

**VIA ELECTRONIC SUBMISSION**

February 20, 2020

Division of Dockets Management (HF A-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**RE: Importation of Prescription Drugs (Docket No. FDA-2019-N-5711)**

The Pharmaceutical Security Institute (PSI) submits the following general comments regarding FDA's recent proposal to implement aspects of the Canadian importation provisions of Section 804 of the Food Drug & Cosmetics Act ("FD&C Act").<sup>1</sup>

PSI is a fact-finding, not-for-profit trade association created over twenty years ago by Security Directors from pharmaceutical manufacturers dedicated to protecting the public health from counterfeit and substandard medicines. PSI's core function is to facilitate the flow of high-quality information on worldwide pharmaceutical crimes, focusing on counterfeit, diverted and theft incidents, among research-based and generic pharmaceutical manufacturers. PSI utilizes the information collected to create a threat assessment which is shared with member companies for global coordination with law enforcement, drug regulators and national customs services.

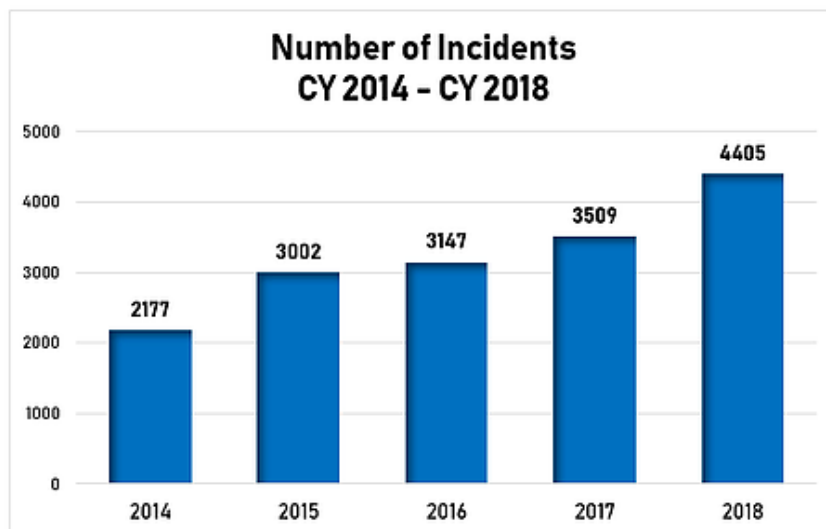
**Pharmaceutical Crime Is A Global Epidemic**

Counterfeit medicinal products are a threat to the health and safety of patients around the world. They range from drugs with no active ingredients to those with dangerous impurities. They can be copies of branded drugs, generic drugs or over-the-counter drugs.

PSI assesses counterfeit medicines to be a growing global problem which, during 2018, impacted on 145 countries including Canada and United States.

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<sup>1</sup> 21 U.S.C § 384.



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The chart shows:

- 4,405 pharmaceutical crime incidents in 2018
- A twenty-five percent increase in incidents from 2017
- The number of incidents were at an all-time in 2018
- Over the past five years, incidents increased by 102%.

### **The Existing Threats of Pharmaceutical Crimes to U.S. Consumers**

Canada and the United States were both in the top ten countries with reported incidents. In fact, the U.S. remains a top target for the criminal organizations attempting to exploit our market. In 2018, the PSI reported more incidents in the U.S. than any other country in the world. Investigations in the U.S. have disclosed significant illegal operations at the wholesale level. For example, there have been recent indictments in major diversion scheme.

On October 17, 2019, the CEOs of LLC Wholesale Supply and Wholesalers Group, along with two associates, were indicted in the Southern District of Florida on charges of money laundering, committing violations of the Federal Food, Drug, and Cosmetic Act, and mail fraud, related to their alleged participation in a scheme to sell diverted pharmaceuticals to unwitting pharmacies and consumers. According to the indictment, the main subjects are alleged to have purchased and distributed millions of dollars in diverted pharmaceuticals, which are prescription drugs illegally trafficked in a secondary or underground market. The FBI and FDA-OCI believe this case has nationwide impact.

This investigation underscores the lack of oversight resources and low threat priority given to the counterfeit medicines issue in the United States today. While the federal investigators covered a time span from 2013 to 2019, PSI intelligence could demonstrate the subjects of the inducement had been in operation since 2003.

<sup>2</sup> <https://www.psi-inc.org/incident-trends>

Law enforcement is already overburdened by pharmaceutical crimes in the United States making it an existing challenge to keep U.S. patients safe from counterfeits and substandard medicines.<sup>3</sup>

Attached: Three U.S. Department of Justice Indictments:        U.S. vs. CANADADRUG.COM LTD  
   U.S. vs. JOSHUA RYAN JOLES, ET AL  
   U.S. vs. PAUL DANIEL BOTTOMLEY

### **The Proposed Rule on Importation from Canada Will Likely Increase the Rate of Pharmaceutical Crime in the United States**

The proposed rule on importation presents a patchwork of new rules and procedures in an attempt to secure the required alternative new supply chain for imported medicines. PSI understands the motivation behind prescription drug importation. However, importing the European Union’s concept of parallel importation among its member states to the United States and Canada is not a workable solution. The European Union has a central governance and regulatory body for pharmaceuticals and this centralized regulatory oversight is critical to protecting the quality of pharmaceuticals that travel within the European Union. On the other hand, there is no central governance or regulatory body that has oversight on the supply chain of Canadian approved drugs imported into the United States.

In its 2004 Task Force Report on Prescription Drug Importation, HHS recognized the dangers of applying the European Union parallel trade model to the United States and a foreign country:

However, the laws and regulations between the U.S. and other countries are not the same, and there is no central regulatory body that has authority over the U.S. and the other country. Therefore, there is no assurance that drug safety, efficacy, purity, potency, handling, labeling, manufacturing, and storage would be the same between the U.S. and other countries, unlike the assurance that exists as there is under the parallel importation/trade system in the EU.<sup>4</sup>

HHS has also already recognized that: “...the opportunities for adulteration increase as the distribution chain and number of entities handling the product increases.”<sup>5</sup> PSI sees this play out today with parallel trade within the European Union even with the central regulatory oversight. In 2018, PSI documented three times the number of counterfeiting incidents in the European legitimate supply chain than that identified in the US system.

Former FBI Director Louis Freeh, in a 2017 comprehensive report, identified how drug importation would increase financial incentives for organized crime to transship counterfeit and substandard medicines through Canada into the U.S. His report underscored how regulators and prosecutors would be overwhelmed trying to adequately investigate the growing number of new cases.<sup>6</sup>

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<sup>3</sup> Freeh, Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement (attached)

<sup>4</sup> HHS 2004 Task Force Report on Prescription Drug Importation, p 61

<sup>5</sup> HHS 2004 Task Force Report on Prescription Drug Importation, p, 30

<sup>6</sup> Freeh, Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement (attached)

## **The Proposed Importation from Canada Will Likely Increase the Number of United States Consumers Turning to Illegal “Canadian” Online Pharmacies**

Many US consumers already turn to illegal online pharmacies to source cheaper “Canadian” versions of their medicines unknowingly putting their health at risk. Our reporting with regard to Canada demonstrates offers of “medicines from Canada” continue to proliferate the online marketplace. In 2019 the National Association of Boards of Pharmacy (NABP) reported 1,500 new websites were identified as operating illegally, furthermore, 31% (465) had offers for scheduled medicines like codeine, fentanyl, oxycodone, Valium, and Xanax. Of the 465 websites identified, 460 (99%) did not require a prescription.

The main concern of offers of “Canadian medicines” is the medicines often are not from Canada. It is PSI’s experience the vast majority of websites offering medicines without the required prescription are actually sourcing their medications from fulfillment centers in India, China and Singapore. These medicines are often counterfeit and/or diverted product. Even if a medicine is sourced from Canada, often Canadian authorities, including Canada Border Services Agency (CBSA) and Royal Canadian Mounted Police (RCMP) have taken little action regarding exports and shipments to the U.S.

Below is data supporting the existing threat to U.S. consumers from medicines imported from Canada:

- In support of the global effort coordinated by Interpol, during October 9-16, 2018, Canadian authorities examined 3586 packages - 87% were seized or denied entry because they contained counterfeit and/or unlicensed health products. Value 1.4M CD
- If same number were examined on an annual basis, they’d review 186,472 packages and 162,231 would be detained. Value would be \$72.8 M. CD.
- September 12 – 19, 2017 Canada examined 4545 packages; 86% were seized or denied entry because they contained counterfeit and/or unlicensed health products. Value 1.76 M CD.
- If the same number were examined on an annual basis, they’d review 236,340 packages and 203,252 would be detained. Value would be 91.5 M. CD.

PSI therefore sees many possible unintended consequences related to this rule change. Although the proposed Importation Rule does not allow for internet sales, PSI fears a Canadian sourced medicine rule will provide misguided legitimacy to the already existing illegal online pharmaceutical crime threat. This threat level is increased, if for some reason, the proposed rule would be expanded allowing medicines to be sourced from additional countries. Another concern, if each participating state can source Canadian medicines from other participating states, this could cause issues like those seen in the parallel trade system in the European Union.

## **The Proposed Importation from Canada Will Likely Weaken the Security of the U.S. Supply Chain**

For the reasons stated above, the importation of medicines from Canada is, at the very least, antithetical to the security and safety features intended by the fully implemented track and trace system required under the Drug Supply Chain Security Act. PSI applauds FDA’s attempts to control the supply chain for drugs imported under the proposed rule. Despite these provisions, however, and given the existing challenges with pharmaceutical crime in the United States, opening the “closed” U.S. supply chain to importation by creating a new alternative supply chain and increasing the number of entities handling the product before it reaches U.S. consumers cannot be done in a way that poses no additional risk to public health and safety. Creating additional distribution channels increases the risk of counterfeits and substandard drugs entering the legitimate U.S. supply chain. In tracking incidents of pharmaceutical

crime worldwide, PSI has learned that criminals are opportunistic and will take full advantage of a weakened supply chain. It will likely start with an increase in illegal diversion, which will lead to an increase in counterfeits reaching patients.

### **PSI Submits the Following Additional Comments in Response to FDA's Request for Specific Comments**

Should HHS decide to issue a final ruling on importation, despite the risks to public health and safety outlined above, PSI provides the following comments to FDA's requests for specific comments on topics relating to the new entities in the supply chain for imported drugs.

- *FDA seeks comments on whether a pharmacist or wholesaler should be able to be both a SIP co-sponsor and an Importer within the same SIP.* PSI does not recommend allowing this possibility as it muddles the oversight function of the SIP sponsor. That is, having a pharmacist or wholesaler be both a SIP co-sponsor and an Importer within the same SIP could create a conflict of interest and weaken the oversight proposed by the rule compromising the suboptimal supply chain that the rule sets forth.
- *FDA seeks comments on whether a SIP co-sponsor can be an entity other than a pharmacist or wholesaler such as a purchasing organization, PBMs, union health and welfare benefit plans.* PSI does not recommend permitting additional entities to play a role in this new alternative supply chain for imported drugs. It is well-understood and recognized that an increase in the number of entities within a supply chain increases the risk of counterfeits and substandard drugs penetrating that supply chain.
- *FDA seeks comments on whether it should be possible for a pharmacist or wholesaler to be a SIP Sponsor without a state, tribal, or territorial government co-sponsor, while posing no additional risk to the public health and safety.* PSI does not support this possibility given the proposed rule requires the SIP Sponsor to play a critical role in ensuring supply chain security compliance and pharmacist and wholesalers will not have adequate resources or authority to manage this oversight function effectively.
- *FDA seeks comments on what additional or alternative background information for the new entities within the new alternative supply chain should be required and whether the background information requirement should cover additional or alternative individuals or entities.* One of PSI's core functions is share information and intelligence on known entities and individuals involved in pharmaceutical crimes. So that SIP importation plans provide FDA with available and updated information relevant to potential safety concerns, PSI recommends that the rule require the Foreign Seller or the Importer to identify its principals, owners, directors, officers, facility managers or designated representatives of such manager. In addition, the Foreign Seller or the Importer should provide complete disclosure of any past civil judgments against or settlements entered into by the Foreign Seller or Importer related to liability for violations of State, Federal or Canadian laws regarding drugs or devices or the sale or distribution of drugs or devices.
- *FDA seeks comments on FDA's review of SIP proposals.* PSI recommends that the process for reviewing and approving or denying SIP Proposals should provide opportunities for public notice and comment. SIP Proposals will likely implicate many entities at all points in the pharmaceutical

supply chain. Due diligence is a normal course of business for our members before engaging in commercial relationships.

- *FDA seeks comments on 804 Pre-Import Request.* In its information sharing and intelligence function, PSI utilizes information of the type shared in Pre-Import Request and therefore recommends that each shipment require a unique Pre-Import Request.
- *FDA seeks comments on re-authorization of Section 804 Importation Programs.* Each re-authorization of a SIP program should be accompanied by a new assessment of whether the SIP program would “pose no additional risk to the public’s health and safety.” If the Foreign Seller or Importer information is updated to include information about criminal convictions or violations, disciplinary actions or civil judgments or settlements, the re-authorization request should be denied.
- *FDA seeks comments on Foreign Seller Requirements.* Many prescription drugs illegally shipped into the US are degraded, not handled or stored correctly. Because importation requires relabeling and relabeling requires an increase in entities handling the product there is an increase in risk of counterfeits or substandard drugs penetrating the supply chain. PSI recommends that Foreign Sellers are required to match the requirements of domestic manufacturers.
- *FDA seeks comments on whether the supply chain for imported drugs can include more than one Foreign Seller.* PSI agrees with the FDA and that any additional entities within a supply chain increases the risk to patients. PSI does not believe there are any safeguards that could be put in place that would enable FDA to authorize a SIP with multiple Foreign Sellers in a single supply chain in Canada.
- *FDA seeks comments on whether FDA should include exemptions from additional DSCSA requirements.* PSI believes that the proposed rule opens new pathways for counterfeit drugs to penetrate the closed U.S. supply chain and undermine security improvements under the DSCSA. PSI struggles to understand how the alternative DSCSA like requirements proposed by the rule are sufficient to claim that importation will not pose any additional risk to public health and safety. While the DSCSA is enhancing the security of the US drug supply chain, FDA cannot ignore the fact that the DSCSA is not fully implemented and US industry is already struggling to comply with the DSCSA for the requirements that are in effect today casting significant doubt as to whether US industry will be ready by the November 23, 2023 deadline for full DSCSA implementation and even more doubt as to when Foreign Sellers in Canada will have systems in place to comply with DSCSA-like requirements.
- *FDA seeks comments on the use of different NDCs for imported drugs under the same brand name.* PSI believes that different NDCs for imported drugs sharing the same brand name as FDA-approved drugs may help in accurately capturing reports on counterfeits or suspect product for the imported drug.