IACC
INTERNATIONAL ANTICOUNTERFEITING COALITION

Submission of the

International AntiCounterfeiting Coalition

to

Department of Health and Human Services

Food and Drug Administration

Comments on Proposed Rule Re:
Importation of Prescription Drugs
84 FR 70796 - 70839 (December 23, 2019)

Docket Number FDA-2019-N-5711

March 9, 2020

---

727 15th Street NW • 9th Floor • Washington, DC 20005 • USA • +1(202)223-6667 • iacc@iacc.org • www.iacc.org

March 9, 2020

Secretary Alex Azar
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Commissioner Steven M. Hahn
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Comments in Response to Proposed Rule – Importation of Prescription Drugs

Dear Secretary Azar and Commissioner Hahn:

The International AntiCounterfeiting Coalition ("IACC") appreciates the opportunity to provide these comments in response to the proposed rule relating to the importation of prescription drugs from Canada, published by the Department of Health and Human Services ("HHS") and the Food and Drug Administration ("FDA") in the Federal Register on December 23, 2019.

We wish to highlight at the outset, that the authority to permit the sort of importations contemplated under relevant provisions of the Food Drug & Cosmetic Act is conditioned upon the Secretary's certification "that the implementation of this Section will pose no additional risk to the public's health and safety, and result in a significant reduction in the cost of covered products to the American consumer." While we offer no assessment of the proposed rule's impact on the latter consideration, we wish to register our significant concerns with regard to its potential adverse impact on the health and safety of American consumers.

The trafficking of counterfeit pharmaceuticals to consumers in the United States has reached epidemic proportions in recent years, a fact readily demonstrated by U.S. Customs and Border Protection's annual IP seizure reports. In its report for Fiscal Year 2011, CBP cited seizures in the pharmaceutical sector with an MSRP of just over $25 million. That number has skyrocketed in the intervening years; the most recent figures provided by the agency, for Fiscal Year 2018, report seizures of pharmaceutical products exceeding $131 million.

Counterfeit pharmaceuticals, produced and distributed in an entirely unregulated supply chain by individuals who have every incentive to cut corners with regard to quality control, pose a clear and obvious threat to American consumers' health and safety. Counterfeit medications often contain no active pharmaceutical ingredients (APIs) at all, in turn, providing no therapeutic benefit to patients. And where they do contain APIs, they may be present in amounts far below an effective dosage, or far above a safe one. Laboratory analysis

of counterfeit drugs has also frequently identified the presence of adulterants and impurities that could pose an even greater threat to patients' well-being than the ailments for which they sought treatment in the first place.

While the proposal seeks to minimize the potential harms to consumers by limiting imports to approved Section 804 Importation Programs ("SIPs"), we believe this approach could open the door to serious consequences. Canada's population is dwarfed by that of the United States, and the ability of the Canadian pharmaceutical system to meet the increased demand for drugs arising from U.S. consumers is highly suspect. For the sake of illustration, we note that Canadian manufacturers and distributors would be required to double their existing capacity in order continue supplying their own domestic consumers while servicing a mere 10% of the U.S. market. We're aware of no credible data to support the belief that the Canadian system is prepared to handle the increased demand that might result from U.S. importation programs.

We have seen all too often however, that where a demand exists, black market producers will gladly step in to ensure that a supply is available to fill it. Counterfeiters will undoubtedly step up their efforts to infiltrate both the Canadian and U.S. pharmaceutical supply chains. And while U.S. Customs and Border Protection's resources are already strained as a result of the escalating volume of illicit imports in recent years, relying upon Canadian authorities' help to effectively combat counterfeiters would be unwise. Canada has consistently appeared on USTR's annual Special 301 Report, in part due to the country's record of "poor enforcement with respect to counterfeit or pirated goods at the border and within [the domestic market]."

Though the proposed rule purports to limit drug importations to approved SIPs, we fear it is also likely to deliver a confusing message to American consumers regarding the safety of "Canadian" pharmaceuticals. As acknowledged in the agencies' Federal Register Notice, unlicensed rogue pharmacies often purport to be based in Canada. Their websites are frequently adorned with Canadian flags and similar indicia in an effort to dupe unwitting consumers into believing that their cheap counterfeits were sourced through a safe and well-regulated supply chain. It's often said that a little bit of knowledge can be a dangerous thing; and American consumers' vague awareness that drugs may be legally imported from Canada (under certain circumstances, by certain parties) will undoubtedly lead many to seek out the dangerous products marketed by bad actors claiming to operate out of Canada.

The Department of Health and Human Services and the Food and Drug Administration should adopt the approach that has historically served as a guide for physicians – "First, do no harm." The safety of American consumers should not be sacrificed in exchange for some uncertain and speculative decrease in prescription drug prices. Accordingly, we recommend that you withdraw the current proposal.

Respectfully submitted,

Travis D. Johnson
Vice President - Legislative Affairs, Senior Counsel

About the IACC

The IACC is the world's oldest and largest organization dedicated exclusively to combating trademark counterfeiting and copyright piracy. Founded in 1979, and based in Washington, D.C., the IACC represents approximately 250 corporations, trade associations, and professional firms, spanning a broad cross-section of industries. IACC members include many of the world's best-known brands in the apparel, automotive, electronics, entertainment, luxury goods, pharmaceutical, software, and other consumer product sectors. Central to the IACC's mission is the education of both the general public and policy makers regarding the severity and scope of the harms caused by intellectual property crimes – not only to legitimate manufacturers and retailers, but also to consumers and governments worldwide. The IACC seeks to address these threats by promoting the adoption of legislative and regulatory regimes to effectively protect intellectual property rights, and to encourage the application of resources sufficient to implement and enforce those regimes.