material.

The costs presented here are estimated for the treatment of a patient for one year or a single adverse event. Given that the cost savings from buying Canadian drugs is estimated for a single year, the treatment of an adverse event is also estimated for a single year. Notably, in many cases, the cost of treatment failure will extend over many years and may present a lifelong burden. Again, this assumption biases the results against the desired finding of eliminating all cost savings.

Anaphylaxis The direct cost of anaphylaxis is estimated by Patel, et.al. (2011) in an article in the Journal of Allergy and Clinical Immunology (link here). The mean cost per patient is estimated to be $4719 (in 2007 dollars).

Care to treat Chronic Obstructive Pulmonary Disease (COPD) Failure to treat COPD, a common lung disease, results in difficulty breathing, further damage to the lungs, and disease progression. According to a 2013 study by Guarascio et al. (link here), "data indicate that with each progressive stage of COPD, as defined in a previous GOLD guideline, patients with stage I COPD experienced the lowest direct cost of $1681 per patient per year, stage II patients $5037 per patient per year, and those in stage III had the highest cost of $10,812 per patient per year." Assuming disease progression moves patients from stage I to stage II, the annual difference in direct cost is $3356 (in 2010 dollars). [Hospitalization for COPD, Healthcare Bluebook's Fair Price: $6,646 on 22 May 2019]

Coronary artery bypass grafting (CABG), Valve Repair, Complex Heart Surgery Stroke and heart attack are typical medical adverse events associated with untreated high cholesterol and heart disease. According to a recent article in the Journal Circulation by Giacomino et al. (link here), the mean price for CABG obtained from the hospitals was $151,784.64, and ranged from $44,824 - $448,039 (in 2014 dollars).

Neurocysticercosis Failure to effectively treat a pork tapeworm may result in Neurocysticercosis. A 2015 study by O'Neal and Flecker (link here) found an estimated 18,584 hospitalizations for neurocysticercosis and associated hospital charges totaling >US $908 million (between 2003 and 2012). This correlates to an average cost of treatment of $48,859 in 2012 dollars.

Diabetic ketoacidosis Failure to effectively treat diabetes may result in diabetic ketoacidosis. As described in a 2018 study by Desai et al. (link here), "[a]lthough our ability to treat diabetes and its associated complications has significantly improved, presentation with uncontrolled diabetes leading to ketoacidosis remains a significant problem." The study reviewed the National Inpatient Sample database for all hospitalizations in which DKA was the principal discharge diagnosis during 2003–2014 and calculated the population incidence by using U.S. census data. The mean hospital charges were $26,566 per admission in 2014.

Esophageal Cancer Failure to treat GI Reflux Disease may result in esophageal cancer. According to the National Cancer Institute (link here) drawing on a study by Mariotto et al. (2011) (link here), the annualized mean net costs of care per patient for esophageal cancer were $79,822 (male, $79,532 female) for the initial year and $6,450 (male, $6,853 female) annually continuing.

HIV/AIDS Failure to prevent a new HIV-1 infection may result in the contraction of HIV-1. According to the CDC (link here), the lifetime treatment cost of an HIV infection can be used as a conservative threshold value for the cost of averting one infection. Currently, the lifetime treatment cost of an HIV infection is estimated at $379,668 (in 2010 dollars).

Liver Transplant Failure to treat Hepatitis C may result in liver failure and the necessity of a liver transplant. According to a 2017 Milliman Research Report (Bentley & Phillips, 2017) (link here), the estimated US average 2017 transplant cost, the amount of billed charges for a liver transplant, was $812,500. [Healthcare Bluebook's Fair Price: $59,301]

Multiple Sclerosis Failure to effectively treat MS may result in a worsening of the disease. The cost estimates used here are based on a systematic review. The article by Ernstsson et.al. (2016) (link here) draws on the results of 1,326 publications from January 1969 to January 2014. The cost estimates were compared across 29 studies. The EDSS Classification of the disease includes groups I, II, and III. The article provides the annual cost per patient according to 2011 US dollar Purchasing Power Parity (USDPPP). The mean annual cost for group I is $22,719, for group II is $40,153, and for group III is $64,853. The difference between group I and group II is $17,434. The difference between group II and group III is $24,700. The difference between group I and group III is $42,134.

Neurocysticerocosis According to a recent CDC article (link here), between 2003 and 2012 there were an estimated 18,584 hospitalizations for neurocysticercosis with associated hospital charges totaling >US $908 million. This equates to approximately $48,859 per hospitalization in 2012 dollars.

Osteoporosis Resulting in Fracture Failure to treat Osteoporosis may result in a fracture. According to a 2011 study by Blume and Curtis (link here), "Of 30.2 million elderly Medicare recipients in 2002. . . [the] estimated mean impact of fractures on annual medical cost was $8,600 (95% confidence interval, $6,400 to $10,800), implying a US cost of $14 billion ($10 to $17 billion)." [Healthcare Bluebook's Fair Price for a femur fracture: $8,554]

Prostate Cancer Failure to treat prostate cancer will result in earlier disease progression and shorter patient survival. According to the National Cancer Institute (link here), the cost of treating prostate cancer in the initial year is $19,710, with an additional cost of $3,201 in subsequent years. [Healthcare Bluebook's Fair Price for prostate removal: $14,075]

Psoriatic Arthritis (PsA) Treatment failure may result in worsening of symptoms and disease progression. A 2016 study by Burgos-Pol et al. (link here) aimed to assess the burden of PsA in five European countries. The authors considered both direct costs (medical and nonmedical) and indirect costs, adjusted for country-specific inflation and converted to international dollars using purchasing power parity exchange rates for 2015 ($US PPP). The study found the total annual cost per patient ranged from $10,924 to $17,050 for psoriatic arthritis. Direct costs were the largest component of total expenditure and the severity of the disease was associated with higher costs. Accordingly, the differential between the lowest cost estimate and the highest is $6126.

Pulmonary Arterial Hypertension (PAH) Failure to treat Pulmonary Arterial Hypertension (PAH) will result in the progression of the disease and worsening symptoms. According to a 2010 article in the Chest Journal (the Official Publication of the American College of Chest Physicians) (link here), mean direct patient costs in 2007 dollars were $2,023 per month. In addition, circulatory/respiratory system-related patient costs were $724 per month.

Schizophrenia Treatment failure may result in the recurrence of symptoms, rehospitalization, and suicide attempts. In a 2008 BMC Psychiatry article by Zhu et al. (link here), direct mental health treatment costs for patients who had experienced 1 or more of 5 recent crisis events were compared to propensity-matched samples of persons who had not experienced a crisis event. "Across all 5 categories of crisis events, patients who had a recent crisis had higher average annual mental health treatment costs than patients in propensity-score matched comparison samples. Average annual mental health treatment costs were significantly higher for persons who attempted suicide ($46,024), followed by persons with psychiatric hospitalization in the past 6 months ($37,329), persons with prior arrests ($31,081), and persons with violent behaviors ($18,778)." The data utilized in the study dated from 1997 to 2003. Given that no information was provided about inflation-adjustment of the costs, it is assumed that the costs are represented in 2003 dollars.

APPENDIX D

This Appendix details the sources and methodology used to calculate the disease prevalence in a representative US state. Additional details for each calculation may be found in the original source material.

Disease Prevalence

In the cases of the 14 unique adverse events listed above the calculations have been extended to provide estimates for a "representative state". The disease prevalence was determined for the entire United States. This number was then divided by 50 to calculate the number of patients for a "representative state".

Anaphylaxis According to an Asthma and Allergy Foundation of America (AAFA) study published in the Journal of Allergy and Clinical Immunology (link here), anaphylaxis, a life-threatening allergic reaction, occurs in approximately one in 50 Americans. Many believe the rate is higher, probably closer to one in 20. Dividing the population of a "representative state" by 50, this amounts to approximately 131,200 patients per state.

COPD The CDC (link here) notes that the "prevalence of COPD varies considerably by state, from <4% in Hawaii, Colorado, and Utah to >9% in Alabama, Tennessee, Kentucky, and West Virginia. States with the highest COPD prevalence are clustered along the Ohio and lower Mississippi Rivers." A conservative estimate is 6% nationally. This equates to 19,620,000 individuals nationally or approximately 392,400 patients in each US state.

Diabetes According to a recent report by the CDC (link here), an estimated 30.3 million people of all ages—or 9.4% of the U.S. population—had diabetes in 2015. Dividing this number by 50, a representative state would have 606,000 patients.

Esophageal Cancer According to the CDC (link here), each year in the United States, about 15,000 people in the United States are diagnosed with esophageal cancer. Dividing by 50, this amounts to 300 patients in each US state.

High Cholesterol necessitating CABG The CDC (link here) estimates that 55% of US adults who need cholesterol medicine are currently taking it. This amounts to 43 million people. Dividing by 50, this amounts to approximately 860,000 patients in each US state.[6]

Hepatitis C The CDC (link here) estimates that 2.4 million people in the United States are living with hepatitis C virus infection. Dividing by 50, this amounts to approximately 48,000 patients in each US state.

HIV The CDC (link here) estimates that at the end of 2015, 1.1 million persons aged 13 and older were living with HIV infection in the United States. Dividing by 50, this amounts to approximately 22,000 patients in each US state.

[6] CABG According a recent article in the Journal of Thoracic Disease (link here), Coronary artery bypass grafting (CABG) is the most commonly performed cardiac surgery procedure worldwide, representing annual volumes of approximately 200,000 isolated cases in the US. Dividing the population of a "representative state" by 50, this amounts to approximately 4,000 patients per state.

Multiple Sclerosis The National Multiple Sclerosis Society (link here) estimates that approximately one million people are living with MS in the United States. Dividing by 50, this amounts to approximately 20,000 patients in each US state.

Neurocysticerocosis According to a recent CDC article by O'Neal and Flecker (2015) (link here), between 2003 and 2012 there were an estimated 18,584 hospitalizations for neurocysticercosis. This equates to approximately 2065 per year. Dividing by 50, this is approximately 41 patients in each US state.

Osteoporosis Citing a recent article in the Journal of Bone and Mineral Research by Wright et al. (2014) (link here), the National Osteoporosis Foundation (NOF) (link here) reports that 10.2 million adults have osteoporosis. Dividing by 50, this amounts to approximately 204,000 patients in each US state.

Prostate Cancer The CDC (link here) reports that 183,529 new cases of Prostate Cancer were reported in 2015, the last year for which incidence data are available. Dividing by 50, this amounts to approximately 3,671 new cases per state.

Psoriatic Arthritis According to Louie (2017) of the Johns Hopkins Arthritis Center (link here), the prevalence of psoriatic arthritis is approximately 0.04-0.1% of the U.S. adult population. The mean value of this estimate is 0.07%. In the 2010 U.S. Census, the number of people under age 18 was 24.0% of the total population. Accordingly, the current adult population in the U.S. is 249280000 people. Given this, psoriatic arthritis effects 174,496 individuals in the U.S. This equates to approximately 3490 people in a "representative state".

Pulmonary Arterial Hypertension (PAH) According to the American Thoracic Society (link here), approximately 200,000 hospitalizations occur annually in the United States with pulmonary hypertension as the primary or secondary diagnosis. For a "representative state" this equates to 4,000 individuals.

Schizophrenia According to the National Institute of Mental Health (link here), across studies that use household-based survey samples, clinical diagnostic interviews, and medical records, estimates of the prevalence of schizophrenia and related psychotic disorders in the U.S. range between 0.25% and 0.64%. This provides a mean value of 0.445%. Assuming that the population of the United States is approximately 328 million, and dividing by 50, a representative state would have a population of 6,560,000 people. Accordingly, a representative state would have 29,192 patients.

United States Senate
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
Committee on Homeland Security and Governmental Affairs

Rob Portman, Chairman
Tom Carper, Ranking Member

COMBATTING THE OPIOID CRISIS: EXPLOITING VULNERABILITIES IN INTERNATIONAL MAIL

STAFF REPORT

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

UNITED STATES SENATE

COMBATTING THE OPIOID CRISIS: EXPLOITING VULNERABILITIES IN INTERNATIONAL MAIL

COMBATTING THE OPIOID CRISIS: EXPLOITING VULNERABILITIES IN INTERNATIONAL MAIL

I. EXECUTIVE SUMMARY

The number of Americans dying due to opioid overdose is staggering. According to the Centers for Disease Control and Prevention ("CDC"), more than 63,600 Americans died from drug overdoses in 2016.[1] Sixty-six percent of those deaths were caused by opioids, including fentanyl and its many analogues.[2] The source of most illicit fentanyl is well known. According to the Drug Enforcement Administration ("DEA"), China is the primary source of supply for fentanyl and its underlying chemical substances (or precursors) headed for the United States.[3] It is widely known how illicit fentanyl enters the United States. According to the DEA, "[c]ustomers can purchase fentanyl products from Chinese laboratories online" and "powdered fentanyls and pill presses" are shipped via mail services.[4]

The Subcommittee learned just how easy it is to find fentanyl advertised online, pay for it using digital currency or other means, and have it shipped to the United States through international mail. As such, the Subcommittee conducted an investigation into measures used to prevent illicit fentanyl from entering the United States by the U.S. Customs and Border Protection ("CBP"), the U.S. Postal Service ("Postal Service"), and the U.S. Department of State ("State Department"). The Subcommittee also reviewed efforts taken by the three largest express consignment operators ("ECOs") operating in the United States, DHL Express U.S. ("DHL"), FedEx Corporation ("FedEx"), and United Parcel Service ("UPS"). Highlights of the Subcommittee's investigative results, including findings and recommendations, are provided below.

Online Fentanyl Sellers. The Subcommittee sought to determine how easy it is to purchase fentanyl from an online seller and arrange to have it delivered to the United States. A simple *Google* search of "fentanyl for sale" returned a number of potential sellers. Over the course of three months, the Subcommittee communicated with representatives from six online sellers, posing as a first-time fentanyl purchaser. All of the online sellers actively sought to induce a purchase of fentanyl or other illicit opioid. Their sales pitches made it sound easy to purchase

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[1] U.S. Centers for Disease Control and Prevention, National Center for Health and Statistics, *Drug Overdoses in the United States*, 1999-2016 (Dec. 2017), https://www.cdc.gov/nchs/products/databriefs/db294.htm.

[2] *Id*.

[3] Drug Enforcement Administration, U.S. Dep't of Justice, DEA-DCT-DIB-021-16, *Counterfeit Prescription Pills Containing Fentanyls: A Global Threat* 2 (July 2016).

[4] *Id*.

fentanyl, and each preferred to ship any purchases to the United States through the international arm of the Postal Service. The online sellers preferred to be paid through cryptocurrencies such as bitcoin, which offers a certain level of anonymity. They also accepted other common payment options, such as Western Union, MoneyGram, PayPal, credit cards, and prepaid gift cards. The online sellers actively negotiated with the Subcommittee to complete a deal by offering flash sales on certain illicit opioids and discounted prices for bulk purchases. When the Subcommittee failed to immediately respond to an offer, the online sellers proactively followed up, sometimes offering deeper discounts to entice a sale.

While the Subcommittee posed as a first-time online purchaser of fentanyl, it never finalized an order or provided payment. Rather, the Subcommittee used information the online sellers provided—such as payment information and shipping addresses—to investigate the extent to which other persons in the United States were conducting business with the online sellers.

Americans Buy Fentanyl Online and Receive it in the Mail. The Subcommittee's investigation confirmed that many Americans are purchasing fentanyl and other illicit opioids online and having them shipped here through the international mail system. The preferred method of the international online sellers is Express Mail Service ("EMS"), a global delivery service for documents and merchandise contained in letters and packages. The EMS network delivers letters and packages worldwide through each member country's postal operations, including the Postal Service in the United States. Through payment information, the Subcommittee identified more than 500 financial transactions by more than 300 U.S.-based individuals totaling $230,000 to the six online sellers. These 300 individuals were located in 43 states, with those in Ohio, Pennsylvania, and Florida making the highest number of purchases.

Through shipment data, the Subcommittee tracked many shipments to individuals who sent money to the six online sellers. This review led to several alarming findings. Most troubling, the Subcommittee identified seven individuals who died from fentanyl-related overdoses after sending money and receiving packages from one of the online sellers. One such individual was a 49-year-old Ohioan who sent roughly $2,500 to an online seller over the course of 10 months—from May 2016 to February 2017. Over that time period, he received 15 packages through the Postal Service on dates that closely corresponded to payments he made to an online seller. He died in early 2017 from "acute fentanyl intoxication." He had received a package from an online seller just 30 days before his death. The Subcommittee further identified 18 individuals who were arrested for drug-related offenses and also made purchases and received packages from the online sellers.

The Subcommittee also identified a likely distributor for one of the online sellers based in Pennsylvania. The Subcommittee identified 120 instances of an individual sending a payment to an online seller and then receiving a package within one-to-two days from the Pennsylvania address. The Ohioan identified above, for example, received seven packages from the Pennsylvania address, including the package he received a month prior to his death.

Analysis of payment and shipping information further identified two additional individuals who were likely distributing illicit opioids. They each made payments to an online seller and received a package from the Pennsylvania address identified by the Subcommittee. These individuals also received other suspect packages with descriptions of items used to mass produce narcotics for distribution, including pill presses, chemical bonding agents, empty plastic pill casings, and chemicals used to dye pills a marketable color. Because these items were shipped through an ECO the sender was required to provide a description of the package contents as further explained below. The Postal Service is not required to collect this information. Under treaty obligations, the Postal Service must rely on foreign posts to collect and transmit data on inbound international mail items, including information on package contents.

Inbound International Mail Volume. The Subcommittee also examined the federal agencies' and private shippers' response to the country's opioid crisis. CBP is the federal agency responsible for identifying suspicious packages sent through the international mail stream that contain illegal items, including fentanyl and other illicit drugs. The Postal Service and ECOs are required to support CBP's efforts by locating and physically handing over or presenting targeted packages to CBP for inspection. This process is known as "presentment."

The volume difference for inbound international packages handled by the Postal Service compared to ECOs is staggering. The three major ECOs examined by the Subcommittee together handled approximately 65.7 million international packages in 2016, while the Postal Service alone handled more than 275 million in the same year, over *four times* the amount handled by the ECOs. The Postal Service's inbound international mail volume increased by 232 percent between fiscal year 2013 and calendar year 2017. However, the Postal Service failed to forecast this growth in inbound international mail volume, which could have helped to ensure some operational measures were in place to handle the growth.

Interdicting Illicit Opioids and Other Contraband in International Mail. International mail packages shipped through the Postal Service primarily enter the United States through one of five International Service Centers ("ISC") located at the following airports: John F. Kennedy International Airport ("JFK") in New York; O'Hare International Airport in Chicago ("ORD"); Los Angeles International Airport

("LAX"); San Francisco International Airport ("SFO"), and Miami International Airport ("MIA"). In years past, CBP would locate suspicious packages at the ISCs by providing the Postal Service with a list of "countries of interest." The Postal Service would then present all the packages from those countries to CBP. CBP would then manually sort through and inspect millions of packages looking for illegal items—the proverbial "needle in a haystack." Although both agencies agreed that the process was inefficient and sought ways to improve it, they are guided by different missions that hinder those efforts. The Postal Service's mission is the speedy processing and delivery of the mail, while CBP's mission is to protect the U.S. border and prevent illicit items from entering the United States.

CBP and Postal Service Pilot Program. More than two years ago, in November 2015, CBP and the Postal Service implemented a pilot program to improve the identification, inspection, and interdiction process for international packages arriving in the United States. The pilot program leveraged advanced electronic data ("AED") that the Postal Service received from certain foreign postal operators. AED is provided by the shipper at the time of package drop-off and includes data such as sender and recipient name and address, as well as a description of the package contents. Prior to the package entering the United States, the Postal Service forwards the AED to CBP. CBP analyzes the AED to identify suspicious packages. Under the pilot program, CBP would use the data to specifically target small packages under 4.4 pounds (called "ePackets") coming from China through the JFK ISC. The Postal Service would then be responsible for locating and presenting the targeted packages to CBP. The JFK ISC receives about half of the Postal Service's international volume.

In December 2016, the Postal Service Office of Inspector General ("OIG") audited the pilot program. The OIG found the Postal Service only presented around 80 percent of the packages targeted by CBP. This was due to a number of problems, including CBP sending hold requests for packages that went to another ISC, the Postal Service not receiving some hold requests until the package had left the JFK ISC, or Postal Service employees missing the package.

The pilot program was a positive development, but its execution suffered from a lack of forethought and cooperation, conflicting missions, and interagency personality conflicts. Before the first package was targeted, the agencies never agreed on specific metrics or goals for the pilot, including how they would measure success. CBP asserted it was entitled to receive every package it targeted for inspection, while the Postal Service explained it was impossible to present packages that were diverted to one of the other ISCs or left the JFK ISC before it was targeted. As of this report, the agencies still have not agreed on common performance measures.

At the same time, the relationship between CBP and the Postal Service was strained. The two agencies were focused on different missions. While CBP sought to protect the border from illicit drugs and other illegal items, the Postal Service needed to move the mail. Moreover, two top officials for the respective agencies at JFK struggled to cooperate. In an effort to increase cooperation at JFK, CBP reassigned a senior official in an attempt to improve the relationship with the JFK Postal Service Plant Manager.

The JFK pilot improved through efforts initiated in 2017 by the Postal Inspection Service, the law enforcement arm of the Postal Service, to automate the process of identifying targeted packages. CBP refused, however, to agree with the Postal Service's suggestion to expand the pilot to the other four ISCs unless the Postal Service was able to present nearly all the targeted packages to CBP. It was not until the Subcommittee held a hearing on May 25, 2017, on the shipment of illicit opioids, that CBP agreed with the Postal Service to expand the pilot to other ISCs. Now, in addition to JFK, the pilot is currently active in Los Angeles and Miami. Three days before the Subcommittee released this report, CBP started targeting packages at the remaining ISCs.

The Universal Postal Union. International mail delivery is governed by a treaty signed in 1874 that created the Universal Postal Union ("UPU"). The United States is one of the 192 members of the UPU, which convenes its Congress every four years to adopt the plans for the international postal community for the next four years. UPU member countries agree to a universal service obligation that mandates the acceptance of packages and other mail items from each other through a network of foreign postal operators. This obligation includes the EMS global network described above. The Postal Service is the designated postal operator for the United States, obligating it to receive, process, and deliver international mail from UPU member countries. For example, a person living in China can ship a package to the United States through China Post – the Chinese equivalent of the Postal Service. When that package reaches the United States, it passes through an ISC and is delivered by the Postal Service.

For close to a decade, the United States (through the State Department) advocated that UPU members adopt the requirement of collecting and exchanging AED for all packages, but little progress has been made. Despite the benefits of using AED to identify suspicious packages, the international postal community has failed to meaningfully adopt its use. In addition, the State Department took a "hands-off" approach to this issue due to concerns about some countries resisting the implementation of AED solely because it is a prerogative of the United States.

In 2008, the United States offered a resolution at the UPU Congress that encouraged the collection of AED to "enhance the efficiency and speed of customs

clearance." This resolution did not require member countries to provide AED, but instead to begin developing a plan for AED implementation. While the resolution was adopted, the original language was altered to remove any requirement for a deadline for implementation, essentially rendering it meaningless.

International events in 2010 highlighted the importance of AED when it was successfully used by law enforcement to thwart a terrorist attack involving explosives packed into printer toner cartridges sent from Yemen to the United States through ECOs. At the next UPU Congress in 2012, the UPU adopted language to develop a strategy for countries to exchange AED on packages. However, the language was qualified to make clear the strategy must be proportionate to the identified risk. This was a way for countries opposed to requiring AED to point out that the United States was a greater target than other countries. Therefore, the United States should not expect other countries to take on as much of the security burden.

The UPU's strategy involved member countries electronically providing the same information currently required on certain customs declaration forms that must be affixed to every package. This information included sender name and address, recipient name and address, and a description of the contents. The UPU has also adopted the use of barcodes to track packages for business purposes referred to as the Integrated Product Plan ("IPP"). While barcodes are required to be on all packages as of January 1, 2018, no AED or other information is required to be loaded onto them. Instead, the goal of the IPP is to require AED on the barcode by 2020, but that date was recently indefinitely delayed due to push-back from certain UPU members.

The amount of AED currently transmitted to the Postal Service on international packages is low. From January 2017 through the end of 2017, only 36 percent (on average) of packages sent to the United States included AED. During that time, the Postal Service received 498,268,405 packages, which means 318,891,780 packages had no AED about who sent the package, where the package was going, or what was in the package. The number of packages with AED is not likely to increase anytime soon.

Express Consignment Operators. In the Trade Act of 2002, Congress required ECOs to collect certain information on all packages shipped through their networks for security purposes following the September 11 terrorist attacks. As a result, all packages shipped by ECOs have AED, including sender name and address, recipient name and address, and a description of the item contained in the package. CBP uses this information to target suspicious packages shipped through the ECOs, just as it uses the AED in the JFK pilot program with the Postal Service. ECOs created proprietary systems that allow customers to track packages, and they also

allow ECOs to identify and present the packages CBP targets. According to CBP statistics, due to AED, ECOs present almost all targeted packages to CBP.

While ECOs are highly efficient at using AED to provide CBP with targeted packages, differences exists between the ECOs and the Postal Service. ECOs control packages in their networks from acceptance to delivery, even for international packages. In contrast, the Postal Service must rely on foreign postal operators to collect AED on internationally shipped packages that are delivered domestically by the Postal Service. ECOs also handle fewer packages than the Postal Service.

A. The Subcommittee's Investigation

The Subcommittee began its review of the opioid crisis during the 114th Congress when it examined the efforts undertaken by the federal government and its main program integrity contractor, the Medicare Drug Integrity Contractor (MEDIC), to address opioid-related fraud and abuse in Medicare Part D. That program serves nearly 35 million senior citizens and seven million Social Security disability benefit recipients. In connection with that review, the Subcommittee also examined the anti-opioid abuse efforts of six of the nation's largest health insurance companies—both in their commercial insurance business and in their role as Medicare Part D plan sponsors. That investigation resulted in a bipartisan report titled *Combatting the Opioid Epidemic: A Review of Anti-Abuse Efforts in Medicare and Private Health Insurance Systems*.

During the current 115th Congress, the Subcommittee expanded its review of the opioid crisis by examining the role that illicit opioids, specifically fentanyl, play in the current national crisis. As previously mentioned, to better understand how illicit opioids enter the United States, the Subcommittee held an initial oversight hearing on May 25, 2017, titled *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs*. Representatives from the Postal Service, the Postal Service OIG, the State Department, CBP, and UPS testified at that hearing. As part of this investigation, the Subcommittee reviewed over 60,000 pages of documents from the Postal Service, CBP, the State Department, DHL, FedEx, and UPS. The Subcommittee also analyzed over two million lines of AED and money transfer information from the Postal Service, CBP, ECOs, Western Union, MoneyGram, and PayPal. The Subcommittee also conducted interviews of key personnel from CBP, the Postal Service, and the State Department. All entities cooperated with the Subcommittee's requests for information. In addition, the Subcommittee traveled to and met with relevant foreign customs and law enforcement officials in Hong Kong and Singapore.

Based on this investigation, the Subcommittee concludes that the federal government's policies and procedures are inadequate to prevent the use of the international mail system to ship illegal synthetic opioids into the United States.

B. Findings of Fact and Recommendations

Findings of Fact

(1) Fentanyl Sellers Operate Openly on the Internet. From May 2017 to June 2017, simple internet searches for "fentanyl for sale" identified websites openly advertising synthetic opioids for purchase. The Subcommittee corresponded with representatives from six websites who actively sought to induce a purchase of fentanyl and other synthetic opioids.

(2) Online Sellers Preferred to Ship Through Express Mail Service/Postal Service. All international online sellers indicated they preferred to ship purchases through EMS. One online seller's website explained the default shipping method was EMS. Another website only guaranteed delivery if EMS was used, and encouraged its use through free EMS shipping for orders over $100. Upon the Subcommittee's request, however, the online sellers offered other shipping options, including DHL, FedEx, and UPS.

(3) Online Sellers Transshipped Purchases Through Other Countries To Reduce Risk of Interdiction. To avoid heightened targeting by CBP of packages from China, online sellers stated that they would divert packages through other countries first before the package ultimately arrived in the United States. This practice is known as transshipment. The online sellers asserted transshipping through these countries reduced the risk of a package containing illicit opioids from being identified and seized by customs officials.

(4) Cryptocurrency Preferred. Bitcoin was the preferred payment method for all online sellers. Other methods to make a purchase were also accepted, including Western Union, PayPal, bank transfers, credit cards, and prepaid gift cards.

(5) Online Sellers Linked to Fentanyl Related Deaths. Tragically, through the review of payment information and AED, the Subcommittee was able to link the online sellers to seven confirmed synthetic opioid-related deaths.

(6) **Arrests for Drug-Related Offenses**. The Subcommittee was also able to link the online sellers to 18 arrests for drug-related offenses.

(7) **Active Domestic Illicit Opioid Distributors**. Through payment information and shipment data, the Subcommittee located an address in Pennsylvania that is likely transshipping purchases made through an online seller located in China. The Subcommittee also identified two other individuals who may be preparing to distribute illicit opioids. These two individuals sent payments to the online sellers and also received packages containing pill presses and other items commonly used in the mass production of narcotics for distribution, including chemical bonding agents to make pills, empty pill casings, and pill coloring agents.

(8) **The Postal Service and CBP Failed to Recognize and Prepare for the Increase in International Shipments**. The Postal Service and CBP were not prepared for the recent rapid growth of inbound international mail packages. In just the last three years, international package volume for the Postal Service has almost doubled, going from 150 million packages in fiscal year 2013 to 275 million in fiscal year 2016. The number of international packages reached more than 498 million in calendar year 2017, a staggering increase from previous years.

(9) **CBP Manually Targeted Packages**. To interdict illegal items entering the United States through the Postal Service, CBP identified "countries of interest." The Postal Service then sent all packages from those countries of interest to CBP for inspection. This resulted in CBP manually searching through packages to attempt to locate illegal items. At times, CBP did not list China as a country of interest due to the high volume of packages China shipped to the United States, which would have been too difficult to manage.

(10) **Lack of Coordination**. A pilot program established by the Postal Service and CBP in November 2015 at the JFK ISC, using AED to target and present small packages from China, lacked effective coordination between the agencies. The two agencies failed to establish any performance metrics or even define what would be considered a success for the pilot. While the Postal Service initially only presented around 80 percent of packages requested by CBP, that number has improved. As of the publication of this report, however, the agencies still disagree how to calculate the percentage of packages

targeted by CBP that the Postal Service presented for inspection ("presentment rate").

(11) CBP Has Not Studied the Effectiveness of Using AED to Target Packages. Although CBP promotes the utility of AED for targeting purposes and insists on receiving every targeted package, CBP has yet to analyze the effectiveness of using AED to target and interdict drugs or other prohibited items.

(12) Postal Service and CBP Did Not Make Timely Improvements and Expansions to the Pilot Program. Despite widespread concerns by CBP and the Postal Service about requiring the manual targeting of packages, the Postal Service did not improve its presentment rate through automation until two years after the pilot began. Further, the agencies did not expand the pilot to other ISCs until the Subcommittee held a hearing about the issue on May 25, 2017. In fact, CBP informed the Subcommittee that it would begin targeting packages using AED at the ISCs in Chicago and San Francisco on January 21 and 22, respectively—just days before the release of this report and a scheduled Subcommittee hearing to examine its findings.

(13) International Delay. Since 2008, the State Department advocated for the UPU to require its members to adopt the use of AED. Recently, the UPU took steps to adopt AED for business-related purposes and to modernize the international postal service with the expectation posts would provide AED on all packages by 2020. Those efforts, like others in the past, are delayed due to requests for studies on how AED requirements will affect countries whose UPU representatives have raised concerns about their posts' ability to collect and exchange sender information.

(14) The Postal Service Receives AED on about 36 Percent of All International Packages. Despite the current lack of requirements for the Postal Service to collect AED from foreign postal operators, the Postal Service does receive AED from some foreign postal operators, including Hongkong Post and China Post. China is capable of providing AED on its packages and currently only does so for about half of the packages it ships to the United States. The AED from China Post pertains to ePackets and includes tracking and delivery confirmation information.

(15) The Majority of International Packages Have No Associated AED. The Postal Service received 498,268,405 packages from foreign posts in 2017; 36 percent of those packages had AED associated with them. Therefore, 318,891,780 packages entered the United States with no associated AED on the sender's name and address, the recipient's name and address, or the contents of the package. With no AED, CBP was unable to target any of these packages for further inspection before they entered the United States.

(16) Low Quality Data. The AED the Postal Service receives from foreign postal operators is of low quality. The data reviewed by the Subcommittee did not contain standard fields or address constructions. Sender name and address were rarely provided. At times, the data was a long line of illogical letters and characters.

(17) ECOs Presented Nearly All Targeted Packages to CBP. Congress mandated that ECOs provide AED on all packages in 2002. Using AED, ECOs present almost 100 percent of packages targeted by CBP for inspection. Unlike the Postal Service, ECOs control packages from acceptance to delivery and manage a significantly lower volume of packages.

(18) ECOs Do Not Share Information on Problem Shippers. While FedEx and UPS maintain lists of individuals and entities that are not allowed to ship packages through their networks, they do not share these lists with CBP, the Postal Service, or other ECOs. DHL does not maintain such a list.

Recommendations

(1) Require AED on All International Packages. The State Department and Postal Service should work together to take steps to prioritize the enactment and implementation of requirements that UPU member countries collect and exchange AED for all international packages. Congress should pass any legislation necessary to facilitate the agencies' efforts.

(2) The Postal Service Should Include Provisions in All Bilateral and Multilateral Agreements to Collect and Exchange Additional and Better Quality AED. Any agreement between the Postal Service and one or more foreign posts for express package delivery should include provisions requiring the foreign posts to provide the Postal Service with quality AED for all packages.

(3) **Proactively Improve the Quality of AED**. The Postal Service should initiate processes to improve the quality of the data received from foreign posts. This should include the consideration of standardized fields to avoid confusion by foreign nationals in constructing an American address. The State Department should also work to improve the quality of data collected internationally.

(4) **Increase Targeting**. CBP should continue to increase the number of packages targeted for inspection through the Pilot Programs at ISCs with an emphasis on locating illicit drugs. This should include a dedicated CBP employee at the National Targeting Center responsible for all mail and package targeting efforts.

(5) **Automated Identification of Targeted Packages**. The Postal Service should fully automate the process of identifying packages targeted for inspection by CBP at all of the ISCs.

(6) **Targeting Analysis**. CBP should conduct a thorough analysis of the effectiveness of its targeting and interdiction efforts under the AED pilot program.

(7) **Agreement on Success Metrics**. CBP and the Postal Service should come to agreement on the methodology used for measuring the Postal Service's presentment rate—the success rate of presenting targeted packages to CBP.

(8) **CBP and Postal Service Resources**. CBP and the Postal Service should deploy sufficient personnel and resources at all of the ISCs to handle the growing volume of international mail and corresponding increase in shipments of illicit drugs. Both agencies should act swiftly to inform Congress of the staffing and technological resources needed to effectively expand their efforts. Congress should pass any legislation necessary to ensure both agencies are capable of maintaining an effective, automated process for targeting and interdicting illicit packages.

(9) **Deepen Cooperation with the Chinese Government to End Opioid Smuggling, including through Online Sellers**. Executive agencies should continue leveraging the high-level partnerships with Chinese officials established through the U.S.-China Law Enforcement and Cybersecurity Dialogue to combat the shipment of illicit opioids to the United States. These efforts should include both scheduling

additional illicit opioids as illegal and shutting down smuggling routes and methods, including online sellers located in China.

(10) Improve Information Sharing. The Postal Service, CBP, and ECOs should form an Information Sharing and Analysis Center ("ISAC") to share information about best practices and known shippers of illegal items. It may also be beneficial to include representatives from entities like Western Union, MoneyGram, PayPal, and other peer-to-peer payment platforms.

(11) Improve Presentment Metrics. ECOs should track their presentment rate for all targeted packages requested by CBP.

II. BACKGROUND

The United States is in the midst of an opioid epidemic. Synthetic opioids, such as fentanyl and its variations, known as analogues, are causing drug overdoses and deaths at an unparalleled rate in communities across our nation. Drug overdoses are now the leading cause of injury-related death in the United States, outnumbering both automobile crashes and gun-related deaths.[5]

Although synthetic opioids enter the country through various streams of commerce, China is the primary source of fentanyl in the United States.[6] These drugs are available for purchase on the Internet. And the rapid growth of international mail packages arriving in the United States has provided cover for bad actors seeking to ship these drugs through the global mail system.

A host of federal agencies are tasked with working together to stop synthetic opioids and other illicit drugs from entering the country. Chief among them is U.S. Customs and Border Protection ("CBP"), which has authority and responsibility for screening both persons and goods entering the country. CBP works closely with the U.S. Postal Service ("Postal Service") and express consignment operators ("ECOs"), such as FedEx Corporation ("FedEx"), United Parcel Service ("UPS"), and DHL Express U.S. ("DHL") to target and interdict shipments of contraband. CBP's targeting efforts benefit from the advance receipt of specific data about inbound international packages and shipments.

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[5] Josh Katz, *Drug Deaths in America Are Rising Faster Than Ever*, N.Y. TIMES (Jun. 5, 2017), https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html.

[6] U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION, FENTANYL: CHINA'S DEADLY EXPORT TO THE UNITED STATES 3 (2017).

The opioid epidemic prompted the Subcommittee to launch an investigation of the federal government's strategy to stop the shipment of synthetic opioids into the United States. The Subcommittee sought to determine whether synthetic opioids are entering the country due to a lack of resources or legal authorities needed to stop these shipments, insufficient coordination among the relevant stakeholders, or other issues. The Subcommittee reviewed the efforts of CBP, the Postal Service, the U.S. Department of State ("State Department"), FedEx, UPS, and DHL to identify, interdict, and prevent these shipments from entering the United States. As part of this investigation, the Subcommittee also visited ports of entry in Baltimore and Long Beach/Los Angeles, as well as the International Service Centers ("ISCs") located in New York at the John F. Kennedy Airport (JFK) and in California at Los Angeles International Airport (LAX). The Subcommittee also visited and interviewed customs officials and law enforcement counterparts in Hong Kong and Singapore. The Subcommittee reviewed over 60,000 pages of documents, two million lines of payment information and shipping data, and conducted a number of interviews and briefings.

A. The Opioid Epidemic

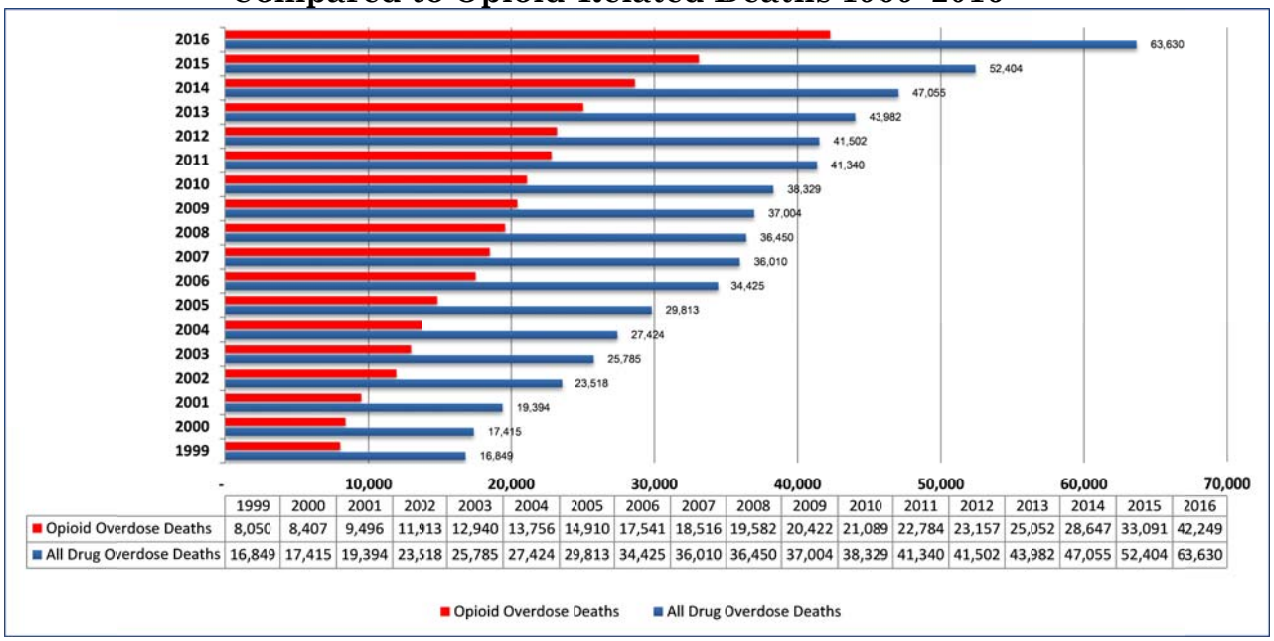
Americans are overdosing and dying from fentanyl and other synthetic opioids at rates that far exceed peak death rates from automobile accidents, gun-related deaths, and AIDS.[7] No age group, race, gender, or region of the country has been immune to this epidemic.[8] The opioid epidemic has devastated communities across the nation and has forced state and local officials to devote an unsustainable level of resources to combat it on a daily basis.[9]

According to the Centers for Disease Control and Prevention ("CDC"), based on a review of 2016 statistics, nearly 63,600 people died from drug overdoses, and 66 percent of those deaths were a result of opioids, including fentanyl and its many analogues.[10] In 2015, 63 percent of drug overdose deaths were a result of opioid

[7] Josh Katz, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, N.Y. TIMES (Sep. 2, 2017), https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html.
[8] U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, DRUG OVERDOSE DEATHS IN THE UNITED STATES (DEC. 2017), https://www.cdc.gov/nchs/data/databriefs/db294.pdf (hereinafter "2016 CDC Opioid Statistics Report").
[9] Press Release, U.S. Drug Enforcement Administration, DEA Warning to Police and Public: Fentanyl Exposure Kills (Jun. 10, 2016).
[10] 2016 CDC Overdose Statistics Report.

overdoses, which have quadrupled since 1999.[11] The chart below depicts the total number of overdose deaths compared to opioid-related deaths from 1999 to 2016.

Total Drug Overdose Deaths
Compared to Opioid-Related Deaths 1999–2016[12]



	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Opioid Overdose Deaths	8,050	8,407	9,496	11,913	12,940	13,756	14,910	17,541	18,516	19,582	20,422	21,089	22,784	23,157	25,052	28,647	33,091	42,249
All Drug Overdose Deaths	16,849	17,415	19,394	23,518	25,785	27,424	29,813	34,425	36,010	36,450	37,004	38,329	41,340	41,502	43,982	47,055	52,404	63,630

1. Fentanyl and Synthetic Opioids

Fentanyl is a synthetic chemical compound that mimics many of the effects of opiates, such as morphine and heroin.[13] It is a powerful synthetic painkiller that is 50 times more potent than heroin and 100 times stronger than morphine.[14] Physicians currently prescribe fentanyl for pain management in various forms, including transdermal patches, lollipops, and lozenges.[15] Small doses of fentanyl have a high potency and, as a fine-grained powder, it is easy to mix into other illicit

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[11] U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, MORBIDITY AND MORTALITY WEEKLY REP. NO. 65 (50–51), INCREASES IN DRUG AND OPIOID-INVOLVED OVERDOSE DEATHS – UNITED STATES, 2010–2015 (2016).

[12] Opioid Overdose Deaths and Opioid Overdose Deaths as a Percent of All Drug Overdose Deaths, Kaiser Family Foundation (2015), https://www.kff.org/other/state-indicator/opioid-overdose-deaths/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[13] U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, WHAT IS FENTANYL?, https://www.cdc.gov/drugoverdose/opioids/fentanyl.html.

[14] NATIONAL INSTITUTE ON DRUG ABUSE, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, WHAT IS FENTANYL?, https://www.drugabuse.gov/publications/drugfacts/fentanyl; Fentanyl, Drug Enforcement Administration, U.S. Dep't of Justice (2016), https://www.deadiversion.usdoj.gov/drug_chem_info/fentanyl.pdf.

[15] U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, WHAT IS FENTANYL?, https://www.cdc.gov/drugoverdose/opioids/fentanyl.html.

drugs such as heroin, marijuana, and cocaine, making those drugs even more potent.[16] Counterfeit versions of other narcotics like OxyContin and Percocet also contain fentanyl as a key ingredient.[17] Fentanyl affects the area of the brain that controls breathing, and high doses can cause breathing to stop completely, which can lead to death.[18] Overdose can occur when users unknowingly take fentanyl or are not aware of its potency.[19]

The Drug Enforcement Administration ("DEA") designated fentanyl and its analogues as Schedule II substances, determining that they have a high potential for abuse and could lead to severe psychological or physical dependence. Several precursors—the chemical substances or compounds used to manufacture fentanyl—are now included on the United Nations Commission on Narcotic Drugs list of illicit substances.[20] According to the United Nations, scheduling substances enables greater control and monitoring of the precursor chemicals, ensuring a concerted international approach.[21]

2. The Impact on State and Local Governments

The opioid epidemic has placed an unsustainable strain on state and local governments. Communities across the country are overextending their financial resources and personnel in an effort to save the lives of opioid overdose victims on a daily basis.[22] According to the DEA, fentanyl is not only dangerous for the drug's users, but also for law enforcement, public health workers, and first responders who may unknowingly come into contact with the drug in its different forms.[23] The DEA has issued safety precautions for first responders and law enforcement officers because fentanyl can be accidentally absorbed through the skin and inhaled through the nasal passages.[24] Because of the drug's lethality, even in small

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[16] *Id*.
[17] Drug Enforcement Administration, U.S. Dep't of Justice, DEA-DCT-DIB-021-16, *Counterfeit Prescription Pills Containing Fentanyls: A Global Threat* (July 2016).
[18] NATIONAL INSTITUTE ON DRUG ABUSE, U.S. DEP'T OF HEALTH AND HUMAN SERVICES: WHAT IS FENTANYL?, https://www.drugabuse.gov/publications/drugfacts/fentanyl.
[19] OFFICE OF DIVERSION CONTROL, NATIONAL FORENSIC LABORATORY INFORMATION SYSTEM, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEP'T OF JUSTICE, SPECIAL REPORT: OPIATES AND RELATED DRUGS REPORTED IN NFLIS, 2009-2014 (2017).
[20] UNITED NATIONS OFFICE ON DRUGS AND CRIME, GLOBAL SMART UPDATE, VOL. 17, FENTANYL AND ITS ANALOGUES – 50 YEARS ON (2017); INTERNATIONAL NARCOTICS CONTROL BOARD, PRECURSORS AND CHEMICALS FREQUENTLY USED IN THE ILLICIT MANUFACTURE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES (2016).
[21] *Id*.
[22] Elizabeth Kneebone and Scott W. Allard, *A Nation in Overdose Peril: Pinpointing the Most Impacted Communities and the Local Gaps in Care*, BROOKINGS (Sept. 25, 2017), https://www.brookings.edu/research/pinpointing-opioid-in-most-impacted-communities.
[23] DRUG ENFORCEMENT ADMINISTRATION, U.S. DEP'T OF JUSTICE, FENTANYL: A BRIEFING GUIDE FOR FIRST RESPONDERS (2017).
[24] *Id*.

quantities, law enforcement, first responders, hospitals, and drug treatment facilities now maintain a supply of Naloxone, a medication used to block the effects of opioids, especially in overdose situations, by quickly restoring normal respiration and breathing.[25] Overdose deaths related to opioids such as heroin, oxycodone, hydrocodone, codeine, fentanyl, and morphine can occur within one to three hours of ingestion but are reversible, during that time period, with the use of Naloxone.[26]

B. How Fentanyl and Synthetic Opioids Enter the United States

Synthetic opioids like fentanyl are openly available for purchase on the Internet and primarily trafficked in packages through the international mail stream.[27] The rise of e-commerce has significantly increased the volume of international mail parcels and packages. The increased volume provides cover for criminals to abuse the international mail system to traffic and distribute illegal substances.

1. Sources of Fentanyl

China is the largest exporter of fentanyl to the United States.[28] The majority of illicit fentanyl smuggled into the United States originates in China, sometimes in the form of precursors that are shipped to Mexico or Canada and mixed with other narcotics before being sent across the border into the United States. Until recently, the production of fentanyl was unregulated in China.[29] Over the course of 2017, China banned several fentanyl-derivatives including both carfentanil, a lethal opioid 100 times more potent than fentanyl, and U-47700, a synthetic opioid also known as "pink."[30]

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[25] NATIONAL INSTITUTE ON DRUG ABUSE, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, What is Naloxone?, https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio.

[26] INSYS DEVELOPMENT COMPANY, INC., JOINT MEETING OF THE ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE (AADPAC) AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE (DSARM), U.S. FOOD AND DRUG ADMINISTRATION, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, "NALOXONE FOR TREATMENT OF OPIOID[] OVERDOSE, ADVISORY COMMITTEE OF OCTOBER 5, 2016,", https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM522690.pdf.

[27] U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION, FENTANYL: CHINA'S DEADLY EXPORT TO THE UNITED STATES 3 (2017); U.N. Off. on Drugs and Crime, World Drug Report, Executive Summary (2017).

[28] *Id*.

[29] Erika Kinetz and Desmond Butler, *Chemical Weapon for Sale: China's Unregulated Narcotic*, AP NEWS (Oct. 7, 2016), https://apnews.com/7c85cda5658e46f3a3be95a367f727e6.

[30] U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION, FENTANYL: CHINA'S DEADLY EXPORT TO THE UNITED STATES 10 (2017).

The DEA and Chinese officials have met regularly to discuss the threat from fentanyl class substances.[31] To improve cooperative efforts between the United States and China, the DEA plans to open a third office in Guangzhou, China, in addition to offices currently in Beijing and Hong Kong.[32] In addition, the U.S. Department of Justice ("Justice Department") recently handed down several fentanyl-related indictments, including two against Chinese nationals who owned and operated several fentanyl laboratories in China.[33] The labs' North America-based traffickers and distributors are also under indictment for separate conspiracies to distribute large quantities of fentanyl, fentanyl analogues, and other opiate substances in the United States.[34] The Justice Department similarly indicted another Chinese national for distribution of opioids and other drugs ordered on Chinese websites and shipped from China to the United States.[35]

2. Convenience of Purchasing on the Internet

The Internet has significantly increased the availability of deadly synthetic opioids in the United States.[36] Because illicit drug dealers and distributors can remain anonymous online, these virtual marketplaces significantly reduce the risk of detection associated with purchasing fentanyl and other synthetic opioids. The illicit market of all drugs for sale online is growing. A 2015 study estimated that revenues from online illicit drug sales increased from between $15-17 million in 2012 to $150-$180 million in 2015.[37] It is not difficult to find illegal drugs such as synthetic opioids advertised for sale on both the open web, and the dark web—a collection of thousands of websites that are publicly visible but use anonymity tools to hide Internet Protocol ("IP") addresses. The dark web is one of the largest marketplaces to purchase illegal drugs and is also the hardest marketplace to police.[38] Today, many individuals still use the dark web as a legitimate means to

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[31] Press Release, Drug Enforcement Administration, China Announces Scheduling Controls of New Psychoactive Substances/Fentanyl-Class Substances (Jun. 19, 2017).
[32] Erika Kinetz, *DEA Opens Shop in China to Help Fight Synthetic Drug Trade*, AP NEWS, (Jan. 6, 2017), https://www.apnews.com/3630050eef274653a54cb70e46c4f72a.
[33] Press Release, U.S. Dep't of Justice, *Justice Department Announces First Ever Indictments against Designated Chinese Manufacturers of Deadly Fentanyl and Other Opiate Substances* (Oct. 17, 2017).
[34] *Id.*
[35] Press Release, Northern Dist. of Ohio, U.S. Attorney's Office, U.S. Dep't of Justice, *Chinese National Living in Massachusetts Arrested and Charged with Distributing Opioids that Were Shipped from China to the U.S. and Ultimately to Ohio* (Jul. 24, 2017).
[36] U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION, FENTANYL: CHINA'S DEADLY EXPORT TO THE UNITED STATES 3 (2017).
[37] Kyle Soska and Nicolas Christin, *Measuring the Longitudinal Evolution of the Online Anonymous Marketplace Ecosystem*, Carnegie Mellon University (Aug. 13, 2015), http://www.usinex.org/conference/usinexsecurity15/technical-sessions/presentation/soska.
[38] Eric Jardine, *The Dark Web Dilemma: Tor, Anonymity, and Online Policing*, Paper Series: No 21, Centre for International Governance Innovation, Global Commission on Internet Governance (Sep. 2015), https://www.cigionline.org/sites/default/files/no.21.pdf; U.S. NAVAL RESEARCH LABORATORY, U.S. DEP'T OF DEFENSE, NRL RELEASE NUMBER 03-1221.1-2602, TOR: THE SECOND-GENERATION

ensure secure everyday Internet usage; however, a host of dark web merchants are increasingly using the anonymity offered by the dark web to sell illicit drugs, dangerous weapons, counterfeit documents, and even human trafficking victims on various online marketplaces.

Online fentanyl sellers engage in sophisticated sales techniques to offer exclusive products and discounts for bulk orders. Accepted payment methods include cryptocurrencies such as bitcoin, bank transfers, mobile payment services, and money orders. Bitcoin is "completely digital money" and "the first decentralized peer-to-peer payment network."[39] Bitcoin describes itself as "cash for the Internet."[40] In addition to anonymity, using bitcoin can be cheaper than processing funds through more traditional means. According to the Financial Crimes Enforcement Network, a user of virtual currency is not a Money Services Business ("MSB") and is therefore not subject to registration, reporting, and recordkeeping regulations with U.S. financial regulators, making detection by law enforcement more challenging.[41]

3. The Growth of E-Commerce

The growth of cross-border e-commerce has dramatically increased the volume of international parcels and packages arriving into the United States. In fact, the chart below shows e-commerce sales worldwide may reach $4.4 trillion by 2021, primarily due to global internet connectivity and the growing shift towards the convenience of online shopping.[42] North America is the largest regional parcels market by value; however, the Asia-Pacific parcels market has experienced double-digit growth with China accounting for 47 percent of the regional total.[43] Chinese parcels volume has increased rapidly from 1.2 billion in 2007 to 20.6 billion in 2015 and it now sends more parcels than the United States.[44]

ONION ROUTER (2004) (The dark web is an outgrowth of software tools developed by the U.S. Naval Research Laboratory in the 1990s. It was initially intended as a means of secure communication and open source intelligence gathering.).

[39] What is Bitcoin?, https://bitcoin.org/en/faq#what-is-bitcoin.

[40] *Id.*

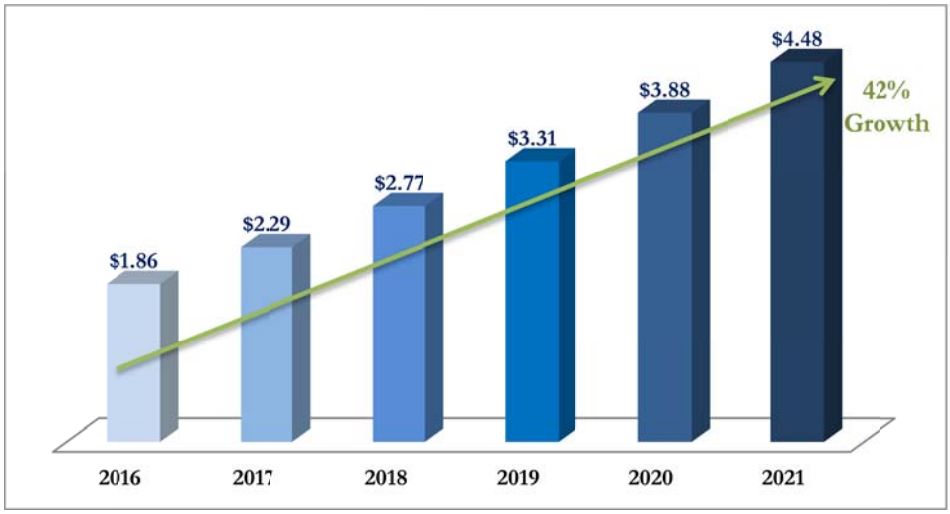
[41] FINANCIAL CRIMES ENFORCEMENT NETWORK, U.S. DEP'T OF THE TREASURY, FIN-2013-G001, APPLICATION OF FINCEN'S REGULATIONS TO PERSONS, ADMINISTERING, EXCHANGING, OR USING VIRTUAL CURRENCIES (2013).

[42] Worldwide Retail and Ecommerce Sales: eMarketer's Estimates for 2016–2021, eMarketer (Jul. 2017), https://www.emarketer.com/Report/Worldwide-Retail-Ecommerce-Sales-eMarketers-Estimates-20162021/2002090.

[43] Global Parcel Market Insight Report 2017, Apex Insight (Jan. 2017), https://www.apex-insight.com/product/global-parcel-delivery-market-insight-report-2017.

[44] *Id.*

Growth of Retail E-Commerce Sales Worldwide
2016–2021 (In Trillions)[45]

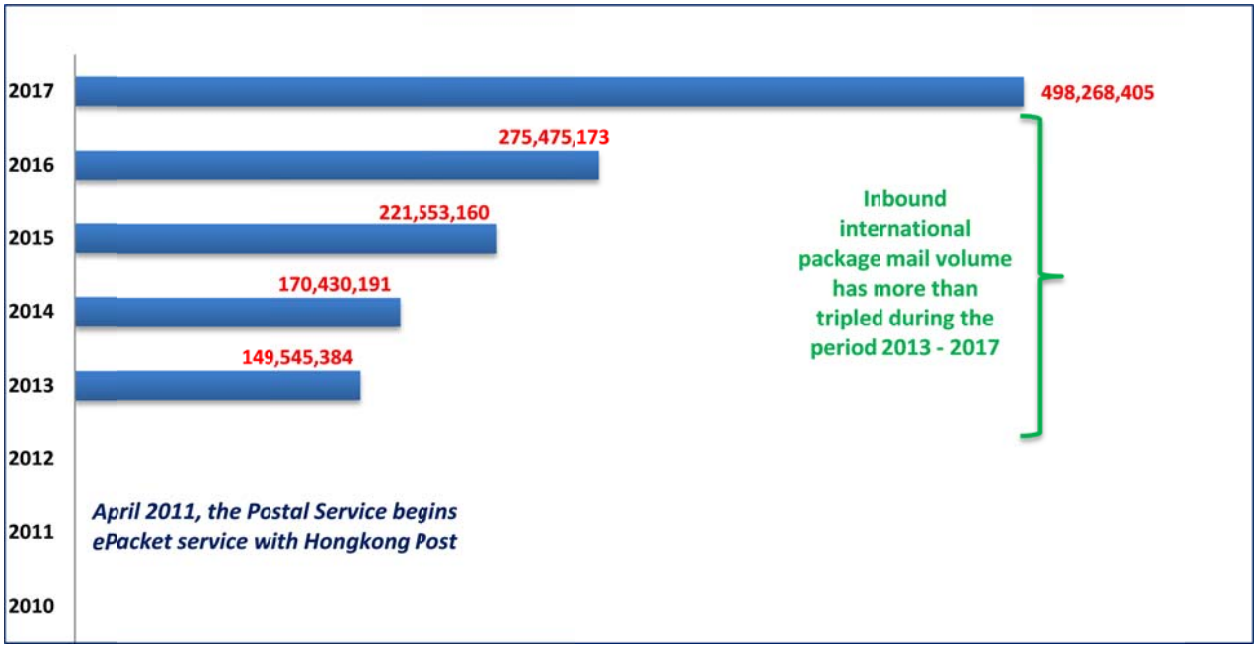


As a result, there has been a tremendous increase in inbound international parcel volume. In 2011, the Postal Service launched a new product and service commonly known as an "ePacket" with Hongkong Post, which includes add tracking and delivery confirmation on certain packages. ePackets are package shipments that weigh less than 4.4 pounds.[46] This facilitated the shipping of lightweight goods and merchandise ordered by consumers in the United States from Hong Kong merchants.

[45] Worldwide Retail and Ecommerce Sales: eMarketer's Estimates for 2016–2021, eMarketer (July 2017), https://www.emarketer.com/Report/Worldwide-Retail-Ecommerce-Sales-eMarketers-Estimates-20162021/2002090.

[46] Press Release, U.S. Postal Service, Postal Service Initiates ePacket Service with Hongkong Post (Apr. 20, 2011).

Growth of Inbound International Mail Volume
U.S. Postal Service[47]



4. The International Mail System

The Universal Postal Union ("UPU") is the primary forum for cooperation between postal operators around the world. It sets the rules for international mail exchanges and makes recommendations intended to stimulate growth in mail and parcel volumes and improve quality of service.[48] Of the 195 countries in the world, the UPU has 192 members. The United States has been a member since the UPU's founding in 1874.[49]

The UPU's universal service obligation requires its members to accept and deliver mail from all member foreign postal operators. As a result, the Postal Service, as the designated postal operator on behalf of the United States is required to accept all international mail from other UPU members under the UPU treaty. Mail from foreign postal operators arrives in the United States via commercial airline carriers at an airport with a Postal Service ISC.

The State Department represents U.S. interests at the UPU, in coordination with the Postal Service. The State Department, as the country's representative at

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[47] United States Postal Service production to the Subcommittee (May 9, 2017) (on file with the Subcommittee).
[48] Annual Report, Universal Postal Union (2013), http://news.upu.int/fileadmin/user_upload/PDF/Reports/annual_report_2013.pdf.
[49] CONSTITUTION GENERAL REGULATIONS: RULES OF PROCEDURE, LEGAL STATUS OF THE UPU, LIST OF RESOLUTIONS AND DECISIONS, International Bureau of the Universal Postal Union (Bern 2014).

the UPU, is responsible for the formulation, coordination, and oversight of foreign policy related to international postal services and other international delivery services.[50]

The Postal Service's primary mission is to accept, process, and deliver the mail within an agreed timeframe, which is typically defined by the type of mail product. Mail products include letters, express mail service ("EMS"), and parcels, all of which have different delivery requirements. To receive and process the international mail, the Postal Service primarily relies on five ISCs in the United States located at the airports in New York ("JFK"), Miami ("MIA"), Chicago ("ORD"), Los Angeles ("LAX"), and San Francisco ("SFO").[51] Once offloaded from the commercial airline carriers, the mail then moves to the ISC where the Postal Service sorts it.

During the Postal Service's initial sorting process, the Postal Service identifies and presents any packages targeted by CBP for screening and inspection. The U.S. Postal Inspection Service ("Postal Inspection Service") also provides assistance with identifying and retrieving packages targeted by CBP, either at the ISCs or in the domestic mail stream.[52] After receiving clearance from CBP, the Postal Service transports mail to processing and distribution plants around the country.

ECOs such as DHL, FedEx, and UPS also accept and deliver parcels and packages bound for the United States from customers in foreign countries. These companies have agreements and package acceptance operations in hundreds of countries around the world. Unlike the Postal Service, ECOs own and operate airplanes used to transport international cargo. These airplanes similarly arrive at private mail processing facilities across the United States.[53] Private express parcels and packages also undergo x-ray screening to ensure they do not contain dangerous or hazardous materials. Like the Postal Service, ECOs are required to accommodate CBP officials at their facilities to allow for screening and inspection before international mail officially enters the U.S. mail stream.[54]

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[50] 39 U.S.C. §§ 407(b)(1), (b)(2)(D) (2016).
[51] U.S. POSTAL SERVICE, 2010 COMPREHENSIVE STATEMENT ON POSTAL OPERATIONS 31 (2010).
[52] 18 U.S.C. § 3061 (2016).
[53] DHL Key Facts: United States, http://www.dhl-usa.com/en/country_profile/key_facts.html; About FedEx, http://about.van.fedex.com/our-story/global-reach/; UPS Air Operation Facts, https://www.pressroom.ups.com/pressroom/ContentDetailsViewer.page?ConceptType=FactSheets&id=1426321563773-779.
[54] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017) (testimony of Norman Schenk, Vice President of Global Customs Policy and Public Affairs, United Parcel Service).

C. Preventing Fentanyl and Synthetic Opioids from Entering the United States

CBP, in collaboration with the Postal Service and ECOs, is tasked with preventing international mail shipments containing illicit drugs from entering the United States. As previously indicated, CBP officials are located at Postal Service ISCs and ECO facilities. The use of advanced electronic data ("AED") linked to each package from shipment manifests enhances CBP's ability to target individual packages potentially containing contraband, including illicit drugs such as fentanyl.

1. U.S. Customs and Border Protection

CBP is among the primary federal agencies responsible for securing America's borders, "while facilitating lawful international travel and trade."[55] CBP has authority to screen shipments from foreign postal operators and ECOs for contraband including illegal drugs or counterfeit goods.[56] CBP monitors international shipments arriving in the United States at airports, maritime ports of entry, and through land borders in the north and south.[57] CBP has enforcement authority to open and inspect all inbound international mail and cargo to ensure compliance with U.S. trade and safety laws, rules, and regulations.[58] The Postal Service and ECOs support CBP's mission to prevent illegal items from entering the United States by providing CBP with targeted packages, parcels, and shipments that will undergo inspection.

2. Advanced Electronic Data and International Mail Acceptance

The growing volume of international mail poses challenges for both the Postal Service and CBP.[59] International mail package volume has more than doubled since 2013, and the Postal Service can receive as many as one million packages each day.[60] More than half of all inbound international packages arrive at New York's JFK airport, one of the country's five ISCs.[61] CBP uses intelligence and

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[55] About CBP, https://www.cbp.gov/about.
[56] 19 C.F.R. § 162.6 (2017); *see also generally* 19 C.F.R. §§ 162.3–162.7 (2017).
[57] *Id.*
[58] *Id.*
[59] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017) (statement of Robert E. Perez, Executive Assistant Commissioner in Office of Operations Support, U.S. Customs and Border Protection).
[60] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017) (statement of Tammy Whitcomb, Acting Inspector General, U.S. Postal Service Office of Inspector General).
[61] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017) (statement of Sen. Rob Portman, Chairman, S.

on-the-ground experience to target specific packages for further inspection.[62] AED from shipment manifests, in part, aids CBP's targeting efforts.[63]

AED typically includes sender and recipient information such as names, addresses, and package content.[64] Foreign postal operators such as Hongkong Post, China Post, and Australia Post collect and provide AED to the Postal Service for international mail shipments.[65] The Postal Service transmits any AED it receives from foreign postal operators to CBP.[66] There is presently no requirement for foreign postal operators to provide AED to the Postal Service,[67] although some bilateral agreements executed by the Postal Service with foreign postal operators do contain such a requirement. However, ECOs require AED as a condition of accepting any shipment in every country where they choose to do business, and they also transmit any AED they receive to CBP.[68] Congress mandated the collection and transmission of AED by ECOs in the Trade Act of 2002. That legislation did not apply to the Postal Service and instead permits the Secretary of the Treasury and the Secretary of Homeland Security, in consultation with the Postmaster General, to determine whether the Postal Service must collect AED. As of the publishing of this report, no such decision has been made.

Although not required to collect AED from foreign postal operators, the Postal Service does receive AED from a number of countries. In total, in 2017 the Postal Service received AED on 36 percent of all inbound international mail volume.[69] The chart on the next page shows the percentage of AED the Postal Service receives from foreign posts on inbound international packages.

Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs).

[62] *See Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017).

[63] *Id.*

[64] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017) (statements of Tammy Whitcomb, Acting Inspector General, U.S. Postal Service Office of Inspector General and Robert Cintron, Vice President of Network Operations, U.S. Postal Service).

[65] *See Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017).

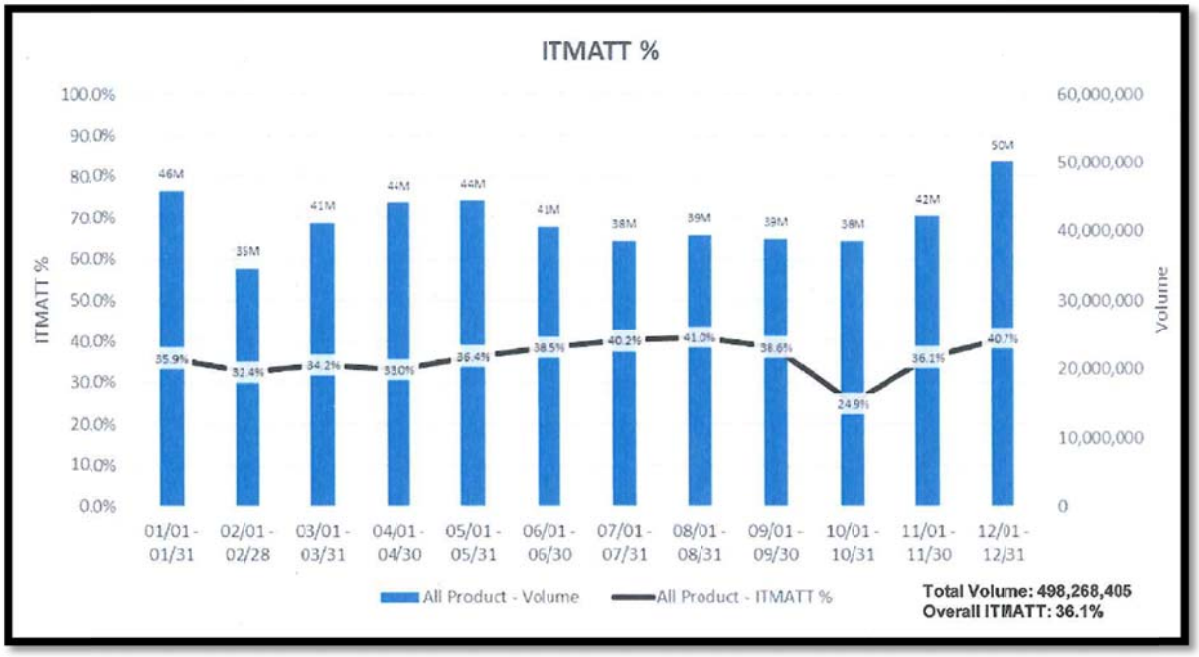
[66] *Id.*

[67] *Id.*

[68] 19 C.F.R. § 122.48a (2017).

[69] United States Postal Service production to the Subcommittee (Jan. 12, 2018) (on file with the Subcommittee).

The Percent of AED Received for Inbound International Packages[70]



In the interim, the Postal Service has already entered into bilateral and multilateral agreements with certain foreign postal operators and international alliances, such as the *Kahala Posts Group* and the *International Post Corporation*.[71] Some of these agreements include provisions requiring the foreign postal operator to share AED on packages bound for the United States.

The UPU has also implemented initiatives to increase the amount of AED provided to the Postal Service from foreign postal operators.[72] Most recently, the UPU approved a roadmap for the implementation of AED-sharing between posts, customs agencies, and air carriers to facilitate the safe and efficient delivery of international mail.[73] According to the UPU, this roadmap will be an essential component to ensuring that all posts are able to exchange AED by 2020.[74] In conjunction with the UPU's development of an Integrated Product Plan ("IPP"), the UPU now requires that barcodes be placed on all international packages containing

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[70] United States Postal Service production to the Subcommittee (Jan. 12, 2018) (on file with the Subcommittee).
[71] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017) (statement of Robert Cintron, Vice President of Network Operations, U.S. Postal Service).
[72] Postal Development on the Move, Universal Postal Union, (Aug. 2017), http://news.upu.int/fileadmin/magazine/2017/en/UPU-3414_UPU0217_EN_Final_Web.pdf.
[73] *Id.*
[74] *Id.*

goods. Although there is no requirement for the barcodes to contain data, their placement on all packages is considered a first step in requiring AED.

III. ONLINE SELLERS OF SYNTHETIC OPIOIDS OPERATE OPENLY USING COMMON SHIPPING AND PAYMENT METHODS

The Internet has significantly contributed to the increased availability of deadly synthetic opioids in the United States.[75] It is not difficult to find illegal drugs such as synthetic opioids advertised for sale on both the open web and the dark web. And since operators and distributors can remain anonymous online, these online marketplaces significantly reduce the risk of detection associated with purchasing fentanyl and other synthetic opioids.

The Subcommittee set out to determine just how easy it is to find synthetic opioids advertised and available for sale online. It found a number of online sellers willing to openly discuss how they could ship illegal synthetic opioids to the United States. The Subcommittee initially used common Internet search tools to discover websites offering drugs for sale on the open web and then searched the dark web with more advanced tools. Over the course of just one month, the Subcommittee identified dozens of websites offering synthetic opioids for sale, the overt techniques used by online sellers to communicate with prospective buyers of illegal drugs, and various forms of readily available payment and shipping methods for use. As shown above, online sellers openly advertise dangerous and deadly synthetic opioids for purchase.[76]

The results are alarming and illustrative of how illegal drug sales brazenly take place online. This section summarizes the Subcommittee's findings and details case studies of the Subcommittee's communications with the websites. First, the

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[75] Briefing with the U.S. Dep't of Homeland Security, Homeland Security Investigations (July 13, 2017); *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs Before Perm. Subcomm. on Investigations*, 115th Cong. 24 (2017) (testimony of Gregory D. Thome, Director, Office of Specialized and Technical Agencies, Bureau of Int'l Org. Affairs, U.S. Dep't of State) ("In addition to shipments that find their way into the United States from across our land borders and through express delivery services, illicit fentanyl and other illicit drugs also enter the country through international mail, typically in small shipments purchased online by individual customers.").

[76] Screenshot (June 20, 2017) (on file with the Subcommittee); Screenshot of ***Website D*** (June 13, 2017) (on file with the Subcommittee).

Subcommittee communicated with numerous websites offering synthetic opioids for sale. Representatives for these websites responded quickly—sometimes within minutes—and engaged in sophisticated sales techniques to offer exclusive products and discounts for bulk orders. Second, the sellers expressed a preference for cryptocurrencies such as bitcoin; but also conveyed a willingness to accept bank transfers, mobile payment services, and money orders. Third, the sellers offered various shipment options, but uniformly preferred the United States Postal Service.

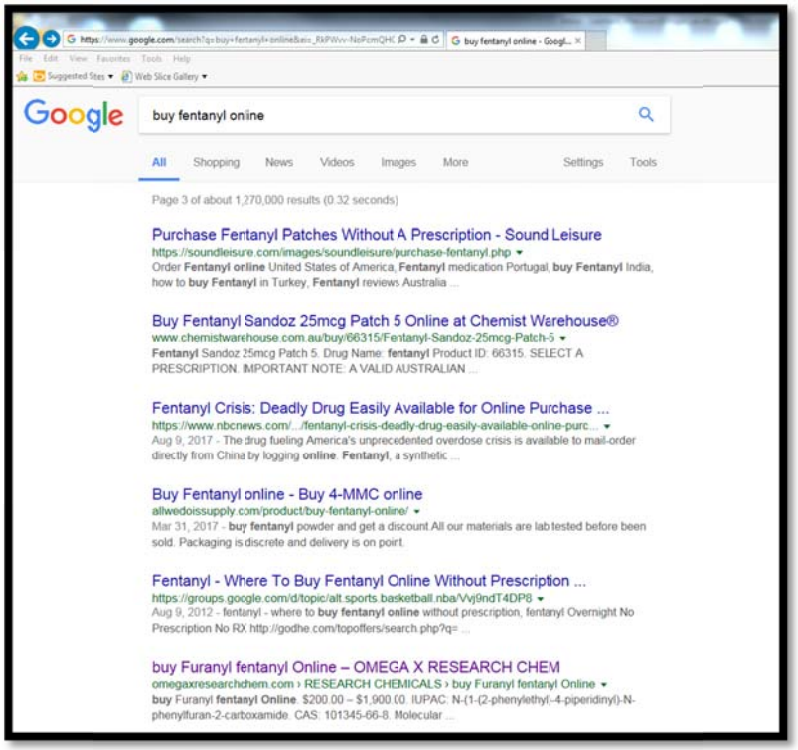
A. Methodology for Identifying and Communicating with Online Opioid Sellers

To locate online sellers offering to ship synthetic opioids to the United States, the Subcommittee posed as a first-time drug purchaser, relying on readily available online tools and search engines. The intent was to mimic an average Internet user by searching common fentanyl-related terms and asking the sellers straightforward questions about their products and available payment and shipping methods. From May 8, 2017 to June 12, 2017, the Subcommittee searched *Google* using basic search terms to identify websites advertising synthetic opioids for sale, as shown in the previous screenshot. These search terms included "fentanyl for sale," "buy fentanyl online," "fentanyl available online," and "buy research chemicals."[77] The Subcommittee identified 24 websites (the "online sellers") offering synthetic opioids for purchase, including fentanyl and carfentanil.

To contact the online sellers, the Subcommittee created an online persona and email address for all drug-related communication with websites offering the sale of synthetic opioids—on both the open web and dark web. The Subcommittee either sent email messages or filled in contact forms on the websites to initiate communication. Five websites appeared to no longer be functional at the time the Subcommittee attempted initial contact. Additionally, some email addresses bounced back as no longer valid, and others never replied.

[77] Screenshot of google.com search "buy fentanyl online" (Nov. 17, 2017) (on file with the Subcommittee).

Six websites the Subcommittee contacted were active and responded to the Subcommittee's email requests. These websites offered potential buyers the opportunity to communicate directly with customer service representatives regarding questions or other concerns. For approximately two months, the Subcommittee communicated directly with several of these customer service representatives for websites offering synthetic opioids and other illicit drugs for sale and shipment to the United States. The Subcommittee focused on these six online sellers who responded in a reasonable time frame and advertised synthetic opioids for sale:



- ***Website A***
- ***Website B***
- ***Website C***
- ***Website D***
- ***Website E***
- ***Website F***

While the Subcommittee engaged in prolonged discussions with individuals associated with the above-listed websites, at no time did the Subcommittee agree to make a purchase, send any payment, or receive any shipments of drugs. Communications with the websites related only to quantity and type of drugs available for purchase, payment methods, and shipping details. Additionally, in order to provide actionable leads to appropriate law enforcement authorities, the Subcommittee is not including the names of the websites in this public report.

B. Online Sellers Responded Within Minutes

Numerous online sellers were eager to engage in communications with the Subcommittee and answer any questions needed to complete a sale. Communicating with the online sellers was critical to learning more about their identity, shipping concealment methods, transit routes, and other information not

posted publicly on the websites. The representatives generally responded quickly, offering fentanyl and other, more powerful, drugs for sale. In many instances, the public websites lacked the specific information detailed below that was later communicated to the Subcommittee in emails by representatives for the online sellers.

The Subcommittee sent the same initial request message to all of the online sellers advertising fentanyl for sale. The message requested information regarding the purported quality of the product, which drugs were being offered, drug prices, preferred shipping method, country of origin, payment method, and how the online seller would attempt to evade law enforcement or customs seizures. None of the online sellers attempted to disguise the drug products for sale, and all communicated openly via email.

The online sellers responded with substantive answers to the Subcommittee's questions. For example, as shown below, ***Website F*** responded within six minutes to the Subcommittee's request to purchase fentanyl and even offered to upsell to carfentanil,[78] an even stronger and more dangerous synthetic opioid.[79]

[78] Carfentanil is a synthetic opioid with a potency 100 times greater than fentanyl, and 10,000 times greater than morphine. Under the Controlled Substances Act, carfentanil is classified as a Schedule II narcotic which is customarily used as a tranquilizing agent for elephants and other large animals. Press Release, *DEA Issues Carfentanil Warning to Police and Public*, U.S. Dep't of Justice, Drug Enforcement Administration (Sept. 22, 2016), https://www.dea.gov/divisions/hq/2016/hq092216.shtml.

[79] Email communication (June 15, 2017) (App. 0285).

From: [redacted]
To: [redacted]
Date: Thu, Jun 15, 2017 at 6:33 PM
Subject: [buy research chemicals online] Your message has been correctly sent #ct363 #tcd6Vphztn3XZ8

Your message to buy research chemicals online Customer Service
Your message has been sent successfully.

Message: Hello,
I am interested in purchasing fentanyl from your website. Can you please provide more information about your fentanyl products and how I order? I am a little concerned with the quality of the product and shipping to the U.S. What is the best way to ship it? Thanks.
Regards,
Leo

Order ID : -
Attached file : -
We will answer as soon as possible.
buy research chemicals online powered by PrestaShop™

From: [redacted]
To: [redacted]
Date: Thu, Jun 15, 2017 at 6:44 PM
Subject: Re: [buy research chemicals online] Message from contact form [no_sync]

Hello [redacted], our fentanyl is very good and our client love the quality, we also have powerful opioid like carfentanil. our product quality is 99.8% of purity. and we sale at a very affordable price. we ship from our branch in [redacted] so delivery is discrete and secured. what quantity do you plan to order ?

Waiting for your response,
Best regards.

[80]

Of the five other online sellers contacted by the Subcommittee, four responded within an hour of receiving the Subcommittee's offer to buy fentanyl and the fifth seller responded in less than 13 hours.

C. Online Sellers Monitor Drug "Scheduling"

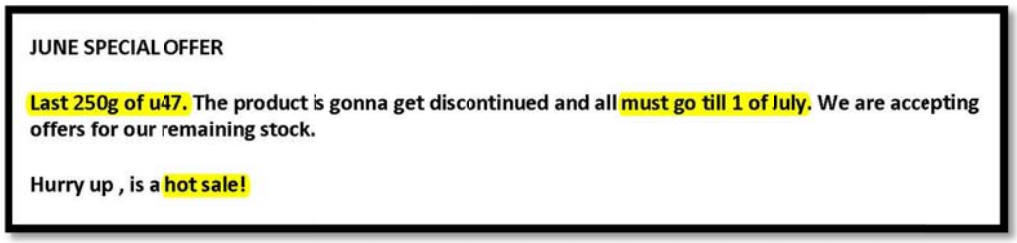
Online sellers showed a high level of sophistication, demonstrating knowledge of recent U.S. and Chinese efforts to combat illicit drug sales. According to the U.S.-China Economic and Security Review Commission, because fentanyl is not widely used as a recreational drug in China, authorities there historically placed little emphasis on controlling its production and sale.[81] However, the Chinese government recently announced several scheduling control orders for

[80] *Id.*

[81] U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION, FENTANYL: CHINA'S DEADLY EXPORT TO THE UNITED STATES 2 (2017) ("According to U.S. law enforcement and drug investigators, China is the main supplier of fentanyl to the United States, Mexico, and Canada. Because illicit fentanyl is not widely used in China, authorities place little emphasis on controlling its production and export.").

fentanyl and related substances.[82] This resulted in both challenges and opportunities for online sellers based in China.

For example, one commonly abused fentanyl product, often referred to by its chemical pseudonym of U-47700, was scheduled and banned by the DEA in September 2016.[83] On June 19, 2017, China added the drug to its list of controlled substances, effective July 1, 2017.[84] ***Website A*** apparently viewed China's scheduling of U-47700 as a unique business opportunity. On June 25, 2017, ***Website A*** notified the Subcommittee that the company was only selling U-47700 until July 1, 2017.[85] The online seller's website publicly advertised this as a "hot sale," even allowing buyers to make offers on the remaining product.[86]



[87]

On October 6, 2017, ***Website A*** informed the Subcommittee that U-47700 was now discontinued. However, U-48800, another fentanyl analog, was available for purchase, as shown in the screenshot below.[88]

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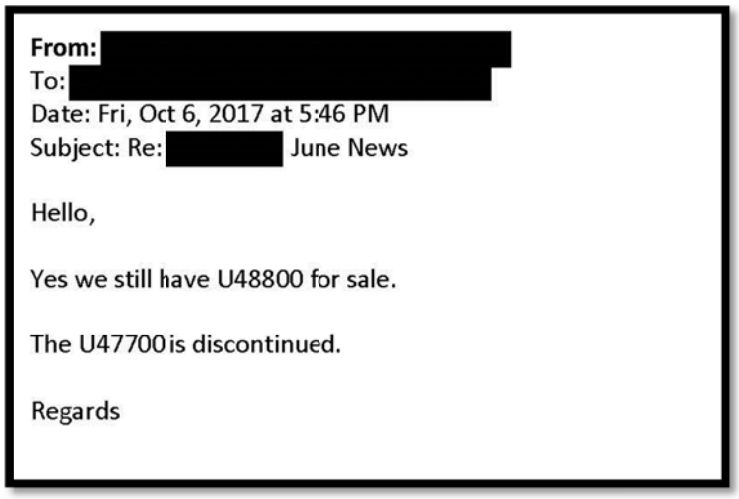
[82] Press Release, *China announces scheduling controls of new psychoactive substances/fentanyl-class substances*, Drug Enforcement Administration, U.S. Dep't of Justice, (June 19, 2017), https://www.dea.gov/divisions/hq/2017/hq061917.shtml.
[83] List of Controlled Substances, Drug Enforcement Administration, U.S. Dep't of Justice (Nov. 17, 2017), https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf; Executive Order 2016-01K, Office of the Governor of Ohio (May 3, 2016), http://www.governor.ohio.gov/Portals/0/pdf/executiveOrders/Executive%20Order%202016-01K.pdf.
[84] Press Release, *China announces scheduling controls of new psychoactive substances/fentanyl-class substances*, Drug Enforcement Administration, U.S. Dep't of Justice (June 19, 2017), https://www.dea.gov/divisions/hq/2017/hq061917.shtml.
[85] Email communication (June 25, 2017) (App. 0260).
[86] *Id.*
[87] *Id.*
[88] Email communication (Oct. 6, 2017) (App. 0262).


From: [redacted]
To: [redacted]
Date: Fri, Oct 6, 2017 at 5:46 PM
Subject: Re: [redacted] June News

Hello,

Yes we still have U48800 for sale.

The U47700is discontinued.

Regards

As of this report, U-48800 is not currently scheduled in either the United States or China. The DEA recently announced it plans to publish a notice of intent to temporarily schedule all fentanyl-related substances on an emergency basis. According to the DEA, the temporary measure will make it easier to prosecute traffickers of all forms of fentanyl-related substances and will be effective for up to two years, with the possibility of a one-year extension.[89]

1. Online Sellers Offered Discounts and Comparable Opioids

The online sellers also routinely offered discounts and other opioid products comparable to fentanyl in an attempt to increase sales and profit. ***Website A*** offered the most refined bulk order discount. As shown below, discounts were based on quantity ordered, payment method, and if the customer wanted a guaranteed shipment.[90] The online seller explained that a guaranteed shipment was essentially an insurance policy—providing the customer with a replacement shipment if the original was seized.[91]

[89] Press Release, *Department of Justice announces significant tool in prosecuting opioid traffickers in emergency scheduling of all fentanyl's*, Drug Enforcement Administration, U.S. Dep't of Justice, (Nov. 9, 2017), https://www.dea.gov/divisions/hq/2017/hq110917.shtml.
[90] Email communication (June 15, 2017) (App. 0261).
[91] *Id*.

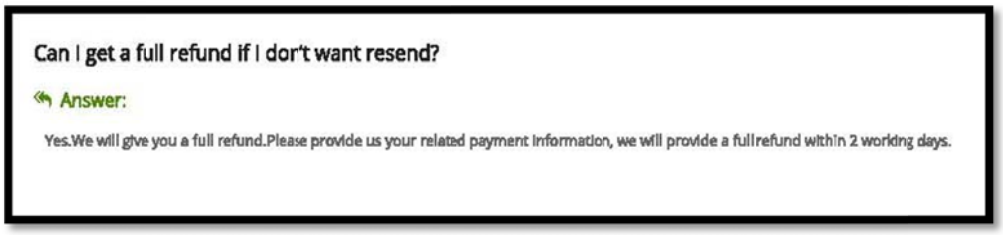
From: [redacted]
To: [redacted]
Date: Thu, Jun 15, 2017 at 3:27 AM
Subject: Re: Research Chemicals For Sale USA Contact: Order Help

Weight	Western Union+ incl. Reship gurantee	Bitcoin + incl. Reship guarantee	Western Union - no Reship	Bitcoin -no Reship
2g	145$	133$	78$	71$
10g	232$	213$	143$	131$
25g	394$	362$	265$	243$
50g	665$	611$	467$	429$
100g	1206$	1109$	873$	803$
250g	2829$	2602$	2091$	1923$
500g	5535$	5092$	4120$	3815$
1000g	10949$	10073$	7573$	7524$

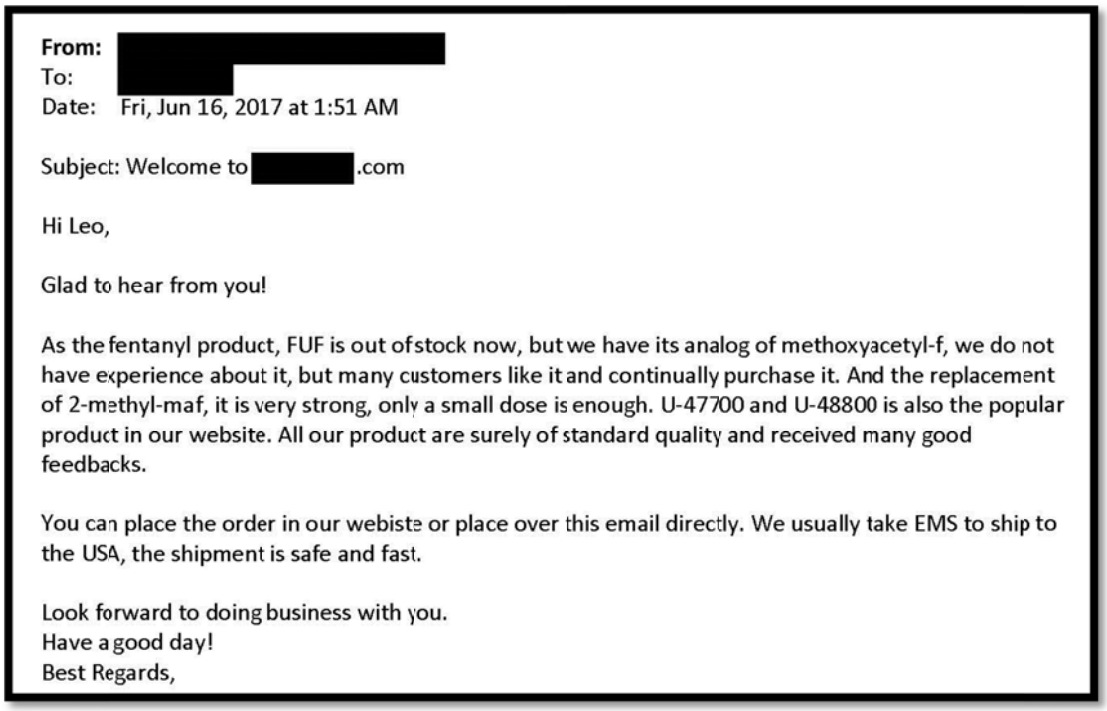
[92]

Website B offered to send another package to the Subcommittee if the original order of fentanyl was held by customs authorities for more than 14 days.[93] If a package was held for more than three weeks, ***Website C*** offered to send a replacement package. However, ***Website C*** only offered reshipment if Express Mail Service ("EMS"), a product offered by many UPU member postal operators, including China Post, was used and would not guarantee other shipping methods. The term "EMS" is generally synonymous with a country's government-run shipping service. As an example, "China Post" and "EMS," both refer to China's official postal delivery service. The same is true for the Postal Service; it, too, could accurately be called "EMS."[94] In addition to reshipment, ***Website C*** offered a full refund within two business days to customers who did not want to have a package reshipped, as shown below.[95]

[92] *Id.*
[93] Email communication (June 15, 2017) (App. 0257).
[94] What is EMS?, Universal Postal Union (2017), http://www.ems.post/what_is_ems.
[95] Screenshot of ***Website C*** (Nov. 17, 2017) (on file with the Subcommittee).



Another online seller, ***Website D***, offered the Subcommittee a 20 percent discount on fentanyl orders over one kilogram.[96] Finally, ***Website C***, as shown below, offered several alternative drugs when the requested fentanyl product was out of stock.



[97]

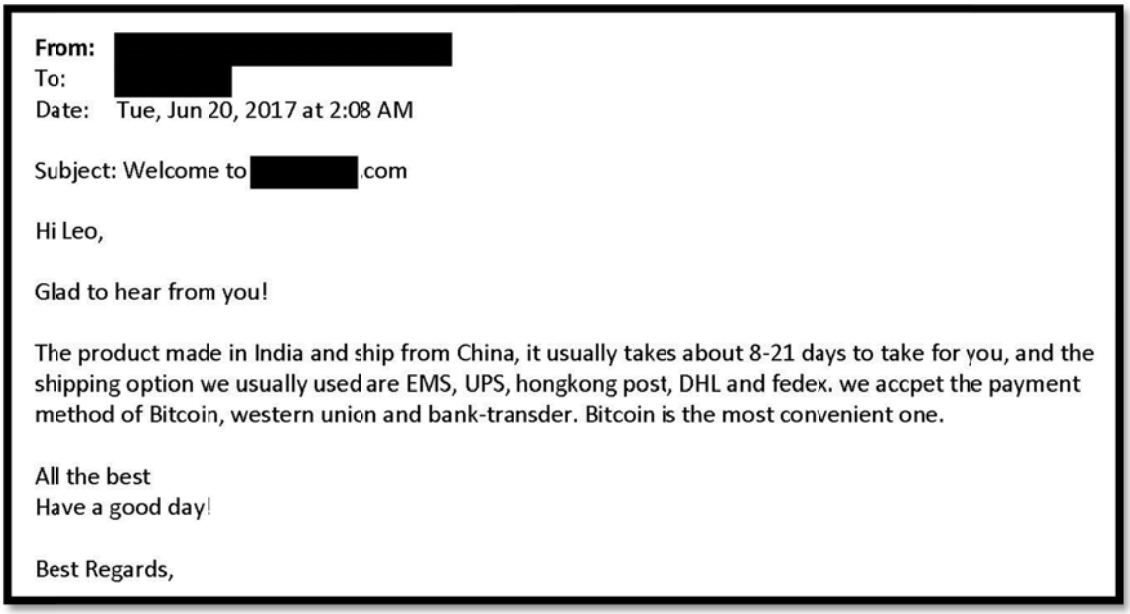
The online sellers also expressed confidence that their products would be delivered as ordered. ***Website A, Website B***, and ***Website C*** all offered reshipment guarantees and agreed to resend products if the package was held by Customs.[98] ***Website A*** required an additional fee for a reshipment guarantee and provided an incentive to order more drugs to save on potential reshipping costs. ***Website A's*** minimum order for two grams of fentanyl with a reshipment guarantee cost $145, versus $78 without a guarantee, for a savings of 7.6 percent if the first shipment

[96] Email communication (June 13, 2017) (App. 0275).
[97] Email communication (June 16, 2017) (App. 0273).
[98] Email communication (June 15, 2017) (App. 00931); Screenshot of ***Website C*** (June 20, 2017) (on file with the Subcommittee).

was seized.[99] ***Website A's*** order of one kilogram of fentanyl with a reshipment guarantee cost $10,949, versus $7,573 without a guarantee, at a savings of 38.3 percent if the initial shipment is seized.[100] ***Website D*** did not offer reshipment, but did offer the Subcommittee a full refund if a purchase was not delivered.[101]

D. Online Sellers Prefer Bitcoin

All of the online sellers accepted payment in the form of bitcoin, which was their preferred payment method. Bitcoin is "completely digital money" and "the first decentralized peer-to-peer payment network."[102] Bitcoin is described as "cash for the Internet."[103] Some of the online sellers contacted by the Subcommittee offered substantial discounts if bitcoin was used for payment.[104] ***Website F*** initially offered bitcoin as the only available form of payment before the Subcommittee requested other payment methods.[105] ***Website C*** described bitcoin as the "most convenient" payment method, as shown below.[106]



From: [redacted]
To:
Date: Tue, Jun 20, 2017 at 2:08 AM

Subject: Welcome to [redacted].com

Hi Leo,

Glad to hear from you!

The product made in India and ship from China, it usually takes about 8-21 days to take for you, and the shipping option we usually used are EMS, UPS, hongkong post, DHL and fedex. we accpet the payment method of Bitcoin, western union and bank-transder. Bitcoin is the most convenient one.

All the best
Have a good day!

Best Regards,

In addition to anonymity, using bitcoin can be cheaper than processing funds through more traditional means, such as wire transfers and money orders. For

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[99] Email communication (June 15, 2017) (App. 0261).
[100] *Id.*
[101] Email communication (June 15, 2017) (App. 0278).
[102] Bitcoin.org, *Frequently Asked Questions*, https://bitcoin.org/en/faq#what-is-bitcoin.
[103] *Id.*
[104] Screenshot of ***Website E*** (Nov. 14, 2017) (on file with the Subcommittee); Email communication (June 25, 2017) (App. 0260).
[105] Email communication (June 15, 2017) (App. 0282).
[106] Email communication (June 20, 2017) (App. 0269).

example, Western Union enforces a $500 per transaction limit and a $1,000 monthly sending limit—and there are fees associated with sending money.[107] Bitcoin, by contrast, does not have these transactional limits. According to the Financial Crimes Enforcement Network, a user of virtual currency is not a Money Services Business (MSB) and is therefore not subject to registration, reporting, and recordkeeping regulations with U.S. financial regulators.[108]

While bitcoin was the preferred payment option, the online sellers contacted by the Subcommittee accepted various other payment forms, including Western Union transfers, MoneyGram, PayPal, credit card, gift card, and even direct bank transfer. For example, ***Website D*** offered the Subcommittee numerous payment options including credit card, Visa/MasterCard gift card, bank transfer, and bitcoin. The website's shipping time even varied depending on the payment method: "Discreet shipping within 30 minutes are [sic] only available for VISA/ MASTERCARD Gift Cards payments. For Credit Card and Bitcoin payments, it will take 1-2 hours before order can be ship [sic] since payment is not instant."[109]

The Subcommittee's investigation further revealed that there is risk for purchasers relying on a traditional MSB, or money remitter,[110] as opposed to the more anonymous cryptocurrencies. On July 21, 2017, the Subcommittee requested payment information from Western Union related to various online seller accounts. Shortly thereafter, Western Union notified the Subcommittee that they were closing the accounts at issue in the Subcommittee's request. As a result of having their Western Union accounts closed, at least two of the websites formally changed their payment policies and began only accepting bitcoin. Specifically, on July 26, 2017, ***Website A*** sent the following email on July 26, 2017, stating it no longer accepted Western Union and would only accept bitcoin:

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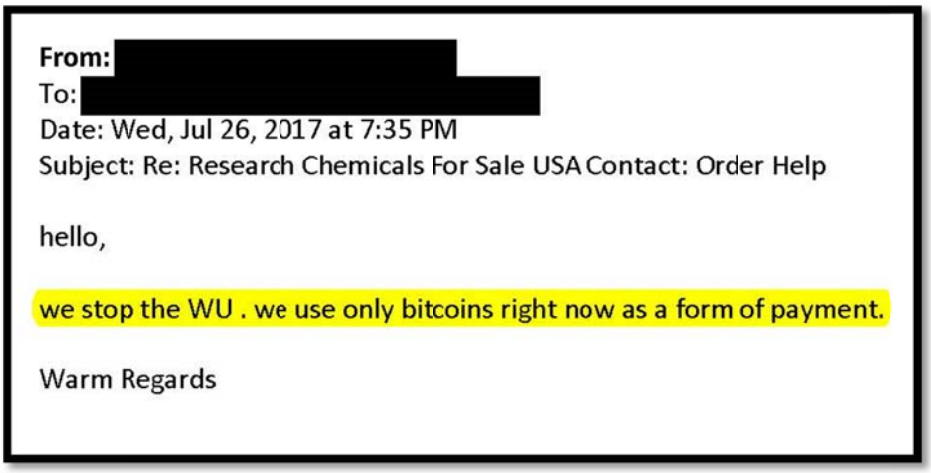
[107] Western Union, *Frequently Asked Questions,* https://www.westernunion.com/us/en/customer-care/cc-faqs.html.

[108] Application of FinCEN's Regulations to Persons Administering, Exchanging, or Using Virtual Currencies, FIN-2013-G001, U.S. DEP'T OF THE TREASURY, FINANCIAL CRIMES ENFORCEMENT NETWORK (Mar. 18, 2013); Money Services Business Definition, U.S. DEP'T OF THE TREASURY, FINANCIAL CRIMES ENFORCEMENT NETWORK (Nov. 1, 2016), https://www.fincen.gov/money-services-business-definition.

[109] Email communication (June 15, 2017) (App. 0275).

[110] A money remitter is any individual who engages in the business of transferring funds abroad through remittance transfer providers such as banks, credit unions, and other financial services companies. *See* 31 C.F.R. § 103.11(uu)(5)(B) (2017); CONSUMER FIN. PROT. BUREAU, *What is a Remittance Transfer?* (2016), https://www.consumerfinance.gov/ask-cfpb/what-is-a-remittance-transfer-en-1161/.



From: [redacted]
To: [redacted]
Date: Wed, Jul 26, 2017 at 7:35 PM
Subject: Re: Research Chemicals For Sale USA Contact: Order Help

hello,

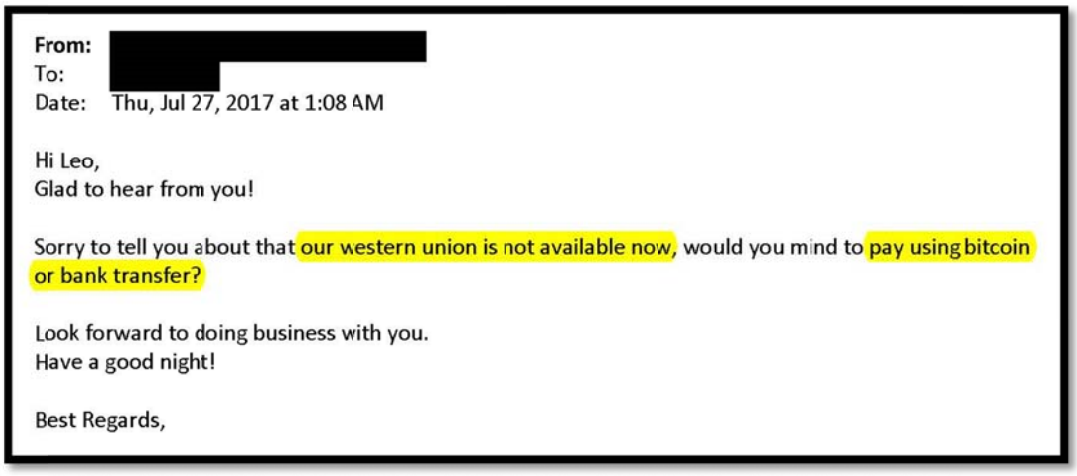
we stop the WU . we use only bitcoins right now as a form of payment.

Warm Regards

[111]

Website A provided the Subcommittee with its bitcoin wallet address, which received bitcoins totaling approximately $500,000.[112]

Additionally, ***Website C*** sent the following email after the Subcommittee requested financial records:



From: [redacted]
To:
Date: Thu, Jul 27, 2017 at 1:08 AM

Hi Leo,
Glad to hear from you!

Sorry to tell you about that our western union is not available now, would you mind to pay using bitcoin or bank transfer?

Look forward to doing business with you.
Have a good night!

Best Regards,

[113]

E. Online Sellers Prefer Shipping Drugs with Government-Run Postal Operators

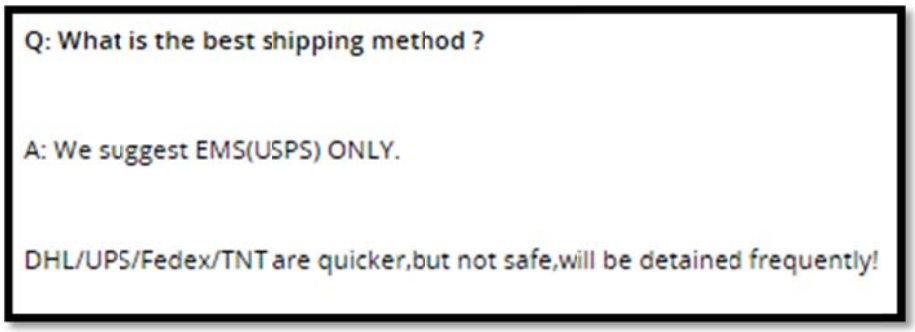
All of the international online sellers who corresponded with the Subcommittee expressed confidence that the drug products they advertised would get delivered to the United States and not be seized by any customs authorities. The shipping methods used by the online sellers varied. After extensive

[111] Email communication (July 26, 2017) (App. 0263).
[112] Records on file with the Subcommittee.
[113] Email communication (July 27, 2017) (App. 0272).

communications, it became clear that three main shipping routes were used by the websites: (1) shipment directly from China to a U.S.-based address; (2) transshipment from China through another country to a U.S. address; or, (3) shipment from China to a U.S.-based distributor and then to a U.S. address.

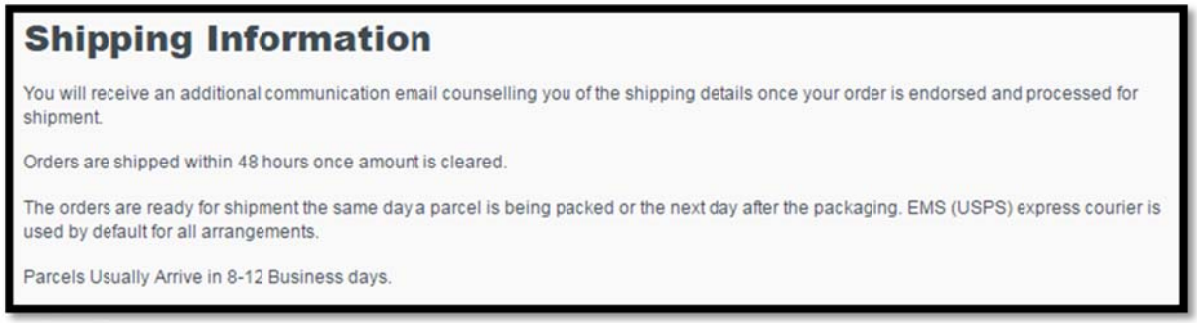
There was one common thread among all three shipping routes: All of the international websites preferred to use the government-operated postal service EMS, a cooperative run by members of the Universal Postal Union, which is discussed in more detail in the background section of this report. Other shipping options were offered when the Subcommittee requested additional information.

Website C suggested a purchaser only use EMS and discouraged use of ECOs, such as DHL, FedEx, and UPS:



[114]

Website A's shipping section, as shown below, states that orders are shipped within one to two days of packing and lists EMS as the default shipping option. The same website also guaranteed delivery for all countries it ships to, including the United States, as long as the purchaser used EMS as the shipping option.



[115]

Additionally, as shown below, ***Website C*** guaranteed delivery only if EMS was used and offered free EMS shipping for orders over $100.

[114] Screenshot of ***Website C*** (Nov. 17, 2017) (on file with the Subcommittee).
[115] Screenshot of ***Website A*** (May 9, 2017) (on file with the Subcommittee).

4.Free shipping and Guaranteed Delivery

When your order is more than $100 you will get the Free shipping services via EMS.

[redacted]Guaranteed delivery only via EMS, other shipping methods will not be guaranteed. When your package via EMS has been kept in the custom for more than 3 weeks, we would resend your order soon and you need to contact us about it. (notice again: only via EMS could be Guaranteed). BTW, packages to some countries cant be Guaranteed all now,you could check the info in the item of "Guaranteed Delivery" .

Warn: All the products are provided as the science research,not used for any other purposes.

116

While all of the international online sellers contacted by the Subcommittee preferred to use EMS, the actual shipment route differed. Below are three examples of the shipment routes the sellers described.

Direct from China to the United States. Three of the six sellers indicated that they would ship the product directly from China to the final destination in the United States. For example, ***Website E*** offered to sell the Subcommittee a 99 percent pure fentanyl analog shipped directly from China using EMS:

From: [redacted]
To: [redacted]
Date: Tue, Jun 20, 2017 at 5:48 PM
Subject: [redacted]

Dear Leo [redacted],

This is the [redacted], we ship from China but all our payments are made to Hungary,Budapest.
We will ship out your package using EMS delivery service and this is tracking number of a package that we just delivered [redacted] .

We look forward to your respond.

Best regards,
[redacted]

Tel: [redacted]
E-mail: [redacted]
URL: http://[redacted]

117

[116] Screenshot of ***Website C*** (June 20, 2017) (on file with the Subcommittee).

Website E also provided several tracking numbers to prove they were capable of delivering their product.[118] The tracking numbers all indicated recent packages successfully shipped from China to various locations throughout the United States.

Transshipment. As mentioned previously, transshipment is the process of shipping goods through a second country, port, or territory before they arrive at their final destination.[119] Investigators with the Department of Homeland Security's Homeland Security Investigations ("HSI") reported seeing packages "purposefully" diverted through various countries as transshipment points to avoid both Chinese and U.S. customs authorities.[120] Additionally, CBP officials indicated that transshipment is a "huge problem" as packages containing illicit goods are being routed through countries with less scrutiny.[121]

One online seller relied on transshipment as a way to give potential buyers confidence that the illegal drugs would arrive without incident. ***Website B*** stated, below, they would ship fentanyl to the United States via EMS. Although the fentanyl was manufactured in China, the dealer indicated it would be transshipped through a European country, which was described as a "low risky [sic] country."[122]

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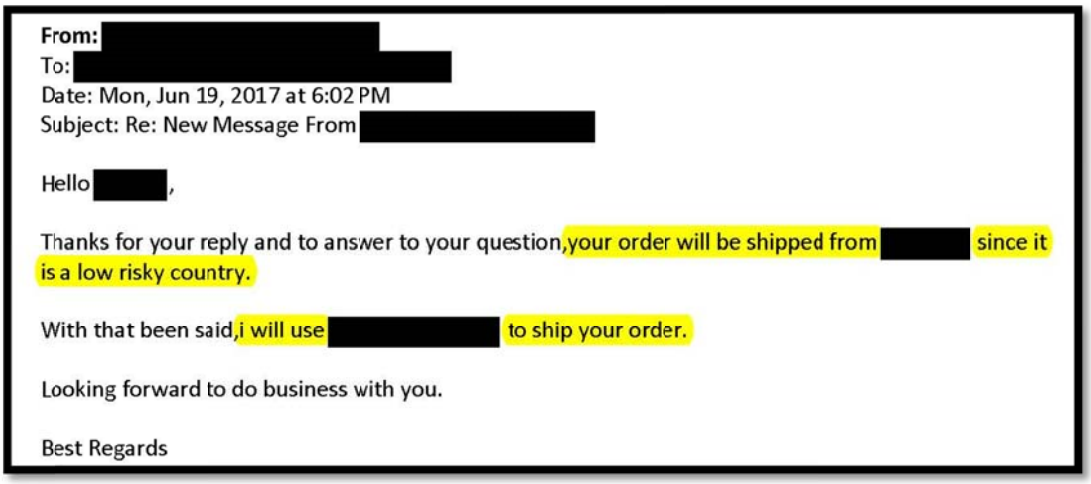
[117] Email communication (June 20, 2017) (App. 0281). As a reminder, the Subcommittee did not complete any purchases: ***Website E*** provided a tracking number solely as evidence that it successfully shipped packages directly from China to the United States.
[118] Email communication (June 15, 2017) (App. 0280); Email communication (June 20, 2017) (App. 0281).
[119] U.S. CUSTOMS & BORDER PROTECTION, CSMS #98-000243, *Textile Transshipment Report* (1998).
[120] Briefing with the U.S. Dep't of Homeland Security, Homeland Security Investigations (July 13, 2017).
[121] Briefing with U.S. Dep't. of Homeland Security, Customs and Border Protection (Aug. 21, 2017); Briefing with the U.S. Postal Service (Aug. 21, 2017).
[122] Email communication (June 19, 2017) (App. 0259).


From: [redacted]
To: [redacted]
Date: Mon, Jun 19, 2017 at 6:02 PM
Subject: Re: New Message From [redacted]

Hello [redacted],

Thanks for your reply and to answer to your question,your order will be shipped from [redacted] since it is a low risky country.

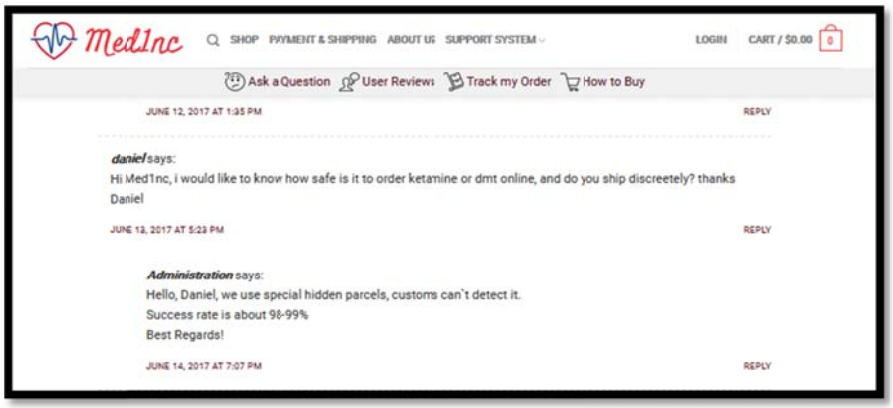
With that been said,i will use [redacted] to ship your order.

Looking forward to do business with you.

Best Regards

[123]

U.S.-Based Distributor. As an alternative to transshipment, two of the sellers indicated that the drugs would be shipped from China to a "U.S. branch," and then to the U.S.-based recipient. ***Website F*** advertised "99.8 percent" pure fentanyl shipped from their Texas branch via ECOs and the Postal Service.[124]



When Subcommittee staff mentioned that they were shopping around for fentanyl, the dealer even offered a $20 discount and additional payment options in an attempt to close the deal.[125]

Finally, most of the online sellers used the terms "stealth," "discrete [sic]," and "unmarked" to describe how the seller would conceal the drugs from detection during the shipping process. ***Website D*** advertised the most elaborate packaging description, labeled "100% Safe and Secure Stealth Discreet Packaging:"[126]

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[123] *Id.*
[124] Email communication (June 15, 2017) (App. 0285).
[125] Email communication (June 21, 2017) (App. 0284).
[126] Email communication (June 13, 2017) (App. 0276).

[127]

IV. IDENTIFYING U.S. INDIVIDUALS RECEIVING SUSPECTED DRUG PACKAGES FROM CHINA

After extended conversations with the online sellers, the Subcommittee sought to uncover the identity and motives of U.S. individuals who were either associated with the online sellers or likely purchasers of illegal and deadly synthetic opioids. The Subcommittee reviewed detailed shipment data and financial records linked to the six previously identified online sellers.

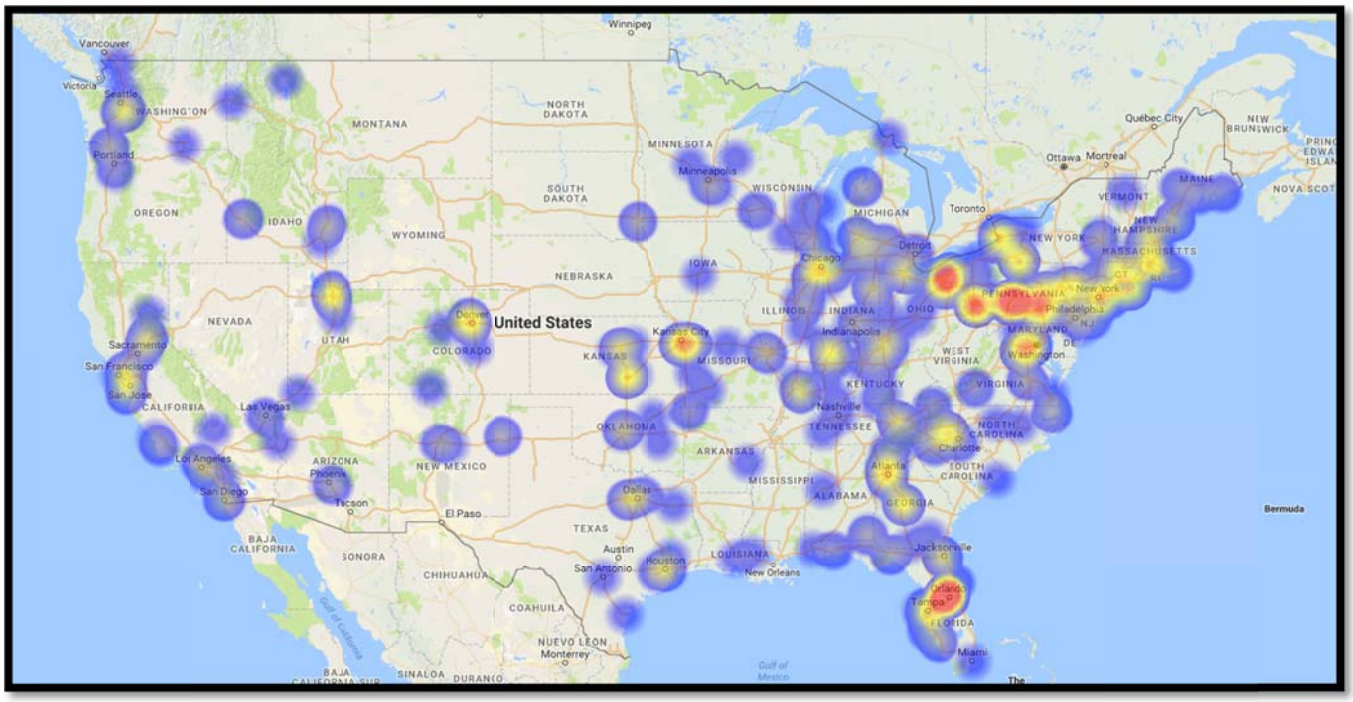
The Subcommittee's review revealed four alarming findings. First, the Subcommittee identified a likely distributor of deadly synthetic opioids from China *based in the United* States. Second, the Subcommittee identified seven individuals in the United States who tragically died from synthetic opioid overdose soon after they wired money to accounts controlled by the online sellers. Third, the Subcommittee identified at least 18 individuals from 11 states who sent money to the online sellers' accounts who were either arrested or convicted of serious drug related offenses. Fourth, the Subcommittee identified at least two more U.S. individuals who are likely engaged in the mass distribution of synthetic opioids.

To provide appropriate law enforcement authorities with actionable leads on potential ongoing criminal activity, the Subcommittee is not revealing in this public report the identity of either the online sellers or any individuals likely associated with the websites. A confidential report and related records containing comprehensive information about the online sellers and any U.S.-based individuals will be provided, as appropriate and in a manner consistent with U.S. Senate rules, to local and federal law enforcement authorities.

[127] *Id.*

A. Methodology for Locating Likely Purchasers of Illegal Opioids

To locate likely purchasers of illegal opioids and their suspected associates, the Subcommittee examined financial and shipment information linked to the six online sellers discussed in the preceding section. U.S. individuals in 43 states completed over 500 financial transactions totaling nearly $230,000 to accounts linked to four of the six online sellers.[128] Individuals in Ohio, Pennsylvania, New York, and Florida had the most financial transactions linked to the online sellers. In just those four states, there were over 200 transactions totaling roughly $100,000.[129] The map below illustrates every U.S. location linked to a payment to the online sellers offering fentanyl and other deadly synthetic opioids for sale.[130] Locations in red indicate the most transactions.



After identifying over 300 individuals who sent money to the online sellers, the Subcommittee requested shipment data linked to those individuals from the Postal Service, CBP, and three ECOs. The goal was to determine which packages likely contained drugs based on payment dates and identified drug sources, both domestic and international, to uncover trends and patterns of how drugs actually make their way into the United States.

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[128] The Western Union Company production to the Subcommittee (Aug. 9, 2017) (on file with Subcommittee); The Western Union Company production to the Subcommittee (Sept. 29, 2017) (on file with Subcommittee) (*hereinafter* "Western Union Productions").

[129] *Id.*

[130] *Id.*

Subcommittee staff examined over two million lines of shipment data produced by the Postal Service, CBP, and the three ECOs. The shipment data examined typically included unique identifiers associated with specific individuals, including the receiver's name, address, and the date of shipping. The Postal Service's international data sometimes lacked sender information, which could have allowed the Subcommittee to determine a common drug shipper or a common pattern of activity to assist with shipment targeting. The Subcommittee searched multiple datasets several different ways by limiting information and conducting a manual review to determine address matches.

Additionally, the Postal Service does not always require a return shipping address. This information was excluded in much of the domestic shipment data reviewed. And even when the return address information was present, some shipments still lacked a definitive house or apartment number or street name. However, the Subcommittee conducted an expanded search of Postal Service records to identify the source location of the suspected drug shipments.

Despite these limitations, the Subcommittee had significant success tracking shipments to individuals in the United States who also sent international money wires within approximately one week of the shipment. This examination led to the Subcommittee's findings discussed below.

Finally, in examining the data, the Subcommittee observed another limitation that impacts the Postal Service or law enforcement's ability to monitor suspicious packages entering the United States. Much of the data the Subcommittee received was not provided as AED to CBP or the Postal Service prior to the package arriving in the United States. Rather, as the package traveled through the domestic mail stream for delivery, Postal Service systems generated the data. At delivery, the data for Postal Service packages mirrored the data collected by the ECOs when they take possession of a package from a customer.

B. The Subcommittee Identified a Likely *U.S.-Based* Distributor for Chinese Produced Fentanyl and Other Deadly Synthetic Opioids

The buyers identified by the Subcommittee lived in more than three dozen states and seemingly had no connection except for making purchases from a common online seller. However, another common thread that emerged is that one Pennsylvania address was used to send *more than 120 packages* tied to payments to an online seller during a two-month period in early 2017.[131] The Subcommittee found a compelling connection between the timing of the payment data and the shipment data. Oftentimes, shipments were sent within one day of the receipt of

[131] United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).

payment. The chart below shows a sampling of the more than 120 shipments that followed payments sent to an online seller advertising opioids for sale.[132]

Payment Amount	Payment Sent to Online Seller	Package Sent from PA Address
$154.00	11/8/2016	11/10/2016
$276.00	1/8/2017	1/9/2017
$341.00	1/11/2017	1/12/2017
$82.00	1/11/2017	1/13/2017
$212.50	1/12/2017	1/13/2017
$334.00	1/19/2017	1/20/2017
$199.00	1/19/2017	1/20/2017
$290.00	1/20/2017	1/23/2017
$322.02	1/21/2017	1/23/2017
$96.20	1/23/2017	1/24/2017
$659.56	1/23/2017	1/25/2017
$133.40	1/28/2017	1/31/2017
$310.00	2/1/2017	2/1/2017
$76.20	2/2/2017	2/6/2017
$232.50	2/4/2017	2/7/2017
$114.60	2/4/2017	2/7/2017
$221.00	2/4/2017	2/7/2017
$104.80	2/6/2017	2/7/2017

In addition, upon further examination of these shipments, the Subcommittee found numerous instances of shipments that went to individuals who (1) were arrested for drug offenses; (2) tragically died from drug overdoses; or (3) were active payers to the online sellers, as further described below.

Based on these findings, it is likely that an active drug distributor in Pennsylvania is acting as a distributor for an internationally-based website that advertises synthetic opioids for sale on the open web.

C. The Subcommittee Identified Seven Individuals Who Wired Money to Online Sellers and Later Died of Drug Overdoses

The Subcommittee's investigation further confirmed the deadly nature of the opioid epidemic. Of the more than 300 individuals identified in the data, the

[132] Western Union Productions; United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).

Subcommittee identified *seven* deceased individuals who died from a fentanyl or other synthetic opioid overdose who wired money to accounts linked to the online sellers identified in this report. The Subcommittee also identified shipments received by those deceased individuals that correspond with the dates when money was wired to the websites. In fact, in one example discussed below, an individual received a package the day before his death.

One such individual identified by the Subcommittee was a 49-year-old Ohio man who paid roughly $2,500 to an online seller over the course of 10 months from May 2016 to February 2017. Over that time period, he received 18 packages through the Postal Service that closely corresponded with the dates he wired money to an online seller. For example, on May 14, 2016 and October 27, 2016, he sent $134 and $310 respectively, and on both occasions packages bound for his address entered the international mail system on the same days he made payments. Nearly all of the other payments coincided closely with the dates a package was sent through the Postal Service. Five international packages sent to this Ohioan coincided with foreign wire payments made to one of the online sellers.[133] At least one of these packages came directly from China and the ISC in Chicago processed it. According to publicly available tracking information, both packages spent less than 24 hours processing through CBP in Chicago.[134] And, as shown below, one of the packages spent roughly an hour in customs before being processed through for delivery.

[133] Western Union Productions; United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).
[134] United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).

At the time of these shipments, the Chicago ISC did not participate in the Postal Service pilot program designed to let CBP target suspected drug packages with AED, as discussed in more detail in the following section.[135] This individual also received seven packages from the likely Pennsylvania distributor identified in the previous section.[136] One of the packages was delivered from Pennsylvania two weeks before he passed away.[137] According to autopsy records provided to the Subcommittee, the cause of death was "acute fentanyl intoxication."[138]

In a similar case, the Subcommittee identified a 25-year-old man from Michigan who sent $543 over the course of three months to an online seller. All three payments corresponded with the dates packages were sent to him through the Postal Service.[139] On November 2, 2016, he sent $341 to an online seller, and on

[135] *See* Section V.
[136] United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).
[137] *Id.*
[138] Autopsy records on file with the Subcommittee.
[139] Western Union Productions; United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).

November 3, 2016, a package was sent to him from the suspected Pennsylvania-based distributor. On February 6, 2017, he sent $104.80 and had a package mailed to him from the suspected Pennsylvania-based address on February 7, 2017.[140] Five months later, he died on July 16, 2017 from a fentanyl overdose.[141]

Finally, another Michigan man sent roughly $400 dollars to an online seller in late 2016.[142] On November 25, 2016, he wired more than $200 to an international online seller and, on December 2, 2016, he received a package linked to the Pennsylvania-based distributor.[143] Public records indicate that just ***one day*** later, he died of an accidental overdose of multiple drugs, including a fentanyl analogue.[144] Over the course of a year before his death, he received at least five additional packages linked to the Pennsylvania-based distributor.[145]

D. The Subcommittee Identified 18 Individuals Who Wired Money to Online Sellers Who Were Arrested or Convicted of Serious Drug-Related Offenses

The Subcommittee identified 18 individuals who were arrested or convicted of serious drug-related offenses who also sent money to online sellers. Ten of these individuals previously had an arrest or conviction for possession or possession with intent to distribute drugs and later sent money to an online seller and received a package. The remaining eight were arrested after they sent money and received a package. Arrests took place in states including Ohio, Pennsylvania, Florida, New York, and Massachusetts. Criminal charges for the individuals ranged from intent to distribute, to endangering the welfare of a child, to possession of controlled substances.

For example, one individual from Ohio was indicted in early 2017 for possession with intent to distribute nearly three pounds of fentanyl.[146] The Subcommittee identified one payment to an online seller in mid-2016 of more than one thousand dollars.[147] Although the individual used a fake name to receive international packages containing large quantities of fentanyl, law enforcement authorities were able to identify him and conducted a controlled delivery.[148]

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[140] *Id.*
[141] Autopsy records on file with the Subcommittee.
[142] Western Union Productions.
[143] Western Union Productions; United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).
[144] Autopsy records on file with the Subcommittee.
[145] United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).
[146] Records on file with the Subcommittee.
[147] Western Union Productions.
[148] *Id.*; *Securing the Maritime Border: The Future of CBP Air and Marine Before the Subcomm. on Border and Maritime Security of the H. Comm. on Homeland Security*, 114th Cong. (2015) (testimony

According to publicly available information, this individual told law enforcement he ordered the fentanyl online from China after a family member showed him how to do it.[149] Under the current sentencing guidelines, this individual is facing a minimum prison sentence of ten years.[150]

Another individual, also from Ohio, sent more than $3,500 over a two-month span in mid-2016 to an online seller located in China.[151] He received four international packages with tracking details indicating they originated in China.[152] According to publicly available information, this individual was charged with intent to distribute fentanyl that would ultimately cause the death of another individual.[153] He was later sentenced to more than 15 years in prison.[154]

Finally, one man from New York was arrested and charged with one count of conspiracy to distribute large quantities of fentanyl.[155] According to payment records reviewed by the Subcommittee, he sent at least one payment in mid-2016 to an online seller located in China worth more than $1,500.[156] In publicly available documents, he was accused of receiving several kilograms of fentanyl and repackaging the drugs into smaller quantities for resale.[157]

E. The Subcommittee Identified Two Individuals Likely Engaged in the Distribution of Synthetic Opioids

The Subcommittee identified at least two additional individuals who are likely engaged in the online purchase and distribution of synthetic opioids, including fentanyl. One individual in Kansas wired nearly $2,500 to an online seller over a two-month period in late 2016.[158] The day after wiring one of those payments, the suspected Pennsylvania-based distributor sent the individual a package.[159] Further, this same individual received more than 30 suspect international packages from ECOs and the Postal Service containing supplies and

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of Randolph D. Alles, Assistant Commissioner, Office of Air and Marine, U.S. Customs and Border Protection) (A controlled delivery is a technique whereby a smuggling suspect agrees to accept and open a package known to contain illegal goods, but is under observation by law enforcement.).

[149] Records on file with the Subcommittee.

[150] *Id.*

[151] Western Union Productions.

[152] United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).

[153] Records on file with the Subcommittee.

[154] *Id.*

[155] *Id.*

[156] Western Union Productions.

[157] Records on file with the Subcommittee.

[158] Western Union Productions.

[159] United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).

other materials typically used to produce mass quantities of pills for distribution.[160] The package description information submitted to CBP included pill presses used to compress powders into tablets.[161] This individual also ordered chemical bonding agents commonly used in the mass production of tablets and pills.[162] Finally, at least one chemical listed on shipment records for merchandise purchased by this individual is commonly used to create a distinctive and marketable color for tablets and pills.[163]

Finally, a different individual in Ohio sent more than $3,000 to an online seller over a four month period from late 2016 to early 2017.[164] He received international packages—three from China and one from Hong Kong.[165] He also received three additional suspect packages containing items commonly used in the mass production of pills and tablets.[166] The shipment data indicated the packages contained chemicals, such as coloring agents, and empty plastic casings commonly used to create tablets and pills.[167] And one chemical listed on the shipment data is known to be used specifically for synthetic opioid production.[168]

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[160] *Id.*; CBP production to the Subcommittee (Nov. 26, 2017) (on file with the Subcommittee); FedEx Corporation production to the Subcommittee (Nov. 17, 2017) (on file with the Subcommittee); FedEx Corporation production to the Subcommittee (Nov. 14, 2017) (on file with the Subcommittee); United Parcel Service, Inc. production to the Subcommittee (Nov. 6, 2017) (on file with the Subcommittee); DHL Express U.S. production to the Subcommittee (Nov. 3, 2017) (on file with the Subcommittee).

[161] Drug Enforcement Administration, U.S. Dep't of Justice, DEA-DCT-DIB-021-16, *Counterfeit Prescription Pills Containing Fentanyls: A Global Threat* 2 (July 2016) ("Clandestine pill press operations also occur in the United States. Traffickers usually purchase powdered fentanyls and pill presses from China to create counterfeit pills to supply illicit U.S. drug markets. Under U.S. law, the Drug Enforcement Administration (DEA) must be notified of the importation of a pill press. However, foreign pill press vendors often mislabel the equipment or send it disassembled to avoid law enforcement detection.").

[162] CBP production to the Subcommittee (Nov. 26, 2017) (on file with the Subcommittee); DHL Express U.S. production to the Subcommittee (Nov. 3, 2017) (on file with the Subcommittee).

[163] FedEx Corporation production to the Subcommittee (Nov. 17, 2017) (on file with the Subcommittee).

[164] Western Union Productions.

[165] United States Postal Service production to the Subcommittee (Nov. 9, 2017) (on file with the Subcommittee).

[166] CBP production to the Subcommittee (Nov. 26, 2017) (on file with the Subcommittee).

[167] *Id.*

[168] Records on file with the Subcommittee.

V. CBP AND THE POSTAL SERVICE ARE ONLY MAKING LIMITED USE OF ADVANCED ELECTRONIC DATA TO IDENTIFY, TARGET, AND SEIZE ILLICIT INTERNATIONAL PACKAGES OF SYNTHETIC OPIOIDS

CBP uses AED to identify international packages that might contain illicit items. To assist in this effort, the Postal Service has made strides to increase the amount of AED it collects through various bilateral agreements with foreign postal operators. Effectively using the data to identify, target, and seize illicit international packages, however, remains a significant challenge. Before June 2017, CBP used AED to target suspect packages at only one of the Postal Service's ISCs through a pilot program. The Subcommittee's investigation found that the pilot program was in considerable disarray and disorganization, which hampered the efficient use of AED to target packages.

This section discusses the development and operation of the pilot program, its inefficiencies, and the decision by the Postal Service and CBP to delay a nationwide expansion.

A. Rapid Growth of Inbound International Mail Presents Challenges for Effective Screening and Inspection

The rapid growth of inbound international mail packages presents challenges for CBP's effective screening and inspection. The inbound international mail processed by the Postal Service and inspected by CBP has experienced double digit percentage growth over each of the last three years.[169] This growth has been disproportionate at the JFK ISC in New York because it is the largest of the five major facilities that the Postal Service uses to receive and process inbound international mail. According to the most recent data available, the Postal Service recorded inbound international mail volume of more than 275 million packages.[170] Nearly half of this volume arrived at the JFK ISC.[171]

CBP and the Postal Service did not adequately plan for this rapid growth of inbound international mail. According to both CBP and Postal Service officials, the recent increase in inbound international mail—specifically ePackets from China—took officials by "surprise" and led to struggles in processing and inspecting the

[169] United States Postal Service production to the Subcommittee (Oct. 23, 2017) (on file with the Subcommittee).
[170] United States Postal Service production to the Subcommittee (May 22, 2017) (on file with the Subcommittee).
[171] *Id.*

mail.[172] This growth also introduced unique operational and technical challenges for CBP and the Postal Service, especially at the JFK ISC.[173]

For example, before November 2015, CBP did not have the ability to target and inspect individual pieces of mail using AED. Instead, CBP inspected international mail from specific countries determined by the agency to be a "country of interest" or "country of concern." CBP officers then manually inspected all of the mail the Postal Service received from those targeted countries. CBP officers told the Subcommittee that the targeted countries periodically changed based on CBP officers' experience, knowledge, and threat assessment.[174] At times, however, CBP did not list China on its country of interest list solely because the incoming volume was too great.[175] CBP also did not consistently inspect ePackets shipped from China until the pilot program began at the JFK ISC in November 2015.[176]

B. The Postal Service and CBP Started a Pilot Program to Target Packages for Inspection Using AED

The Postal Service and CBP recognized the significant challenge of processing and screening hundreds of thousands of international mail packages

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[172] Interview with Charles Conti, United States Postal Service, Plant Manager, John F. Kennedy International Airport, International Service Center (Oct. 26, 2017) (*hereinafter* Conti Interview (Oct. 26, 2017)); Interview with Quanla Owens, U.S. Customs and Border Protection, former Program Manager, International Mail and Express Consignment Facilities, New York Field Office (Nov. 20, 2017) (*hereinafter* Owens Interview (Nov. 20, 2017)); Interview with Manuel Garza, U.S. Customs and Border Protection, Director, Manifest & Conveyance Security (Nov. 1, 2017) (*hereinafter* Garza Interview (Nov. 1, 2017)); CBP-PSI-000075 (App. 0002) (A Postal Service email on May 5, 2015 to CBP officials stated that the Postal Service did "not have a project growth rate for ePackets over the next year at this time." The Postal Service official indicated CBP could examine historic growth rate patterns instead of a prediction.).

[173] USPS-PSI-00009844 (App. 0053) ("The growing inbound volume has outgrown the facility and is causing congestion at the JFK ISC, which overloads the operations. In order to alleviate the issues caused by the growing inbound volume, the JFK ISC is interested in a one-year pilot test to move some of the handling of Chinese inbound ePacket mail to a new Annex facility near the JFK airport, provided by the supplier."); *see also* Office of the Inspector General, United States Postal Service, MS-AR-17-003, *Inbound International Mail Operations* 1 (Dec. 30, 2016).

[174] Subcommittee staff visit to JFK ISC (Sept. 14, 2017); Subcommittee staff visit to LAX ISC (Aug. 22, 2017).

[175] CBP-PSI-000083 (App. 0008) ("When we were out at the LA IMF they were working off of a [*sic*] Enforcement Countries list for July which consisted of 22 countries. China was not one of the countries on the list."); Interview with Leon Hayward, U.S. Customs and Border Protection, Acting Director, New York Field Operations (Oct. 31, 2017) (*hereinafter* Hayward Interview (Oct. 31, 2017)) (indicating that at some points China was "excluded" from the country of interest list because of the volume).

[176] Office of the Inspector General, United States Postal Service, MS-AR-17-003, *Inbound International Mail Operations* 6 (Dec. 30, 2016) ("Specifically, CBP does not inspect all mailpieces and often requests that only certain samples or mailpieces be presented by Postal Service employees for inspection. For example, CBP did not typically inspect ePackets from China at the JFK ISC prior to November 2015.").

arriving in the United States each and every day.[177] It is important to note that the two agencies' very different missions added to the complications that came with the increased volume of packages. The Postal Service accepts all international mail from foreign postal operators and delivers that mail within certain timeframes to its intended recipient. CBP, meanwhile, has a national security mission to review suspect international cargo, including packages, without concern for speedy delivery. This tension contributed to difficulties between the two agencies over the course of the pilot program.

To better handle the growing international mail volume, the Postal Service and CBP collaborated on a pilot program at the JFK ISC designed to limit the overall number of packages CBP manually screened.[178] In January 2014, senior Postal Service and CBP officials circulated an early draft work plan for "[i]nbound pilot procedures."[179] According to this document, "[A]n advance system will allow CBP to move away from a primarily manual method of targeting inbound mail to a more selective processing approach."[180] The plan would also allow "for a more systematic enforcement effort by CBP while at the same time enabling the USPS to facilitate the mail through its process in a more expeditious manner."[181] Postal Service and CBP officials told the Subcommittee that the pilot program started at the JFK ISC because it receives the majority of inbound international mail.[182] However, those same officials later admitted that the pilot program would have been more effective had it started at an ISC receiving less volume.[183]

Originally, the pilot program reviewed AED for packages from France and China.[184] The Postal Service provided CBP with AED, which CBP then analyzes to identify packages for the Postal Service to "hold" for inspection.[185] CBP then entered a "hold request" that is transmitted electronically to Postal Service employees at the ISC. When Postal Service employees conducted initial verification

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[177] Conti Interview (Oct. 26, 2017); Owens Interview (Nov. 20, 2017); Garza Interview (Nov. 1, 2017).
[178] USPS-PSI-00006720 (App. 0042) ("The sheer volumes of this mail and the risk profiles need to be assessed."); USPS-PSI-00009217 (App. 0048) ("[B]y leveraging the data, USPS can improve the efficiency of mail processing.").
[179] USPS-PSI-00001983 (App. 0038).
[180] *Id*.
[181] *Id*.
[182] Interview with Freemont Rigel, United States Postal Service, Executive Director, International Strategy and Business Development (Nov. 2, 2017) (*hereinafter* Rigel Interview (Nov. 2, 2017)); Hayward Interview (Oct. 31, 2017).
[183] Conti Interview (Oct. 26, 2017).
[184] USPS-PSI-25256 (App. 0074) (Postal Service PowerPoint detailing the full data elements in ITMATT message: Item ID, Sender Receiver Name and Address, Description of Contents, Content Type, Quantity, Weight, Value, Harmonized Tariff code, Country of Origin, License Numbers, Insurance Value, and Postage).
[185] Subcommittee staff visit to U.S. Customs and Border Protection's National Targeting Center (Sept. 12, 2017).

scans of inbound international mailings, they received notice if a package is targeted for hold by CBP.[186] Initially, CBP limited targeting to only ten packages a day—a number that at least one CBP officer indicated was "just scratching the [surface]" of the threat of illicit, dangerous goods entering the country via the mail.[187]

The act of locating and providing a package to CBP for inspection is formally known as "presentment."[188] At the beginning of the pilot program in November 2015, once the Postal Service was informed that a package had been targeted by CBP, Postal Service employees would then locate and present either the package or the full sack of mail believed to contain the package to CBP for inspection. While the Postal Service eventually automated the presentment process, for most of the pilot program's operation, Postal Service employees or CBP officers located the targeted package by manually sorting through large sacks of mail containing hundreds of individual packages. This "resource intensive"[189] process required searching through hundreds of international packages to find the targeted package—the proverbial "needle in a haystack" according to one CBP officer working at the JFK ISC.[190]

C. The Postal Service and CBP Did Not Make Timely Improvements to the Pilot Program

While both agencies recognized the inefficiencies of the manual process to identify and present packages, just months after the pilot program began, it took more than a year before the issues were resolved.[191] As the CBP Program Manager for the New York Field Office bluntly wrote in an email, "There has been no meaningful improvement as the China ePacket Pilot approaches its second year."[192] The most significant shortcoming of the pilot program, according to internal Postal

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[186] The Postal Service Inspector General issued a "management alert" to Mr. Conti in his capacity as JFK ISC plant manager in January 2016 detailing concerns regarding this scanning and verification process at both the JFK and LAX ISCs. The Inspector General found that the Postal Service was not consistently complying with its verification scanning processes of inbound international mail. *See* Office of the Inspector General, United States Postal Service, MR-MT-16-001, *Management Alert: International Inbound Mail Verification* 2 (Jan. 28, 2016); Mr. Conti would later tell the Subcommittee that while he signed the Postal Service's formal response to the Inspector General as a "Responsible Official," he did not write or read the letter before signing it. Conti Interview (Oct. 26, 2017).
[187] CBP-PSI-000078 (App. 0003).
[188] Office of the Inspector General, United States Postal Service, MS-AR-17-003, *Inbound International Mail Operations* 7 (Dec. 30, 2016).
[189] CBP-PSI-000078 (App. 0003).
[190] Subcommittee staff visit to JFK ISC (Sept. 14, 2017).
[191] CBP-PSI-000095 (App. 0014).
[192] CBP-PSI-000114 (App. 0020).

Service and CBP emails and documents, was that the Postal Service did not consistently present 100 percent of targeted packages to CBP.

In a June 2016 email, CBP's Internal Mail Security Director acknowledged the program's shortcomings, stating that "[t]he lack of consistency with the pilot is the issue. [The Postal Service's JFK Plant Manager] continues to cite human error whenever targeted mail is not presented to CBP for inspection. Full bags of mail with possible targets continue to take additional resources, as you know CBP has to look for each target in a bag of mail."[193] In an interview with the Subcommittee, the plant manager for the Postal Service's JFK ISC explained that the human error mentioned in the email referred to the manual process of searching through large bags of mail for an individual parcel. He indicated that if the process had been automated sooner, the pilot could have been more efficient and accurate.[194]

The Postal Service did have plans in place to automate and present individual packages to CBP in 2016. According to the Postal Service's Assistant Director for Global Trade Compliance, Cheri DeMoss, "[e]nhanced functionality" to allow the Postal Service to provide CBP with the individual targeted piece rather than the entire bag of mail was set to be in place by September of that year.[195] According to the Postal Service, the automation did not begin then because of required software updates.[196] Additionally, one Postal Service official claimed that CBP continued to request entire bags of mail rather than individual targeted packages until late 2016, rendering automation by the Postal Service unnecessary at that time.[197]

The two agencies did not begin working together to make meaningful improvements to the pilot until March 2017 when the program moved away from manual sorting to automation. Automation improved the Postal Service's presentment rate.[198] Below is an image of the machine Postal Service installed, the "Automated Parcel and Bundler Sorter." The machine relies on imaging and barcode technology to automatically sort large volumes of packages. This

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[193] CBP-PSI-000264 (App. 0130).
[194] Conti Interview (Oct. 26, 2017).
[195] USPS-PSI-00017312 (App. 0058).
[196] Interview with Cheri DeMoss, United States Postal Service, Manager, Trade Systems and Analysis (Oct. 25, 2017) (*hereinafter* DeMoss Interview (Oct. 25, 2017).
[197] *Id*.
[198] CBP-PSI-000486 (App. 0026) (Ms. DeMoss wrote in an email to CBP officials detailing the anticipated improvement after automation was installed: "Yes JFK is placing ATS advance holds on China epacket and French Express Mail items. USPS is working to improve the success rate and implementing the ability to sort out China epacket hold bags on automated equipment. The testing on automated equipment is in progress and we expect this to improve the success rate."); CBP-PSI-000116 (App. 0022) (Mr. Garza wrote in an email on June 6, 2017 that his supervisor "would like to spend a few hours at the mail facilities to see the package sort automation and success that the adjustments on the machine have had.").

equipment is now in place at the JFK ISC, as shown below during a Subcommittee site visit to the facility.

D. The Postal Service and CBP Still Do Not Agree on How to Measure the Pilot Program's Success

The Postal Service and CBP have not developed an agreed upon measurement of success for the pilot program. When asked if the AED pilot program is successful, both agencies gave different responses. As a result, the program's expansion to other ISCs around the country faced continual delays.

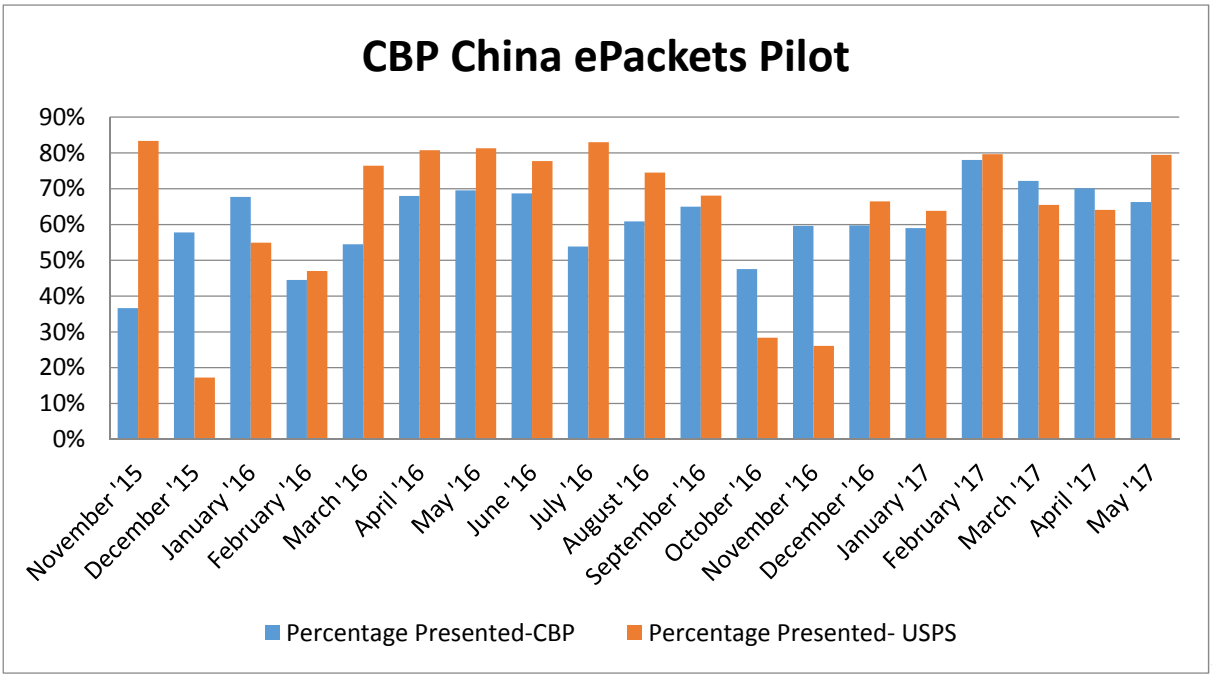
As previously described, the program was effectively simple in design. After analyzing AED provided by the Postal Service, CBP targeted particular packages it believed contained illicit goods. The Postal Service then located and presented that package to CBP for additional inspection and possible seizure.

During the JFK pilot program, CBP and the Postal Service collected performance data on the percentage of targeted packages the Postal Service presented to CBP for inspection, which is the "presentment rate." The number of packages that slip through the cracks and are not presented to CBP is an important statistic to determine the success of targeting and intercepting packages. However, the Postal Service and CBP still have not agreed on specific goals for the pilot and how to measure those goals. As a result, they differ on what the Postal Service's presentment rate is and how success should be defined in the program. [199]

[199] CBP-PSI-000114 (App. 0020) (As one CBP officer working closely on the pilot program stated, "The measurement of holds are not consistent between CBP and the USPS.").

According to one CBP official, "CBP simply reports the total amount of Holds that we place compared to how many holds USPS presents to us for inspection. If CBP views the target in the ATS [Automated Targeting] system, our impression is that a hold may be placed on it."[200] However, the Postal Service uses different metrics. It measures what it refers to as "actionable holds"—meaning items the Postal Service is actually capable of intercepting. This measure exempts any holds that are deemed not actionable. For example, the Postal Service exempts any package that has already left the ISC prior to CBP's request for a hold, is diverted and delivered to a different ISC, or never arrived in the United States. Exempting these packages boosts the Postal Service's presentment rate, showing what appears to be greater success at locating and presenting packages to CBP.

The difference in how the Postal Service and CBP measure success is significant. Below is a chart that shows the percentage of holds presented for inspection as identified by both CBP and the Postal Service. In 13 of the 19 months since the start of the pilot program, the Postal Service calculated a higher presentment rate than CBP. On average, as shown below, the Postal Service and CBP had a 17 percent difference in reported success rates over the last 20 months:



[201]

Last year, however, both CBP and the Postal Service realized they need to agree on how to measure success for the good of the program. A summary of a "USPS/CBP Executive Meeting" held at CBP Headquarters on June 8, 2017,

[200] CBP-PSI-0000246 (App. 0024).
[201] United States Postal Service production to the Subcommittee (Oct. 18, 2017) (on file with the Subcommittee); CBP production to the Subcommittee (July 7, 2017) (on file with the Subcommittee).

summarizes discussions about these concerns. CBP indicated that the Postal Service's presentment rate at JFK was "at +/- 70%."[202] But a Postal Service representative claimed that it has a higher success rate on actionable holds because a target piece of mail may arrive at an alternate ISC or was never sent.[203] At this meeting CBP agreed that the agencies needed "to determine one source of measurement used by both agencies."[204]

Unfortunately, despite this recognition, as of the release of this report, the agencies still rely on different performance measurements. In fact, a September 1, 2017 Memorandum of Understanding between the Postal Service and CBP concerning the expansion of the pilot program to the other ISCs failed to articulate a definable standard of success. The Memorandum of Understanding states,

> As it relates to electronic advance data, [the agencies would] ***work to develop*** a measurable performance goal for the presentation of packages targeted by CBP for examination, including a corresponding mutually agreed upon performance goal in each local SOP, and provide periodic status reports to each other regarding their progress in meeting such goal.[205]

When asked why the agencies still have not resolved this longstanding issue, one CBP official told the Subcommittee that the issue was the topic of regular conversation throughout the course of the pilot, both internally and with the Postal Service and that a meeting was scheduled between the agencies to discuss how to come to an agreement on measuring success.[206] This meeting was scheduled for early November 2017, two years after the start of the pilot program.

Given this debate, the program's effectiveness and ability to expand suffered. As the U.S. Government Accountability Office found in August 2017, "Because USPS and CBP have not agreed to specific performance goals or targets, it is difficult to make well-informed decisions regarding the possible expansion of these pilots in the future."[207] While there have been efforts to increase the Postal Service's presentment rate using automated sorting, packages still slip through the cracks and ultimately get delivered.[208] This remains a problem. CBP spends time and resources to target specific packages it believes contain illicit goods—including

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[202] USPS-PSI-00047061 (App. 0121).
[203] *Id.*
[204] *Id.*
[205] United States Postal Service production to the Subcommittee (Oct. 11, 2017) (App. 0163) (emphasis added).
[206] Garza Interview (Nov. 1, 2017).
[207] U.S. Gov't Accountability Office, GAO-17-606, *Costs and Benefits of Using Electronic Data to Screen Mail Need to Be Assessed* 23 (2014).
[208] Subcommittee staff visit to JFK ISC (Sept. 14, 2017).

synthetic narcotics such as fentanyl.[209] The Postal Service is bound by federal regulations[210] to make all mail available to CBP and must present all inbound international mail that CBP requests.[211]

E. The Postal Service and CBP Officials Did Not Expand the JFK Pilot Program until after the Subcommittee's May 2017 Hearing on International Mail Security and the Importation of Deadly Drugs

While both the Postal Service and CBP discussed expanding the pilot program to other ISCs, both agencies routinely missed their own internal deadlines over the last year and a half. It was not until after the Subcommittee's hearing in May 2017 that both the Postal Service and CBP formally agreed to expand to the other four ISCs. CBP began targeting some packages at the remaining ISCs three days before this report was released.[212]

Not expanding the program to the other ISCs limited the success of CBP's targeting efforts using AED. CBP was only targeting packages arriving from China at the JFK ISC, which constitutes roughly 50 percent of inbound international mail volume. Additionally, suspect mail packages targeted by CBP destined for the JFK ISC would not get inspected if they were rerouted to a different ISC.[213] In those instances, the packages were delivered to the addressee.

Recognizing these and other issues, nearly one year after the pilot program began at JFK, CBP and the Postal Service discussed expanding to other ISCs—most notably, the ISC located near the Los Angeles International Airport (LAX). In 2016, the LAX ISC received the third highest volume of inbound international mail (behind JFK and Chicago).[214] Postal Service officials indicated that they were ready to "start the same type of pilot" at LAX in October 2016.[215] Freemont Rigel, the Postal Service's Director of Global Trade Compliance wrote in an email that the JFK pilot program allowed the Postal Service to "put a positive spin" on steps taken

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[209] CBP-PSI-000246 (App. 0024).
[210] 19 C.F.R. § 145.2 (2017).
[211] Office of the Inspector General, United States Postal Service, MS-AR-17-003, *Inbound International Mail Operations* 8 (Dec. 30, 2016).
[212] U.S. Customs and Border Protection email to the Subcommittee (Jan. 19, 2017) (on file with the Subcommittee).
[213]Interview with Abby Martin, United States Postal Service, Director, Global Trade Compliance (Oct. 24, 2017) (*hereinafter* Martin Interview (Oct. 24, 2017)); USPS-PSI-00019360 (App. 0067) (In a November 2016 email, Mr. Rigel wrote to CBP officials concerning the expansion: "But based on the sheer volume – they also see the value to both USPS and CBP if we can get [the pilot] in place ASAP at all locations [ ].").
[214] United States Postal Service production to the Subcommittee (May 22, 2017) (on file with the Subcommittee).
[215] USPS-PSI-00017730 (App. 0062).

to combat illicit drug trafficking in the mail system.[216] Mr. Rigel continued that the Postal Service was "ready to start [the] same type of pilot in LAX—another good news pro-active USPS International ops."[217]

Around the same time in late 2016, Postal Service officials started urging CBP to expand the pilot program to LAX. Ms. DeMoss, the Postal Service's Assistant Director for Global Trade Compliance, sent an email to Mr. Manuel Garza, CBP's Director of the Manifest and Conveyance Security Division, stating "[w]ith all of the attention on advance data and the drugs found in the mail we are getting pressure to expand the ATS targeting at the other ISCs."[218] Ms. DeMoss explained further, "[w]ith the extreme volumes of China epacket for peak and the attention on the drugs I think we need to move quickly on this. The last time we discussed getting this in place by November [2016]. We have the capability to expand to all ISCs and the advance data on China epacket is now at 97%."[219]

However, CBP officials expressed concern that, contrary to Postal Service employees' emails, the Postal Service was actually not prepared to handle additional locations. Mr. Garza argued that the presentment rate was roughly 65 percent at the JFK ISC and that CBP officials believed "USPS had agreed to a much higher success rate for delivering targeted epackets than they have been able to achieve."[220] Mr. Garza later explained to the Subcommittee that the program did not have any formal, written targets or goals, but that the overall sentiment was that the Postal Service would have a 90 percent presentment rate.[221] According to Mr. Garza, the fact that this pilot did not "identify goals early on" was different than other CBP programs that outlined specific goals at the start.[222]

Additionally, Ms. Owens, CBP's then-Program Manager for International Mail and Express Consignment Facilities in the New York Field Office, surveyed CBP employees on the ground and compiled the following internal feedback about the problems with the pilot to date regarding why the Postal Service was not ready to expand:[223]

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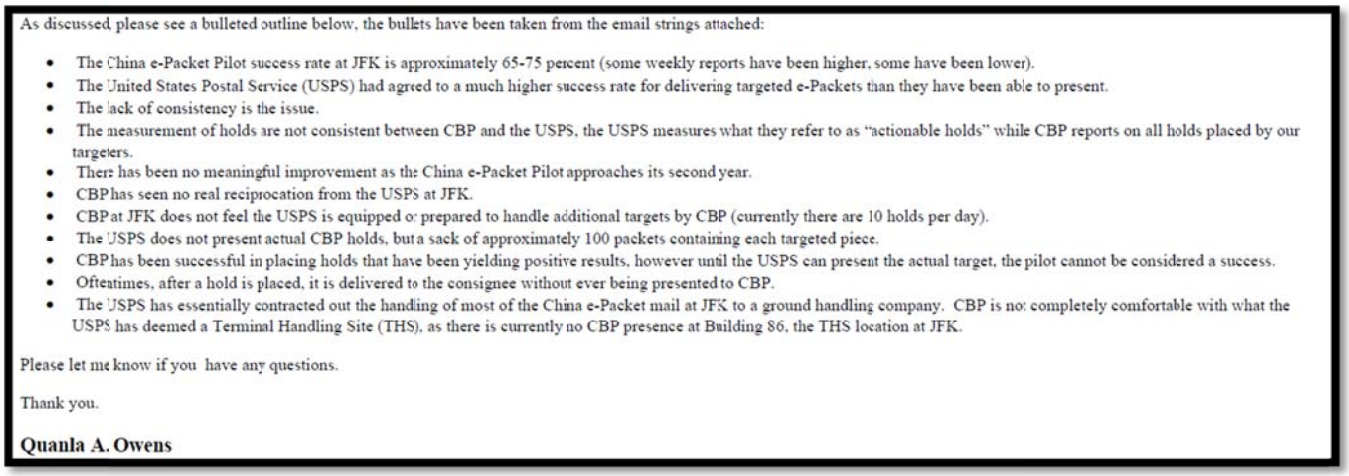
[216] *Id.*
[217] *Id.*
[218] USPS-PSI-00019351 (App. 0064).
[219] *Id.*
[220] CBP-PSI-000102 (App. 0016).
[221] Garza Interview (Nov. 1, 2017).
[222] *Id.*
[223] CBP-PSI-000114 (App. 0020).



As discussed please see a bulleted outline below, the bullets have been taken from the email strings attached:

- The China e-Packet Pilot success rate at JFK is approximately 65-75 percent (some weekly reports have been higher, some have been lower).
- The United States Postal Service (USPS) had agreed to a much higher success rate for delivering targeted e-Packets than they have been able to present.
- The lack of consistency is the issue.
- The measurement of holds are not consistent between CBP and the USPS, the USPS measures what they refer to as "actionable holds" while CBP reports on all holds placed by our targeters.
- There has been no meaningful improvement as the China e-Packet Pilot approaches its second year.
- CBP has seen no real reciprocation from the USPS at JFK.
- CBP at JFK does not feel the USPS is equipped or prepared to handle additional targets by CBP (currently there are 10 holds per day).
- The USPS does not present actual CBP holds, but a sack of approximately 100 packets containing each targeted piece.
- CBP has been successful in placing holds that have been yielding positive results, however until the USPS can present the actual target, the pilot cannot be considered a success.
- Oftentimes, after a hold is placed, it is delivered to the consignee without ever being presented to CBP.
- The USPS has essentially contracted out the handling of most of the China e-Packet mail at JFK to a ground handling company. CBP is not completely comfortable with what the USPS has deemed a Terminal Handling Site (THS), as there is currently no CBP presence at Building 86, the THS location at JFK.

Please let me know if you have any questions.

Thank you.

Quanla A. Owens

CBP officials also cited personnel issues at the JFK ISC as a reason the pilot was not ready to be expanded. Leon Hayward, CBP's Acting Director of Field Operations at the New York Field Office, wrote in an email that CBP went "to great lengths to enhance our local relationship and to develop the capabilities necessary to target and examine ePackets expeditiously. We have seen no real reciprocation from USPS at JFK."[224] Mr. Hayward would later explain to the Subcommittee this meant that a senior CBP officer at the JFK ISC did "not like progress" and was not in favor of expanding the pilot, so CBP management made the decision to transfer this official in order to move forward. Mr. Hayward also explained that there was a strong personality conflict between the Postal Service JFK Plant manager and the former CBP Deputy Chief Officer.[225]

As a result of these performance and personnel challenges, the program did not expand in 2016. In early November 2016, a Postal Service official stated that the plan to expand to the LAX ISC was delayed to allow for the improvement of the presentment rate and to have the other ISCs running no later than March 2017.[226] In an email Mr. Rigel stated, "So we will start in February and complete by end of March—one site at a time since they will also have a HQ CBP presence at each site as it comes up (ORD, LAX, SFO, MIA). CBP has to train their personnel on the new process—how to identify holds, etc."[227]

In late February 2017, the Postal Service again sought to expand the pilot in an effort to address mail processing backlogs in customs it was experiencing at LAX due to the transfer of CBP officers to border protection duty.[228] The LAX ISC Plant

[224] CBP-PSI-000487 (App. 0027).
[225] Hayward Interview (Oct. 31, 2017).
[226] USPS-PSI-00021004 (App. 0071).
[227] USPS-PSI-00021005 (App. 0072).
[228] USPS-PSI-00031818 (App. 0036) ("In our discussions, they communicated heavy resources being diverted to border [ ].").

Manager advised senior Postal Service officials that the plant was "experiencing a backlog/delay at LA ISC Customs Facility. CBP has advised they are unable to staff all the belts under current operating conditions."[229] Abby Martin, the Postal Service's Director of Global Trade Compliance, responded that the Postal Service could activate the targeting program to help with the backlog: "One path to pursue is asking CBP HQ to allow us to turn on the Advanced Targeting in LAX (expanding the JFK pilot, essentially), as that would cut down on the volume needing to go through customs. We could be ready to do that within a day or two if that is agreed to by all parties."[230] The LAX ISC Plant Manager also stated that "[t]his is a perfect opportunity for [the] advanced data pilot for LA."[231]

However, Mr. Raines responded that the Postal Service was not "ready to expand and certainly not at the piece level."[232] In an interview with the Subcommittee, Ms. Martin stated that while the Postal Service was looking to decrease the backlog, Mr. Raines believed that the automated sorting system was still being tested at the JFK ISC and that he did not believe it was ready to be implemented at LAX.[233]

In mid-March 2017, it was clear the expansions were not going to be finalized and officials set a new deadline for the following month. Ms. DeMoss explained in an email, "We are on track to expand the capability to place holds in all ISC's [sic] by April 2017."[234] However, that "target date" came and went.[235] And as of mid-May, neither the Postal Service nor CBP had a timeline for expansion.[236] Ms. DeMoss wrote that, "So far CBP has agreed to getting LAX going by the end of May," but there was no timeline for any other ISCs.[237] And a May 12, 2017 PowerPoint, as shown below, was shared internally within the Postal Service, but lacked a target date:

[229] USPS-PSI-00031818 (App. 0234).
[230] USPS-PSI-00031817 (App. 0233).
[231] USPS-PSI-00032309 (App. 0077).
[232] USPS-PSI-00031817 (App. 0233).
[233] Martin Interview (Oct. 24, 2017).
[234] USPS-PSI-00036254 (App. 0080).
[235] USPS-PSI-00039877 (App. 0081) ("We had a milestone to emulate the Customs JFK pilot to all 4 ISCs. The target date was May 1.").
[236] USPS-PSI-00040144 (App. 0084).
[237] USPS-PSI-00040207 (App. 0087).

[238]

It was not until the Subcommittee's May 25, 2017, hearing, *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs* that both the Postal Service and CBP appeared to develop a new sense of urgency.[239] The pilot program was a critical topic discussed at the hearing. The Acting Inspector General for the United States Postal Service Office of Inspector General, Tammy Whitcomb, testified that "expanding that pilot quickly across the country to the other International Service Centers" was vital "so that the data that is being received from these countries can be used to target specific and dangerous packages."[240] According to internal Postal Service documents, Postal Service and CBP officials watching the hearing quickly realized that expanding the program to the other ISCs needed to be a priority.

While there was a discussion of a "kickoff meeting" regarding expanding to the LAX ISC, that meeting was not scheduled prior to the Subcommittee's hearing. As detailed below, it is clear from internal Postal Service documents that the Subcommittee's oversight hearing changed the timeline of the pilot program expansion. Ms. Martin sent the following email to Robert Woods, CBP's Program Manager for International Mail, during the Subcommittee's hearing about the expansion:

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[238] USPS-PSI-00041584 (App. 0092).
[239] *See Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs Before Perm. Subcomm. on Investigations*, 115th Cong. 45-46 (2017).
[240] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs Before Perm. Subcomm. on Investigations*, 115th Cong. 60 (2017) (testimony of Tammy Whitcomb, Acting Inspector General, United States Postal Service).

From: Martin, Abigail D - Washington, DC [redacted]
Sent: Thursday, May 25, 2017 11:34 AM
To: WOODS, ROBERT [redacted]
Cc: CLARKE, QUINTIN [redacted] Raines Jr, Robert H - Washington, DC [redacted]
Subject: RE: Kickoff Meeting for LAX Pilot Expansion

Hi Bob - Not sure if you are watching the hearing or not, but we need to move on the expansion of the pilot, not just to LAX but all the ISCs. Any update on getting the kick off set up? Should we invite all of the ISCs/IMFs to the kickoff in order to get everyone started preparing for expansion?

241

Mr. Woods promptly replied back:

From: WOODS, ROBERT [redacted]
Sent: Thursday, May 25, 2017 12:20 PM
To: Martin, Abigail D - Washington, DC [redacted]
Cc: CLARKE, QUINTIN [redacted] Raines Jr, Robert H - Washington, DC [redacted] GARZA, MANUEL A [redacted]
Subject: RE: Kickoff Meeting for LAX Pilot Expansion

Abby,

Yes, we were viewing the hearing and agree that we definitely need to get moving on the expansion. L.A. CBP has responded that next Wednesday the 30th will not work for them. Let me know if your team is able to make adjustments to accommodate Thursday the 1st. If not, let's look at trying to get together early the following week (June 5th).

242

According to Ms. Martin, before the hearing, the effort to expand the pilot was stalled by CBP; however, the discussion about the pilot program at the hearing "really lit a fire" under both the Postal Service and CBP.[243] Mr. Garza also told the

[241] USPS-PSI-00045215 (App. 0104).
[242] USPS-PSI-00045213-45214 (App. 0145-0146).
[243] Martin Interview (Oct. 24, 2017).

Subcommittee that after the hearing, CBP officials decided it was appropriate to expand.[244] The Postal Service and CBP also started having weekly meetings to discuss both the pilot expansion and the use of AED generally—something that had not taken place before.[245]

In the hours after the Subcommittee's hearing, concern about the lack of progress in expanding the pilot program rose to the highest ranks of the Postal Service. According to Ronald Stroman, the Deputy Postmaster General, the Postmaster General asked him to "convey her request that [the Postal Service] develop a project plan, including [a] timeline, to expand the JFK Pilot to all of our ISCs as soon as possible."[246] Robert Raines, the Executive Director of International Operations for the Postal Service, wrote to Ms. Martin, "We will need to develop [the project plan] quickly."[247]

Other Postal Service and CBP officials also initiated internal email exchanges on the same day as the Subcommittee hearing to address the failure to expand the pilot program. For example, Robert Cintron, the Postal Service's witness at the hearing and the Vice President of Network of Operations, wrote to his senior staff the same day as the Subcommittee's hearing that the JFK expansion was one "[k]ey thing" to "focus on and accelerate."[248]

One week after the Subcommittee's hearing, the Postal Service and CBP finally agreed to start the pilot program at the Los Angeles ISC ("LAX ISC") on June 19, 2017.[249] According to internal documents reviewed by the Subcommittee, the Postal Service was then ready to expand the pilot program to the other ISCs by June 30, 2017.[250] While the technical components and equipment were in place to expand beyond the JFK ISC, CBP needed to train its employees at the other ISCs, and the two agencies needed to work out additional details. At a planning meeting held on June 8, 2017, CBP still could not provide a specific number of parcels they planned to target at the other ISCs.[251] And in mid-June, CBP was not able to provide substantive updates to the Postal Service concerning expansion beyond JFK

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[244] Garza Interview (Nov. 1, 2017).
[245] Garza Interview (Nov. 1, 2017); CBP-PSI-000501 (App. 0033) ("With all of the activity going on with the JFK pilot expansion and the STOP Act, I would like to propose setting up a weekly touch point with your team, USPIS [sic] and us to ensure that we have time to share updates, discuss progress and next steps, and in general keep appraised of what each group is doing.").
[246] USPS-PSI-00045225 (App. 0112).
[247] USPS-PSI-00045224 (App. 0113).
[248] USPS-PSI-00045135 (App. 0101).
[249] USPS-PSI-00045541 (App. 0117) (June 1, 2017 email indicating the start date for the LAX ISC is June 19, 2017).
[250] USPS-PSI-00046680 (App. 0118).
[251] USPS-PSI-00047061 (App. 0121).

and LAX.[252] As of publication of this report, the pilot program is in place at the ISCs located at JFK, LAX, and MIA.[253] Below is a photograph of the bins used to process targeted mail taken during a Subcommittee visit to the LAX ISC:[254]

The Postal Service told the Subcommittee that the capability is in place to expand the program to the remaining ISCs, and three days before the Subcommittee released this report CBP officials began targeting at the remaining ISCs.[255]

VI. THE UNITED STATES IS A MEMBER OF THE UNIVERSAL POSTAL UNION, WHICH GOVERNS THE FLOW OF INTERNATIONAL MAIL

As a signatory to the Universal Postal Union ("UPU") treaty, the designated operator for the United States, the Postal Service, is required to accept and deliver any packages shipped from other member countries' designated operators. While this arrangement provides for global delivery of the mail, it is currently compromising the U.S.'s ability to fully monitor international shipments coming

[252] USPS-PSI-00047829 (App. 0122) (Ms. Martin wrote in an email: "We have no idea when CBP is going to be ready or willing to expand beyond LA and JFK. Today is just working with the plants to make sure they understand what they need to do to be ready to go by June 30.").
[253] Martin Interview (Oct. 24, 2017); DeMoss Interview (Oct. 25, 2017); Conti Interview (Oct. 26, 2017); Hayward Interview (Oct. 31, 2017); Garza Interview (Nov. 1, 2017); Rigel Interview (Nov. 2, 2017).
[254] Subcommittee staff visit to LAX ISC (Aug. 22, 2017).
[255] Martin Interview (Oct. 24, 2017); Garza Interview (Nov. 1, 2017).

into the country through the Postal Service. This is due, in part, to the lack of an international requirement for all countries to provide AED for packages. While many of the U.S.'s largest trading partners have the ability to collect and provide AED on packages, the majority of packages have no AED associated with them. Other countries assert they do not have the capability to provide AED on packages, either at all or in certain rural areas.

The majority of proposals the UPU considered requiring countries to collect and share AED were designed to address aviation security following a thwarted terrorist attack in 2010. More recently, AED has taken on a new importance as part of the effort to interdict shipments of synthetic opioids. While CBP, the agency primarily responsible for protecting our borders, asserts that AED is of the utmost importance in locating and interdicting these illicit drugs, the State Department maintains there is a lack of worldwide consensus on this issue.[256]

Currently, there is no international requirement to provide AED, but the UPU has made some strides over the past decade since the United States first introduced the idea of exchanging AED for packages in 2008. Starting January 1, 2018, all packages must display a barcode, regardless of whether AED is loaded onto the barcode. The original expectation was for AED to be loaded on the barcode by 2020. However, the requirement that data be loaded onto the barcode by 2020 has been delayed, as countries are requesting studies on the impact the requirement would have on designated operators and mail delivery. According to Joseph Murphy, the State Department representative to the UPU, a country can currently require AED from another member country if that country has the ability to provide AED. For example, the United States could require countries like China, which provides AED on around 50 percent of packages already,[257] to provide AED on all packages.

In the interim, the Postal Service recently started pursuing bilateral and multilateral agreements with foreign posts that would require the transmission of AED for certain postal products.

This section explains the complicated structure of the UPU through the entity's decade-long consideration of requiring AED on international packages. This section also includes a discussion of an attempt by the European Union to protect its own national security by requiring AED on all packages. Finally, the section highlights the hands-off approach taken by the United States at the UPU with regard to AED.

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[256] Interview with Joseph Murphy, U.S. Department of State, Chief, International Postal Affairs (Nov. 9, 2017) (*hereinafter* Murphy Interview (Nov. 9, 2017).

[257] App. 0256. (Stating China provides AED on 48.4 percent of packages and Hong Kong on 0.7 percent of packages); *see also* CBP-PSI-000506 (App. 0225) (stating as of March 2017, 53 percent of products from China had AED).

A. The Complicated Structure of the UPU Creates Confusion Regarding Priorities and Responsibilities

Headquartered in Bern, Switzerland, the UPU is an international organization established in 1874 comprised of 192 participating members, including the United States.[258] As a condition of membership in the UPU, all members agree to accept and deliver packages from all other designated operators. According to the UPU, this "helps to ensure a truly universal network of up-to-date products and services."[259] While the Postal Service is the designated operator for the United States, the State Department represents the interests of the United States before the UPU, as provided in the Postal Accountability and Enhancement Act of 2006.[260]

The UPU is divided into four bodies: (1) the Congress; (2) the Council of Administration; (3) the Postal Operations Council ("POC"); and (4) the Internal Bureau. The POC is the "technical and operational mind of the UPU and consists of 40 member countries, elected during Congress."[261] The POC is tasked with "helping Posts modernize and upgrade their postal products and services."[262] It is also responsible for making "recommendations to member countries on standards for technological, operational or other processes…where uniform practices are necessary."[263] Given these responsibilities, the POC has, and continues, to play a major role in globalizing the use of AED.

The POC is comprised of 40 member countries, including the United States, Great Britain, China, Canada, France, Germany, and Japan.[264] There is a robust and complex structure within the POC to divide and consider the issues under its jurisdiction. The United States currently serves, with India, as the Co-Chair of Committee 1 on Supply Chain Integration.[265] The POC also writes the Acts of the

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[258] *The UPU*, UNIVERSAL POSTAL UNION, http://www.upu.int/en/the-upu/the-upu.html.
[259] *Id.*
[260] Postal Accountability & Enhancement Act of 2006, Pub. L. No. 109-435, § 407, 39 U.S.C. § 407 (2016).
[261] *About Postal Operations Council*, UNIVERSAL POSTAL UNION, http://www.upu.int/en/the-upu/postal-operations-council/about-poc.html.
[262] *Id.*
[263] *Id.*
[264] *See Postal Operations Council member countries*, UNIVERSAL POSTAL UNION, http://www.upu.int/en/the-upu/postal-operations-council/member-countries.html (detailing a full list of countries that are part of the POC).
[265] Under Committee 1 there are a number of other Committees and Groups, including: (1) Standards Board; (2) Operations and Accounting Review Group; (3) Customs Group; (4) UPU-WCO Contact Committee; (5) Transport Group; (6) UPU-IATA Contact Committee; (7) Postal Security Group; (8) UPU-ICAO Contact Committee. This list does not include ad hoc subcommittees created for certain issues. *See Postal Operations Council key documents*, UNIVERSAL POSTAL UNION, http://www.upu.int/en/the-upu/postal-operations-council/key-documents.html.

Union, "which are the rules of the road for international mail exchange."[266] Each of the committees, subcommittees, and working groups meet at various times throughout the year. These meetings are opportunities for member countries to travel to Bern and voice concerns or support for UPU proposals regarding international mail. With regard to AED, however, these meetings have resulted in considerable discussion, but only incremental progress.

B. For a Decade, the UPU has Struggled to Require Member Countries to Collect and Share AED for International Mail

The consideration of AED at the UPU has been a protracted process. Many member countries resist adopting requirements related to exchanging AED for international mail. There are several reasons for this resistance including a lack of infrastructural capability for some developing countries to collect AED. Indeed, at the May 25 Hearing, Mr. Gregory Thome of the State Department testified:

> The technical ability to exchange [AED] does not, however, translate directly into the ability to collect and enter it. Many post offices in rural areas of the developing world do not have Internet connectivity or even reliable sources of electricity, which makes collection and transmission of data for postal items extremely difficult. Even in developed countries, some postal services have been slow to invest in the needed infrastructure for item-level electronic data exchange – and few, if any, countries now have the ability to provide it for 100 percent of their mail requiring customs declarations.[267]

While advancements were made at the UPU over the last decade, there is still no global requirement to provide AED on international mail packages. As Mr. Thome explained:

> Regulations approved by the [UPU] last February will allow members to impose requirements for [AED] on items containing goods, provided they take into account whether the requirements they are imposing can be met by those to whom they apply. The thinking behind the regulation was that demanding something that is impossible as a condition for delivering another's country's mail is the same as

[266] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs Before the S. Perm. Subcomm. on Investigations*, 115th Cong. (2017) (testimony of Gregory D. Thome, Director, Office of Specialized and Technical Agencies, Bureau of International Organization Affairs, Department of State).
[267] *Id.*

refusing to receive it at all. Such requirements would undermine the reciprocity that is at the heart of the UPU.[268]

The Postal Service and CBP have struggled to adapt to the current international package environment, but the international community has only started to understand the utility of using AED to stop shipments of illicit drugs.

C. The 2008 UPU Congress Considered the First-Ever Proposal Regarding the Use of AED Offered by the United States

The UPU's consideration of AED first began at the 2008 UPU Congress when the United States offered a resolution to expand the use of AED.[269] The proposal focused on "enhanc[ing] the efficiency and speed of customs clearance" to allow posts to compete with the express consignment operators.[270] Specifically, the resolution required three things:

> (1) [D]evelop and maintain standards for UPU-Customs [AED] messaging, through the Standards Board, in cooperation with the World Customs Organization;
>
> (2) [P]romote, in cooperation with the World Customs Organization, the use of [AED] transmission among postal administrations and from postal administrations to local customs authorities for the clearance of postal items; and
>
> (3) [D]raw up a plan with deadlines for the implementation of transmission of [AED] customs messages on postal items in a phased-in manner, starting with required transmissions by developed countries by a date or dates to be determined after appropriate study.[271]

According to Joseph Murphy,[272] the resolution was referred to a working group where it was amended and then adopted by consensus.[273] The adopted

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[268] *Id.*
[269] *See* PSI-UPU-01-00003-4 (App. 0350-0351). The UPU Congress meets every four years in a designated host country. The other UPU bodies meet more frequently, usually at the UPU headquarters in Bern, Switzerland.
[270] *Id.*
[271] App. 0351.
[272] Mr. Murphy's title is currently Chief, International Postal Policy and Executive Director, Advisory Committee on International Postal and Delivery Services at the Department of State.
[273] Email from Patricia X. McNerney (Dec. 01, 2017) (*clarifying* Mr. Murphy's testimony during his Subcommittee Interview on Nov. 9, 2017). During his interview, Mr. Murphy inaccurately reported the resolution was defeated because other countries viewed the measure as something the United States was trying to push on the rest of the world. Murphy Interview (Nov. 9, 2017).

version of the resolution removed all references to any deadline for providing AED as follows:

> (3) [D]raw up a plan involving the relevant POC groups and in consultation with the UPU-WCO Contact Committee ~~with deadlines~~ for the implementation of transmission of [AED] customs messages on postal items in a phased-in manner, ~~starting with required transmissions by developed countries by a date or dates~~ to be determined after appropriate study, including identifying products, types of mail impacted, customer and operator capabilities, operational impacts, and performance measures.[274]

While the AED measure contained no planned date for implementation, subsequent events that occurred before the next Congress in 2012 would highlight the value of AED.

D. AED was used to Thwart an Al Qaeda Attempt to Ship Explosives in UPS and FedEx Packages

In October 2010, foreign officials interdicted two packages containing explosives packed into printer toner cartridges.[275] The explosives were rigged with a remote cell phone trigger and shipped via two express consignment operators, UPS and FedEx.[276] Intelligence from Saudi Arabia helped locate the two packages through the use of AED in the form of tracking numbers.[277] The tracking information indicated the packages were sent from Yemen and bound for delivery in the United States.[278] The express carriers were able to track the packages and locate one at East Midlands Airport in the United Kingdom and the other in Dubai after traveling on two Qatar Airways passenger jets.[279] Al Qaeda in the Arabian Peninsula (AQAP) ultimately claimed responsibility for the thwarted attack.[280] In its statement, AQAP claimed they "intend[ed] to spread the idea to our mujahedeen brothers in the world and enlarge the circle of its application to include civilian aircraft in the West as well as cargo aircraft."[281]

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[274] App. 0461.
[275] CDP-2017-00015–00941 (App. 0326).
[276] *Yemen parcel bomb "was 17 minutes from exploding*," BBC NEWS (Nov. 4, 2017), http://www.bbc.com/news/world-europe-11692942.
[277] *Id.*
[278] *Id.*
[279] *Id.*
[280] CNN Wire Staff, *Yemen-based al Qaeda group claims responsibility for parcel bomb plot*, CNN (Nov. 6, 2010), http://edition.cnn.com/2010/WORLD/meast/11/05/yemen.security.concern/?hpt=T2.
[281] *Id.*

The international mail community took notice. Mr. Murphy explained, "everything changed in 2010 with the printer cartridge bombs in courier shipments, because people realized that mail had the same vulnerabilities."[282] As a result, a great deal of international mail delivery shut down for four months after the thwarted attack.[283]

The United States began to work with European allies to develop a strategy for the UPU to adopt the use of AED.[284] The goal was to include an article in the 2012 UPU convention document for the UPU Congress scheduled to meet in Doha, Qatar.[285] The focus of the proposed article would be the use of AED for security purposes, similar to how it was used to locate the explosives in the two express carrier packages. This marked a shift from past AED considerations, which primarily focused on clearing packages through the customs process.[286] Twenty of the twenty-seven European Union countries in the UPU proposed language that "would add text to state that the security strategy should include complying with the legal requirements for providing electronic advance data in accordance with UPU technical messaging standards."[287] To reduce the burden on some members, the proposal would rely on "a phased-in approach and the use of pilots to ease the transition to providing advance data."[288]

Ultimately, the 2012 Doha Congress adopted the following language as Article 9 of its Convention document:

> Article 9
> Postal security
>
> 1. Member countries and their designated operators shall observe the security requirements defined in the UPU security standards and shall adopt and implement a proactive security strategy at all levels of postal operations to maintain and enhance the confidence of the general public in the postal services, in the interests of all officials involved. This strategy shall, in particular, include the principle of complying with requirements for providing electronic advance data on postal items identified in implementing provisions (including the type

[282] Murphy Interview (Nov. 9, 2017).
[283] *Id.*
[284] *Id.*
[285] *Id.*
[286] *See* CDP-20017-00015-01414 (App. 0349) ("Resolution C 56, adopted by the 2008 UPU Congress, called for intensified efforts in providing advance electronic information on international postal packages for customs purposes.").
[287] CDP-2017-00015-01413 (App. 0348) (The 20 countries included: Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Great Britain, Hungry, Ireland, Italy, Latvia, Luxemburg, Malta, Netherlands, Poland, Portugal, Romania, Slovenia, and Spain.).
[288] *Id.*

> of, and criteria for, postal items) adopted by the Council of Administration and Postal Operations Council, in accordance with UPU technical messaging standards. The strategy shall also include the exchange of information on maintaining the safe and secure transport and transit of mails between member countries and their designated operators.
>
> 2. Any security measures applied in the international postal transport chain must be commensurate with the risks or threats that they seek to address, and must be implemented without hampering worldwide mail flows or trade by taking into consideration the specificities of the mail network. Security measures that have a potential global impact on postal operations must be implemented in an internationally coordinated and balanced manner, with the involvement of the relevant stakeholders.[289]

Mr. Murphy explained that the Article 9.2 language was directed at the United States, given its higher risk as an international terrorism target.[290] Therefore, since the United States was considered to be susceptible to higher risk, it was expected to do more.

As mandated by Article 9, the POC began working on adopting the security standards for AED, which resulted in the "Roadmap for Implementing the UPU Electronic Data Global Postal Model ("Roadmap")."[291] Mr. Murphy explained that the United States as the Co-Chair (with India) of POC Committee 1 on Supply Chain Integration, took an active role in ensuring the Roadmap was an operational document.[292] As such, the Roadmap "provides an overview of the proposed way forward for UPU designated operators, the International Bureau, and other relevant stakeholders involved with postal supply chain security to meet emerging requirements in the postal sector for the provision of electronic advance data."[293] Further, the Roadmap intended to "clarify the roles, goals, and timelines that the UPU will be pursuing over the next several years."[294]

The Roadmap focused on the "capture, exchange, and use of electronic-item content" for eight data elements "sent by the origin Post, through the destination

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[289] Decisions of the 2012 Doha Congress, Universal Postal Union 122 (final texts of the Acts signed at Doha and of the Decisions other than those amending the Acts), http://www.jcampbell.com/UPU/Acts_2012/UPU_2012_0_CongressActs_20130517_Published.pdf.
[290] Murphy Interview (Nov. 9, 2017).
[291] CDP-2017-00015-00939 (App. 0324).
[292] Murphy Interview (Nov. 9, 2017).
[293] CDP-2017-00015-00941 (App. 0326).
[294] *Id.*

Post, to the destination authorities for every relevant item."[295] These eight data elements include:

(1) Sender's name
(2) Sender's address
(3) Addressee's name
(4) Addressee's address
(5) Detailed content description
(6) Gross weight
(7) Number of packages (one by default)
(8) Item ID[296]

Many of these data elements were already required on customs declaration forms CN22 and CN23,[297] which some posts were already exchanging electronically through "item level exchanges of attributes" or "ITMATT."[298] Overall, the Roadmap was a step forward in advancing the use of AED for security purposes, but it was not absolute. As Mr. Murphy explained, the Roadmap only requires countries to provide AED to the extent of their capability to provide it.[299] Despite its limitations, the Roadmap gives the United States the immediate ability to require AED from additional countries who have the capability to share it.

The Roadmap focuses on aviation security, as opposed to the interdiction of contraband such as illegal drugs. It specifically states, "items that contain prohibited substances like drugs are not targeted by [AED]."[300] Mr. Murphy downplayed this statement and explained, "nothing is targeted by [AED], it's just data. The targeting is done by the recipients of the data."[301] He also noted that the United States is the only country whose designated operator has a law enforcement component, the Postal Inspection Service, which informs the United States' view that data can be used to target illicit drugs and other prohibited items.[302]

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[295] CDP-2017-00015-00942 (App. 0327).
[296] *Id.*
[297] Forms CN22 and CN23 are customs declaration forms required to be affixed to all international packages under the Acts of the UPU. The form requires the sender to provide the following fields of information: sender name and address; recipient name and address; a detailed description of the contents; quantity; weight; value; tariff; and country of origin. *See* Universal Postal Union, WCO-UPU Postal Customs Guide (June 2014), https://www.icao.int/Meetings/AirCargoDevelopmentForum-Togo/Documents/WCO-UPU_PostalCustomsGuide-June2014.pdf.
[298] *Id.*
[299] Murphy Interview (Nov. 9, 2017).
[300] CDP-2017-00015-00942 (App. 0327).
[301] Murphy Interview (Nov. 9, 2017).
[302] *Id.*

E. To Protect its own National Security, the European Union Attempted to Require AED for all Packages by May 1, 2016

As the UPU wrestled with how to implement AED requirements, the European Union passed a law in direct response to the 2010 printer cartridges incident to protect its security.[303] In October 2013, the EU adopted the Uniform Customs Code ("UCC") which required AED on all packages entering the EU by May 2016.[304] As reported: "One of the major items [of the UCC] covered the quality and availability of [AED] for goods entering the EU customs territory, including postal flows to the EU transported under the UPU Acts."[305] Under the UCC, AED was required before the parcel was assigned to a bag for transport.[306] "The source for the data to be used would be the UPU CN 23."[307] The UCC would take effect on May 1, 2016, but would be a "phased-in implementation" starting with EMS and parcels, and "other postal products would be implemented at a later stage."[308]

Several countries raised concerns about the UCC requirement as a whole, but they primarily expressed concerns over meeting the May 1, 2016 implementation date, since they likely could not meet the deadline. For example, when the European Union representative presented on the UCC at the Council of Administration, "an intense debate of the issues" followed.[309] The delegate from France expressed strong views on the European Union's requirements and instead argued for "the need to take coordinated action in Berne" as well as "the need to adopt a global standard."[310] France also made clear "the EU was not alone in wanting to implement such requirements – other countries were preparing similar legislation."[311] Mr. Murphy confirmed this was a reference to the United States and potentially Australia.[312]

Other countries followed France in protest of the law and raised a number of specific issues with the UCC. Japan, for example, "expressed its strong concerns, particularly regarding the following two factors: the implementation date set by the EU and privacy and data protection when using CN 23 data for security purposes."[313] Greece, Great Britain, and Germany expressed similar concerns.[314] China "was also concerned about the confidentiality of data in the context of the

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[303] CDP-2017-00015-00659-663 (App. 0313-0317).
[304] Commission Regulation 952/2013, 2013 O.J. (L 269) 1.
[305] CDP-2017-00015-00659 (App. 0313).
[306] *Id.*
[307] CDP-2017-00015-00660 (App. 0314).
[308] *Id.*
[309] CDP-2017-00015-00661 (App. 0315).
[310] CDP-2017-00015-00662 (App. 0316).
[311] *Id.*
[312] Murphy Interview (Nov. 9, 2017).
[313] CDP-2017-00015-00662 (App. 0316).
[314] CDP-2017-00015-00663 (App. 0317).

transfer of data to third countries."[315] India and South Korea "also expressed a variety of concerns, similar to those that had already been voiced, particularly in terms of implementation deadlines, privacy concerns and the permanence of the exemption for letter post items."[316] India further asserted "the data required could not be captured at all post offices in a large country, and that advance data was not particularly effective as a security measure; physical inspection was the only sure way to keep the mail safe."[317]

The United States decided, however, to publicly take a hands-off approach.[318] In response to the specific concerns raised above, "the United States stressed the UPU's commitment to the development of the exchange of electronic data and was of the opinion that its provision enhanced security of the mail stream and air cargo."[319] After the meeting, Mr. Murphy wrote:

> Over-all we are, of course, supportive of what the EU is trying to do but its timetable is, in fact, unrealistic and its approach a bit high-handed. The reaction in [Committee 1] to the EC presenter is a function of these factors, and I judged that there was little benefit in trying to deflect the well-earned ire of the Indian and other delegations or in associating the U.S. with the EU's ham-handed approach at that juncture, particularly given that we had laid out our overarching position in [Committee 1]'s Customs Group.
>
> I should add that, in addition to reiterating our view of EU data privacy concerns…the very brief U.S. [Committee 1] intervention on this issue also took exception to India's assertion that [AED] offered no security benefits and re-iterated the importance to posts, especially in the context of e-commerce, of moving forward.[320]

Mr. Murphy continued that he planned to convey to the group that "although [AED] implementation by posts cannot be rushed and haphazard, too slow an implementation could impede the continued expansion in use of the mail for international e-commerce shipments."[321] Further, Mr. Murphy made clear that "[i]f a postal item contains an item requiring a customs form, there should be [AED] for it."[322] He also planned to assuage any privacy concerns by highlighting "that no more data is being provided through [AED] than is already provided on the

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[315] *Id.*
[316] *Id.*
[317] *Id.*
[318] Murphy Interview (Nov. 9, 2017).
[319] CDP-2017-00015-00663 (App. 0317).
[320] CDP-2017-00015-00696 (App. 0354).
[321] CDP-2017-00015-01114 (App. 0341).
[322] CDP-2017-00015-01115 (App. 0342).

[handwritten] customs declaration."[323] By providing the data, posts are "accelerating the submission to customs authorities in the receiving country of data provided by customers for that express purpose."[324]

The European Union felt the backlash for the legislation from a number of UPU members. For example, following a briefing by the European Union on the new requirements Mr. Murphy noted there was a "palpable sense of hostility in the room toward the EU rep, not least from France but also from India and Japan, which both pretty much said they won't comply."[325] Japan continued to raise privacy concerns after the European Union presentation and wrote Mr. Murphy to thank him "for supporting [Japan]'s concern on [AED] privacy."[326] In response, Mr. Murphy sent his talking points to the UPU representative from Japan regarding these issues and explained "although [AED] implementation by posts cannot be rushed and haphazard, too slow an implementation could impede the continued expansion in use of the mail for international e-commerce shipments."[327] With regard to any privacy concerns, Mr. Murphy explained:

> [W]hile it must be acknowledged that packaging data electronically does heighten privacy concerns by making data more accessible, it is worth highlighting the memorandum's observation that no more data is being provided through [AED] than is already provided on the customs declaration.
>
> In this sense, posts are not so much exchanging personal data through [AED] as they are accelerating the submission to customs authorities in the receiving country of data provided by customers for that express purpose.[328]

F. The UPU's Senior Leadership Lobbied its Members Against the European Union's UCC Implementation Date for Providing AED

As concerns about the UCC mounted, the UPU took action and formally requested that the European Union extend the implementation date of the law and its requirements. On December 11, 2014, Pascal Clivaz, the Deputy Director General of the UPU, wrote to Pierre Moscovici, the European Union Commissioner of Economic and Financial Affairs, Taxation and Customs "to communicate [the UPU] members' concerns about the implementation of the Union Customs Code,

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[323] *Id.*
[324] *Id.*
[325] CDP-2017-00015-01174 (App. 0345).
[326] CDP-2017-00015-01113 (App. 0340).
[327] CDP-2017-00015-01114 (App. 0341).
[328] CDP-2017-00015-01115 (App. 0342).

and the adoption of 1 May 2016 as the implementation date for non-EU countries to provide pre-advice of postal traffic in advance of import into the EU for risk assessment purposes."[329] Deputy Director General Clivaz continued:

> Briefly, many UPU members are concerned that the deadline of 1 May 2016 does not allow enough time for the consultations needed in order for a globally acceptable consensus model to evolve. It is also felt that this deadline does not allow enough time for all stakeholders to put the necessary technical and regulatory infrastructures in place.[330]

He also pointed out that the UPU, under Article 9, was tasked with "developing the relevant security requirements and implementing provisions on advance electronic information [AED] for postal items."[331] Given the UPU concerns, Deputy Director General Clivaz requested the European Union "take full account of the comments and concerns of UPU member countries" and suggested that "extending the deadline for consultations…would allow further discussions and enable solutions to be reached that suit the needs of, and are able to be implemented by all parties."[332]

In its continued attempt to convince the European Union to postpone the UCC implementation date, UPU senior leadership lobbied its members. On December 15, 2014, Deputy Director Clivaz wrote to all UPU members reminding them the Postal Operations Council was working to enact requirements for advance electronic information for postal items.[333] However, "the 1 May 2016 deadline for the provision of such information in the European Union approaches rapidly."[334] He made clear the "deadline will have an effect on mail exchange with Europe for all other UPU member designated operators."[335] According to the Deputy Director, "It is imperative that a single global solution be developed for advance electronic information for customs and for security purposes."[336] The Deputy Director urged members to take action by contacting the European Commission and expressing this view.[337]

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[329] CDP-2017-00015-00679 (App. 0318).
[330] *Id.*
[331] *Id.*
[332] CDP-2017-00015-00680 (App. 0313).
[333] CDP-2017-00015-00658 (App. 0312).
[334] *Id.*
[335] *Id.*
[336] *Id.*
[337] *Id.*

G. The European Union Postponed the Start Date of the UCC to 2020

Ultimately, the European Union postponed the start date for mandatory use of AED on postal packages. At a presentation during a UPU Standing Group Meeting in February 2017, the European Commission reported the new target date was 2020, which aligned with the UPU roadmap.[338] Providing AED would no longer be mandatory, but instead would start on a voluntary basis. Further, there would be a grace period for implementation of mandatory compliance until 2023, with no penalties before that date.

Ms. Cheri DeMoss of the Postal Service represented the United States at the February 2017 UPU meeting. Ms. DeMoss felt the European Union's legislation was needed to speed the process of other countries preparing to provide AED. She believed the delay of the UCC and lack of penalties until 2023 would extend the time other countries would take to develop the capacity to comply and simultaneously "delay implementation of [AED] from posts."[339]

H. The 2016 UPU Congress in Istanbul Initiated a Proposal for AED through the Integrated Product Plan

While the Roadmap from the 2012 Congress in Doha focused on the operational side of providing AED for international mail, the 2016 Congress in Istanbul worked to develop a business-centric strategy to modernize international mail called the Integrated Product Plan ("IPP"). While the IPP was not focused on AED, it had certain implications for the exchange of AED between posts. For purposes of AED, the IPP is broken into two steps. The first step requires all designated operators "to apply S10 barcodes to small packets" by January 1, 2018.[340] Designated operators would ultimately use the barcode to track the package. No information, however, is initially required to be loaded on to the barcode. The IPP explains that "by proposing the obligatory application of S10 barcodes on small packets containing goods in 2018 already, we are acting pragmatically by driving behaviour so that we are aligned in advance of the 2020 supply chain requirements."[341] By 2020, the IPP expected – but did not require – all posts would be able to load AED onto the barcode, which is Step 2.

While Step 1 requiring barcodes was implemented at the beginning of 2018, the goal of implementing Step 2 by 2020 is no longer considered possible. In his

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[338] CDP-2017-00015-01078 (App. 0293) (U.S. POSTAL SERVICE, 2017 UPU Standing Group Meetings Report, Postal Operations Council (Feb. 20, 2017)).
[339] DeMoss Interview (Oct. 25, 2017); *See also* U.S. POSTAL SERVICE, 2017 UPU Standing Group Meetings Report, Postal Operations Council (Feb. 20, 2017).
[340] CDP-2017-00015-00214 (App. 0302).
[341] *Id.*

interview with the Subcommittee, Mr. Murphy explained such a delay was likely, given that the implementation date of 2020 now "seems ambitious." Instead, there is discussion of adding several steps before requiring that data to be loaded onto the barcode.[342]

I. Countries Again Argued Against Any UPU Requirements to Provide AED; the United States Distanced Itself from the Proposal

Some UPU countries responded strongly to the IPP. In an *ad hoc* group of Committee 3, a number of countries pushed back. For example, India requested "a thorough, comprehensive impact study should be carried out, including all the UPU member countries before implementing Step 1."[343] India also asserted that "applying barcodes on small packages should not be made mandatory."[344] Several other countries, including Botswana, Japan, South Korea, and China, raised the issue that no impact study was conducted prior to implementation.[345]

The international view of the value of AED, however, has clearly changed. Not all countries responded negatively to the IPP and some even took a proactive and positive stance. Australia asserted "step 1 is a good first step," noting posts "must address our customers' needs."[346] Denmark requested that the IPP "move swiftly forward."[347]

Once again, the United States took a decidedly understated public role in the advancement of the IPP. A memo described the State Department's position with regard to the IPP:

> The US is strongly supportive of the IPP, although it has concerns with the pace of its implementation (which may not successfully meet the electronic customs manifesting deadlines set by the European commission). However, US concerns on the '*need for speed*' must also be weighed against the greatest *'need for adoption'* of the IPP plan. Many countries have already expressed their concerns with the IPP, and more aggressive timelines might scare away those countries currently supporting this IPP concept.
>
> Consequently, the US is taking a 'supportive' role in this matter and letting the POC Physical Services Co-Chairs (UK and Canada) take

[342] Murphy Interview (Nov. 9, 2017).
[343] CDP-2017-00015-00218 (App. 0306).
[344] *Id.*
[345] *Id.*
[346] *Id.*
[347] CDP-2017-00015-00219 (App. 0307).

> the lead in the campaign to have this IPP adopted. While the US sees several areas that need fine-tuning, to avoid creating doubts on the IPP package, US will only make minimal suggestions for change – in cases there were clear drafting errors. Once the IPP is adopted, the US can then turn to achieving better versions of the definitions at the mini-Congress in 2018.[348]

J. Multiple AED Proposals at the UPU Led to Confusion Regarding Member Countries Requirements and Efforts have "Slowed Down to a Crawl"

As the UPU closes in on almost a decade of considering AED, there appear to be several proposals regarding AED, but none that require all Posts to exchange AED. While Mr. Murphy explained that the Roadmap and IPP are designed to operate concurrently,[349] neither proposal has resulted in the global exchange of AED by designated operators. In fact, there appears to be confusion as to which document governs and what is required. On September 2, 2016, Peter Chandler, the Manager of UPU Relations at the Postal Service, was asked in an email "is there a specific proposal on advance electronic customs data for the [2016] UPU Congress?"[350] He explained:

> There is no single proposal that directly says…by some date you shall be providing electronic customs information on your items….The February 2016 POC adopted a Road Map to advance work on electronic advanced data for security purposes [AED] but it never overtly said it was mandatory for everyone also. I've also noted a couple of recent country proposals to Congress that touch upon customs [AED].
>
> There was supposed to be a progress report to Congress on the road map for [AED]—however, things have slowed down to crawl on this at the International Bureau after a change in management of this program.[351]

Mr. Murphy stated that this email addressed the fact that there were no proposals regarding AED at the 2016 Istanbul Congress, since the Roadmap was in response to the addition of Article 9 at the 2012 Doha Congress.[352] However, it seems clear from the above exchange that UPU members do not consider the sharing of AED mandatory. Notably, as indicated above, a change in UPU personnel has resulted in efforts surrounding AED at the UPU to slow dramatically.

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[348] CDP-2017-00015-00401 (App. 0311) (emphasis in original).
[349] Murphy Interview (Nov. 9, 2017).
[350] CDP-2017-00015-00341-342 (App.0309-0310).
[351] *Id.*
[352] Murphy Interview (Nov. 9, 2017).

K. The UPU Takes Notice of Posts being used to Ship Illicit Drugs

While the international community initially focused on AED for security purposes and expediting customs, the conversation has since shifted to targeting illicit drugs. On February 23, 2017, the POC Postal Security Group met in Bern, Switzerland to discuss the issue of using posts to ship illicit drugs. During that meeting, the use of posts to ship synthetic opioids was discussed:

> The [Postal Security Group] Secretariat provided information that was presented to the Council of Europe on the rise of the Dark web and cryptomarkets, and the use of covert internet means which enables illicit drug producers to directly market to users. This business model shift has resulted in an increased volume of illegal drugs in the letter mail rather than parcels, which creates additional challenges for posts. In addition, new highly potent forms of synthetic opioids and other toxic chemicals are being transported in the post. These chemicals are deadly in minute quantities, and pose a risk to postal employees. It is imperative for posts to be prepared to appropriately respond to inadvertent exposure to toxic chemicals to protect employees and the postal supply chain.[353]

While CBP has asserted that it relies heavily on AED to target packages containing illicit drugs, the State Department maintains there is a lack of worldwide consensus on this assertion. The State Department has internally questioned whether AED is helpful in targeting packages containing illicit drugs. A February 1, 2017 internal State Department memoranda to Deputy Assistant Secretary (DAS) Nerissa Cook questioned the impact AED would have on targeting packages containing illicit drugs. In explaining the IPP, the memorandum stated:

> One component of this modernization is expanding the collection and transmission of [AED] for individual mail items–a topic of high interest on the Hill, ***ostensibly because of the presumed contribution [AED] would make to preventing synthetic opioids from arriving in the United States through the international mail.*** Because of its clear benefits for aviation security, customs operations and expeditious handling, accelerating the use of [AED] is one of our highest priorities at the UPU this Congress cycle. (We will also soon initiate interagency consultations on ways to accelerate [AED] exchange through bilateral engagement.)[354]

[353] CDP-2017-00015-01073 (App. 0335).
[354] CDP-2017-00015-00811 (App. 0321) (emphasis added).

The State Department's skepticism with regard to the utility of AED continued to increase. A May 9, 2017 memorandum again updating Deputy Assistant Secretary Nerissa Cook on the implementation of AED in the IPP noted:

> This topic is of high interest on the Hill, ostensibly because of the presumed contribution [AED] would make to preventing synthetic opioids from arriving in the United States through the international mail. ***Despite its uncertain benefits for this purpose***, accelerating the exchange of [AED] is one of our highest priorities at the UPU this Congress cycle because of its clear benefits for aviation security, IPR enforcement and expeditious mail handling.[355]

Mr. Murphy explained he drafted these updates on behalf of his supervisor, Mr. Gregory Thome. When questioned whether he believed AED aided CBP in targeting packages, he explained there was a perception in the global postal community that the benefits of AED for targeting packages were uncertain.[356] He continued "from a policy standpoint, it does not matter why we want it, we just want it."[357] Mr. Murphy took the position that foreign posts need to exchange AED for purposes of modernization.[358]

VII. EXPRESS CARRIERS USE ADVANCED ELECTRONIC DATA TO LOCATE PACKAGES TARGETED BY CBP

Unlike the Postal Service, Express Consignment Operators (ECOs) are mandated under the Trade Act of 2002 to collect AED on all packages and provide that information to CBP. The ECOs examined by the Subcommittee were DHL, FedEx, and UPS. While those three ECOs maintain they present all packages targeted by CBP for inspection, the volume handled by ECOs is much less than that delivered by the Postal Service. Further, ECOs are able to control a package from the time it is accepted to delivery. This is unlike the Postal Service, which has no control of international packages at their point of origin and is obligated under the UPU treaty to accept and deliver packages it receives from foreign posts. A number of items, however, are prohibited from being shipped under the UPU treaty, including "narcotics and psychotropic substances…or other illicit drugs which are prohibited in the country of destination." [359]

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[355] CDP-2017-00015-00821 (App. 0359) (emphasis added).
[356] Murphy Interview (Nov. 9, 2017).
[357] *Id.*
[358] *Id.*
[359] Universal Postal Union, Universal Postal Convention, Article 18, "Items not admitted. Prohibitions,"

Drug traffickers also use ECOs to ship illicit opioids. According to an August 2017 report from the U.S. Government Accountability Office, 30 percent (92,878 items out of 308,360) of CBP's seizures of all inbound international shipments from 2012–2016 came from ECOs.[360] Of the total seizures (both Postal Service and ECOs), 47 percent (or 144,117 items) were illegal or inadmissible drugs while the remaining seizures were merchandise.[361]

For example, earlier this year, CBP seized 83 DHL shipments containing 36 pounds of fentanyl at Cincinnati/Northern Kentucky International Airport. A CBP press release reported that the shipments were from China and "were addressed to individuals in multiple locations throughout seventeen U.S. states and Canada."[362] The shippers attempted to disguise the contents by mislabeling packages with descriptions of "silicone resin, hardware nuts, snap hooks, plastic sheet sample, and nano hydrophobic coatings."[363]

This section explains how Congress mandated ECOs to collect AED on all international packages entering the United States following the terrorist attacks on September 11, 2001. In response, the ECOs developed proprietary systems to transmit AED. This has resulted in ECOs identifying and presenting almost all of the packages targeted and requested by CBP for inspection.

A. Congress Mandated Express Consignment Operators to Provide CBP with AED on all Packages

Congress passed the Trade Act of 2002 following the terrorist attacks against the United States on September 11, 2001. The Trade Act required ECOs to collect certain information for all international packages.[364] However, as discussed below, Congress did not mandate the collection of AED on Postal Service packages.

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http://www.upu.int/uploads/tx_sbdownloader/universalPostalConventionArticle18ItemsNotAdmittedProhibitionsEn.pdf.

[360] U.S. GOV'T ACCOUNTABILITY OFF., GAO-17-606, INTERNATIONAL MAIL SECURITY: COSTS AND BENEFITS OF USING ELECTRONIC DATA TO SCREEN MAIL NEED TO BE ASSESSED 8 (2017), https://www.gao.gov/assets/690/686377.pdf.

[361] *Id.*

[362] Press Release, U.S. Customs and Border Protection, Cincinnati CBP Seizes 290 Pounds of Designer Drugs (Mar. 29, 2017), https://www.cbp.gov/newsroom/local-media-release/cincinnati-cbp-seizes-290-pounds-designer-drugs.

[363] *Id.*

[364] 19 U.S.C. § 2071 (note), Mandatory Advanced Electronic Information for Cargo and Other Improved Customs Reporting Procedures (2016).

1. The Trade Act Required ECOs to Collect AED to Provide to CBP

Trade Act regulations state that the ECOs must provide CBP with AED on all incoming foreign shipments prior to arriving in the United States at a designated port of entry.[365] The data elements ECOs must provide electronically to CBP include:

- Country of origin for the merchandise
- Shipper name, address and country
- Ultimate consignee name and address
- Specific description of the merchandise
- Quantity
- Shipping Weight
- Value.[366]

Regulations explain "CBP must receive the required cargo information no later than 4 hours prior [to] the arrival of the [package] in the United States."[367] ECOs that fail to provide the required AED are subject to civil penalties "in a monetary amount up to the value of the cargo, or the actual cost of the transportation, whichever is greater."[368] Each year the ECOs pay penalties to CBP for failing to provide AED as reflected in the chart below. In contrast, the Postal Service is not required to pay penalties for failing to provide AED on any of its international packages.

Annual Amount Paid to CBP in Manifest Penalties by DHL, FedEx, and UPS[369]

2012	2013	2014	2015	2016
$308,500	$230,650	$34,675	$124,619	$267,850

In addition to penalties, the Trade Act imposed certain costs on the ECOs regarding CBP's inspection of their packages. Specifically, Trade Act regulations require each ECO to "provide, without cost to the Government, adequate office space, equipment, furnishings, supplies and security as per CBP's specifications."[370] This is in addition to the requirement that ECOs pay CBP a fee of one dollar for each international package valued at $2,500 or less shipped through the ECO.[371]

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[365] 19 C.F.R. § 128.21 (2017).
[366] *Id.*
[367] 19 C.F.R. § 122.48a (2017).
[368] 19 U.S.C. § 2071 (note), Mandatory Advanced Electronic Information for Cargo and Other Improved Customs Reporting Procedures (2016).
[369] These figures represent aggregated information for the three ECOs reviewed by the Subcommittee.
[370] 19 C.F.R. § 128.21 (2017).
[371] 19 C.F.R. § 24.23(b)(1)(i) (2017).

This fee is related to processing the package by CBP and clearing it through U.S. customs.[372] That fee results in significant amounts paid to CBP each year by the ECOs:

Annual Amount Paid to CBP in One Dollar Per Package Fees by DHL, FedEx, and UPS[373]

2012	2013	2014	2015	2016
$33,725,745*	$52,066,414	$54,402,127	$59,816,258	$67,030,218

**Quarter 4 only provided by DHL.*

ECOs have the option of passing the one-dollar-per-package-fee and the CBP-associated costs on to consumers by building the fees into the shipping costs.[374] In contrast, the Postal Service does not pay CBP one-dollar-per-package to process international packages sent through its network.

It is important to note that the package volume carried by the ECOs is significantly less than the Postal Service's volume. However, ECOs also experienced growth over the past five years.

Annual ECO International Shipping Volume Into the United States for DHL, FedEx, and UPS[375]

2012	2013	2014	2015	2016
28,138,472*	51,915,823	54,440,116	59,353,177	65,772,320

**Quarter 4 Only provided by DHL.*

B. Congress Delegated the Decision to Require Postal Service to Provide AED

While the Trade Act of 2002 statutorily mandated that the ECOs provide CBP AED on packages in their networks, Congress did not impose the same requirements on the Postal Service. In fact, Congress left the decision up to the Secretary of the Treasury and Secretary of Homeland Security, in consultation with the Postmaster General.[376] Specifically, the Trade Act states:

> With respect to the requirements imposed on the carriers, the Secretary, in consultation with the Postmaster General, shall

[372] *Id.*
[373] These figures represent aggregated information for the three ECOs reviewed by the Subcommittee.
[374] For example, UPS explained it includes the one-dollar-per-package fee and other costs in the amount it charges customers to ship a package through its network. Briefing with UPS (May 5, 2017).
[375] These figures represent aggregated information for the three ECOs reviewed by the Subcommittee.
[376] 19 U.S.C. § 2071 (note), Mandatory Advanced Electronic Information for Cargo and Other Improved Customs Reporting Procedures (2016).

> determine whether it is appropriate to impose the same or similar requirements on shipments by the United States Postal Service. If the Secretary determines that such requirements are appropriate, then they shall be set forth in regulations.[377]

To date, the requirement to provide AED has not been imposed on the Postal Service because no decision has been made by the Secretaries or Postmaster General.

C. ECOs use AED to Track Packages Throughout Their Networks

Pursuant to Trade Act requirements, ECOs provide AED to CBP on all packages delivered to the United States. Each ECO has extensive practices and procedures for accepting delivery of a package.[378]

1. ECOs Control Packages from Drop-Off to Delivery

From the time a package is dropped off by the customer until it is delivered to the final address, it is controlled and tracked by an ECO. DHL noted that packages are booked by a DHL customer service employee through proprietary systems while "Pick Up includes…picking up and accepting the shipments from the Customer."[379] FedEx policy includes the following:

> FedEx's responsibility for a package begins when an employee accepts it. All packages must be prepared and packed by the customer for safe transportation with ordinary care in handling. Customers may use packaging supplied by FedEx Express, or they may use their own packaging if it meets standards set by FedEx Express.
>
> FedEx reserves the right to refuse to do business with parties suspected of using FedEx services for illegal or unethical purposes. All FedEx employees are required to report senders they suspect of abusive, illegal, or unethical activities to Customer Service or the Operations Manager at their location. The Operations Manager must inform Security, Legal, and Marketing groups in the affected region.[380]

FedEx also retains the ability to open any package being shipped through its network. FedEx policies indicate "all items offered or accepted for shipment are subject to inspection. If a complete description of the contents of any international

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[377] *Id.*
[378] *Id.*
[379] DHL_PSI00000075-78 (App. 0360-0362).
[380] FDXPSI0000187 (App. 0455).

shipment is not available, FedEx has the option of opening and inspecting the shipment to verify the description of its contents."[381]

In his testimony before the Subcommittee at the May 25 hearing, Norm Schenk, UPS Vice President of Global Customs Policy and Public Affairs explained UPS "picked up [packages] from foreign customers bound for the U.S."[382] He also testified, "We even require [AED] through subcontractors in countries where we work, if we do not have a physical presence there, as a high-risk package can be sent from anywhere at any time."[383]

D. ECOs Require Customers to Provide Information Mandated by the Trade Act

The three ECOs examined by the Subcommittee require customers to provide certain information in order to ship a package through their networks. The information requested aligns with the fields of information required under Trade Act regulations.[384]

1. DHL

DHL policy requires shippers to include certain information in the form of an Air Waybill during the processing of any shipment.[385] DHL international shipping requirements include providing the following fields of information:

- Address (including city name)
- Country (where pickup will be made)
- Company name (if not residential)
- Location/Specific floor/ room number
- Contact name
- Phone number
- Ready time

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[381] FDXPSI0000086 (App. 0456).

[382] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017) (testimony of Norman Schenk, Vice President of Global Customs Policy and Public Affairs, United Parcel Service).

[383] *Id*.

[384] 19 C.F.R. § 128.21 (2017).

[385] DHL_PSI_00000076 (App. 0360). An Air Waybill is the customer's receipt for their shipment that ensures delivery. The Air Waybill information is provided by the customer and "details the basic information about [the] shipment, including where it's being sent from and to, the weight, [] a brief description of the goods,…where [the] shipment is going, what service [is] required, and how [the customer] intends to pay." The Air Waybill also includes "the terms and conditions upon which [DHL] will provide service." DHL, Shipping Documentation, DHL (Jan. 10, 2018), https://dhlguide.co.uk/going-global/customs/carrier-documentation/.

- Close time (if morning pickup request for break time hours)
- Special instructions (supplies/packing material)
- Payment method
- Account number
- Destination
- Special Handling Requests
- Product
- Paperwork confirmation
- Weight (if known)
- Dimensions (if known)
- Total number of pieces[386]

2. FedEx

FedEx policy states that it "requires every package to be properly identified, marked and labeled to ensure a smooth customs clearance and on-time delivery, as well as reduced missorts and lost revenue."[387] FedEx gathers certain information and "[e]ach package must display the following unique identification and labels that allow FedEx Express to handle it with the greatest possible efficiency,"[388] in part:

- The sender's name and complete address
- The recipient's name and complete, deliverable address on all pieces
- A completed international air waybill
- Where available, an air waybill peel-off tracking number label (placed on the commercial invoice)
- Backup tracking number
- Other appropriate service or handling labels such as Fragile, Actual & Dim, Perishable, Heavy, and Dangerous Goods[389]

For international shipments, FedEx policy states "[d]ocumentation is required for every international shipment" and "[t]he International Waybill is required for all express shipments."[390] The FedEx International Waybill is "a legal document for shipping, manifesting, customs clearance, tracking, and billing," and serves as "a contract between the sender and carrier to transport international cargo."[391] Information collected on the International Air Waybill by FedEx includes: (1) description and quantity of the goods; (2) value of the shipment; (3) number of

[386] DHL_PSI_00000076 (App. 0360).
[387] FDXPSI0000146 (App. 0396).
[388] *Id.*
[389] *Id.*
[390] FDXPSI0000124 (App. 0394).
[391] *Id.*

pieces (packages) in the shipment; (4) weight of the shipment; (5) type of mail service requested; and (6) type of payment (freight, duty, and taxes).[392]

FedEx policy states the VISA MANIFEST System exists to: (1) expedite the customs clearance process; (2) track international shipments; (3) invoice international shipments; (4) prevent overages and shortages; (5) support customer service/customer inquiries; (6) allow regulatory agencies to select and hold shipments for examination; (7) provide screens and reports that allow users to ensure an accurate manifest is provided for customs clearance; and (8) capture export proof of reporting for regulatory agencies.[393]

On the day of the shipment, FedEx enters shipment information into an electronic record of shipment information called VISA MANIFEST System. In total, information for all international shipments on a VISA MANIFEST Report includes:

- Sender's account information
- Reference Information
- Origin
- Destination
- Recipient's account number, phone number, name, address, city, state, province, country, and postal code
- Broker's name, city, country, phone number, and postal code
- Service type
- Special handling codes (Hold at Location, Saturday Delivery, and Dangerous goods)
- Billing information
- Account number
- Country code
- Weight
- Manufacturing code
- Currency type
- Carriage value
- Customs value
- Exporter's license
- Description
- MPS (Multiple Piece Shipment) information[394]

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[392] *Id*. at App. 0394-0395.
[393] FDXPSI0000312-313 (App. 0398-0399).
[394] FedEx Ship Manager Server Transactions Guide, FedEx Corporate Services, Inc. 2013–2014. Generating FedEx Shipping Forms and Reports, FedEx Express International Reports, International Visa Manifest Report-FedEx Express, 17.6.5. https://www.fedex.com/us/developer/WebHelp/fsms/1401/dvg/DVG-WebHelp/index.htm#1_Introduction_to_FedEx_Ship_Manager_Server.htm.

FedEx indicated that the VISA MANIFEST System is an electronic record of shipment information that begins the clearance process of an international shipment before it arrives at its destination. It also serves as a legal document that describes the cargo being transported, allowing "origin, transit, and destination locations to print a manifest."[395] For further verification of accuracy, personnel at the origin, transit, and destination locations are responsible for changing the manifest as needed. This would occur, for example, when a flight is delayed, rerouted, or cancelled.[396]

3. UPS

To ship a package with UPS, a customer is required to provide certain information submitted in the form of an International Air Waybill (IAWB), which serves as the "contract of carriage between the shipper and the carrier."[397] As Mr. Schenk of UPS testified at the May 25th hearing, UPS has "been using electronic data for years, even before it was required by the Trade Act of 2002, to provide CBP with item-level detail about every shipment entering the country." These data consist of seven data points:

- The sender's name and address
- The recipient's name and address
- The value of the contents
- A description of the contents and
- The piece count for the shipment[398]

Mr. Schenk continued "this not only helps [UPS] reduce the potential for dangerous goods entering the United States through our system, but also aids in meeting manifesting and compliance requirements, ensuring payment of duties and fees and expediting clearance through customs."[399]

UPS uses an electronic database called the UPS WorldShip System, which collects and enters data provided almost entirely by the customer.[400] In locations where customers submit shipments with hard copies of the shipment data, a UPS

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[395] FDXPSI0000312 (App. 0398).
[396] FDXPSI0000102 (App. 0393).
[397] App. 0404-0405; *see also* UPS Air Freight Terms and Conditions of Contract For UPS Air Freight Services in the United States, Canada, and International, Effective July 10, 2017, 3-4, https://www.ups.com/assets/resources/media/en_US/AirFreight_TandC.pdf.
[398] *Stopping the Shipment of Synthetic Opioids: Oversight of U.S. Strategy to Combat Illicit Drugs: Hearing Before the S. Permanent Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs,* 115th Cong. (2017) (testimony of Norman Schenk, Vice President of Global Customs Policy and Public Affairs, United Parcel Service).
[399] *Id.*
[400] In locations where customers submit shipments with hard copies of the shipment data, a UPS employee would enter the data into the WorldShip System. PSI-UPS-01-000002 (App. 00622).

employee enters the data into the WorldShip System. The system requires the shipper to provide:

- A valid UPS account number
- Contents of the shipment
- Contact name and telephone number for the shipper
- A consignee contact name, telephone number, address, and zip/postal code
- Accurate dimensions and weight of the shipment[401]

E. Automated Systems Assist ECOs in Tracking Packages

Policies and procedures from each ECO described proprietary systems used to track packages throughout each carrier's network.

1. DHL

DHL policies state a number of requirements for international shipments throughout the DHL express global network, including validation of shipment information to ensure delivery through the DHL network.[402] This includes reviewing the data entered for each package for errors and ensuring any missing information is included.[403] DHL also reviews the description of goods to ensure that information is accurate.[404]

When CBP or law enforcement seizes a shipment at a DHL facility, the DHL facility staff must take note of: (1) the Air Waybill number; (2) the agency taking possession of the shipment; (3) the name of the representative of the agency and; (4) the commodity contained within the shipment.[405] The DHL facility manager is then required by policy to enter the seizure/intercept information into the appropriate DHL database.[406]

DHL has taken further steps to partner with DHS regarding the shipment of drugs through the DHL network. In January 2014, DHL entered into a Memorandum of Understanding with HSI and CBP regarding narcotics

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[401] App. 0404-0405; UPS Air Freight Terms and Conditions of Contract For UPS Air Freight Services in the United States, Canada, and International, effective July 10, 2017, 3-4, https://www.ups.com/assets/resources/media/en_US/AirFreight_TandC.pdf.
[402] DHL_PSI_00000080 (App. 0363).
[403] DHL_PSI_00000160 (App. 0379).
[404] DHL_PSI_00000160-165 (App. 0379-0384).
[405] DHL_PSI_00000142 (App. 0377).
[406] *Id*.

enforcement at DHL facilities in an effort to reduce drugs being smuggled into the country through the DHL network.[407]

2. FedEx

FedEx policy states the Global Enterprise Network for the Entry of Shipment Information at the Source ("GENESIS") is used to enter manifest data for all international shipments. Document images are also digitally stored in the GENESIS Global Document Archive for future use, and manifest information is uploaded to the VISA MANIFEST System where the manifest can be viewed, printed, or electronically sent to customs, the broker, within FedEx, or to other government agencies.

FedEx policies also state that "[a]ll shipments offered to or accepted by FedEx are subject to inspection," and that "[c]orporate [s]ecurity may open and inspect any package (except diplomatic bags and military shipments) at any time for safety and/or security reasons."[408] Further, "[o]perations management may open shipments in order to obtain a better address or description of the contents."[409] However, FedEx Security does not have consolidated tracking or logging of illegal items found in shipments.[410]

Based on the originating location of the package, FedEx provided country-specific procedures for accepting a package for delivery. For example, because India requires shippers to know their customers, FedEx created the "Unknown Shipper Authentication Program" for India.[411] FedEx policy states these procedures "capture the mandatory information of every walk in customer who books his shipments at the FedEx counters using cash."[412] An unknown shipper is required to provide proof of identification, such as a passport or driving license.[413]

Further, FedEx employees are advised to look for certain specific signs in identifying a suspicious package.[414] Other countries where FedEx accepts packages for delivery also have specific policies and procedures, including China, Colombia, Dominican Republic, Canada, Hong Kong, Singapore, and the United Kingdom.[415]

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[407] DHL_PSI-00000094-101 (App. 0376).
[408] FDXPSI0000170 (App. 0397).
[409] *Id.*
[410] Email from Brian Heberlig, counsel for FedEx, to the Subcommittee (Nov. 28, 2017).
[411] FDXPSI0002510–2512 (App. 0451-454).
[412] *Id.* at App. 0453.
[413] *Id.*
[414] *Id.*
[415] Letter from Brian Heberlig & Jason Weinstein, counsel for FedEx, to the Subcommittee (Sept. 29, 2017).

3. UPS

UPS produced a number of policies and procedures regarding proprietary systems used to track packages using AED. UPS explained how it interacts with CBP at its facilities: "UPS express and hub facilities have sophisticated automation and scanning procedures, and routinely present packages to CBP, whose officers are stationed at these facilities."[416]

Manuals for the UPS operating system ("OPSYS") international data system appear to allow an employee to run a number of queries and reports to track a package at any point during the delivery process.[417] The OPSYS system also allows UPS employees to access the data associated with a specific package and to locate a specific package by searching for the shipper's name.[418]

F. ECOs Do Not Share Information Related to Shippers of Illegal Items

While the ECOs work to maintain the integrity of their networks, there is currently no coordinated effort to share information regarding shippers of illegal items among the ECOs or with CBP.

1. DHL

DHL reported that it does not accept packages from individuals or entities appearing on denied parties' lists, such as the U.S. Department of Treasury Office of Foreign Assets Control, but does not have a DHL-generated denied shipper list. Instead, "DHL relies on its robust communications from across the DHL global network to cancel problematic customer accounts."[419] DHL explained this is the current course of action because it found "customers will continually change shipping names and other contact information making any DHL-generated list insufficient to be relied upon."[420]

2. FedEx

FedEx also provided a "list of parties from which FedEx refuses to accept packages, or from whom FedEx only accepts certain types of packages, because the party failed to comply with FedEx policies for shipping Dangerous Goods."[421] The undated list consisted of 116 entries, including 100 domestic shippers and 16 foreign shippers, with several located in China. Most of the listed entities have names indicative of a business, some of which are household names. The list contained no individuals, unless that person was associated with a business. From

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[416] Letter from Laura Lane, President, UPS Global Affairs, to the Subcommittee (Nov. 21, 2017).
[417] PSI-UPS-01-000002 (App. 0389).
[418] UPS Production to the Subcommittee (Nov. 21, 2017).

a review of the businesses on the list by Subcommittee staff, none of them appeared related to openly selling illicit drugs. FedEx stated it does not share its list with other ECOs or CBP.[422]

3. UPS

UPS stated that it "regularly works to update its systems to ensure that it does not do business with customers who traffic in illegal merchandise. When UPS identifies such customers, it works to block that person from shipping through the UPS network."[423] UPS provided a list of individuals and entities from which it no longer accepts packages.[424] However, UPS indicated it does not share its internal lists of these individuals with other ECOs.[425]

G. ECOs Provide Almost All Targeted Packages to CBP for Inspection

According to statistics provided by CBP, as depicted below, the ECOs provide almost all of the packages targeted for inspection.

CBP Analysis of ECO Presentment Rates of Targeted Packages[426]

Fiscal Year	Total Express Bills	Penalties for Non-presentment	Presentment Rate
2013	29,375,103	4,626	99.9%
2014	50,066,460	7,041	99.9%
2015	78,296,817	3,680	99.9%
2016	104,223,263	341	99.9%
2017	108,327,947	207	99.9%

[419] Letter from Matt Miner, counsel for DHL, to the Subcommittee (Nov. 16, 2017).
[420] *Id.*
[421] *See also* Letter from Brian Heberlig & Jason Weinstein, counsel for FedEx, to the Subcommittee (Sept. 13, 2017). Dangerous Goods is the international equivalent of "Hazardous Materials," defined in 49 CFR 171.8 as "a substance or material that the Secretary of Transportation has determined is capable of posting an unreasonable risk to health, safety, and property when transported in commerce, and has designated as hazardous under section 5103 of Federal hazardous materials transportation law (49 U.S.C §5103)." These substances may be lawfully shipped by customers and transported by ECOs provided they are appropriately marked, labelled, packaged, and documented.
[422] Email from Brian Heberlig, counsel for FedEx, to the Subcommittee (Nov. 13, 2017).
[423] Letter from Laura Lane, President, UPS Global Affairs, to the Subcommittee (Oct. 11, 2017).
[424] UPS Production to the Subcommittee (Nov. 21, 2017) (on file with the Subcommittee).
[425] Letter from Laura Lane, President, UPS Global Affairs, to the Subcommittee (Nov. 21, 2017).
[426] CBP Production to the Subcommittee (Dec. 7, 2017) (on file with the Subcommittee).

Both FedEx and UPS internally tracked the number of packages targeted by CBP and provided presentment rates, along with statistics regarding packages that were targeted, inspected, and seized by CBP. For 2012, FedEx's presentment rate was 98.9 percent.[427] From 2013 to the present, FedEx has presented more than 99 percent of the packages CBP targeted for inspection.[428] UPS also reported rates of providing targeted packages to CBP for inspection, which have improved over the past five years, as depicted below:[429]

Year	Packages Missed
2012	334
2013	71
2014	32
2015	13
2016	13
2017	4

DHL reported it "neither keeps track nor maintains records sufficient to report the number of DHL packages: (1) identified or targeted by CBP for inspection; (2) interdicted by CBP; or (3) with a 'deny shipment' order placed by CBP."[430] DHL did state it "has processes in place to X-ray and otherwise screen for potential threats."[431] Later, DHL provided specific statistics on exams and detentions by CBP for years 2016 and 2017 and reported it had the ability to provide the same statistics for 2013-2015, but not prior to the release of this report.[432]

[427] FedEx Production to the Subcommittee (Sept. 6, 2017) (on file with the Subcommittee).
[428] *Id.*
[429] UPS Production to the Subcommittee (Dec. 4, 2017) (on file with the Subcommittee).
[430] DHL was originally unable to provide statistics regarding the number of packages presented to CBP for inspection. Letter from Matt Miner, counsel for DHL, to the Subcommittee (Oct. 13, 2017).
[431] *Id.*
[432] Email from Matt Miner, counsel for DHL, to the Subcommittee (January 23, 2018).