

Comments on Notice of Proposed Rulemaking titled "Importation of Prescription Drugs," Docket No. FDA-2019-N-5711

We are responding to the FDA's proposed amendment to its regulations to implement section 804(b) through (h) of the FD&C Act (21 U.S.C. 384(b) through (h)) to allow importation of certain prescription drugs shipped from Canada. While the stated purpose of the proposed rule is to lower prices and reduce out of pocket costs for American patients, the proposed rule will fail to achieve these outcomes, and will in fact create several unintended consequences that we believe render the proposal unworkable and potentially unsafe for American patients. There are four main reasons why this proposal cannot work.

#1. Canada Lacks Sufficient Drug Supply for the U.S. Population

Canada simply does not have the drug supply or capacity to service the American market. Canada does not manufacture most of the medicines needed by Canadian patients and produces less than ten percent of the active ingredients. Canada is allocated certain quantities of pharmaceuticals, based on estimated national requirements, by manufacturers with global supply chains. Canada's hospital and community pharmacies and supply chains are therefore resourced to serve the Canadian public only. They are not equipped to respond to the needs of another country without creating significant access or quality issues for Canadians. Canada's population is only 38 million compared to 331 million in the United States.

Canadian patients already face persistent drug shortages for a large number of drugs for complex reasons. As of this writing, there are over 2000 drug shortages reported on Canada's drug shortage list.¹ Any attempt to divert bulk or wholesale drugs from Canada to the U.S. will exacerbate Canada's existing drug shortage challenges, doing harm to Canadians. Currently, droves of U.S. patients are crossing to Canada to access medicines in border communities. As a result, pharmacists are being placed in an ethical dilemma, where they must decide between protecting the domestic drug supply for Canadian patients and meeting their professional duty to serve patients in need of life-saving medicines. Put simply, Canada's health system cannot withstand further external pressures on our drug supply.

#2. Canadian Wholesalers Have No Interest in Partnering under Section 804 Importation Programs (SIPs)

Second, the proposed rule requires Canadian drug wholesalers to partner with U.S. Section 804 Importation Programs (SIPs). Canadian wholesalers have made it abundantly clear that they have no interest in partnering with SIPs for the export of drugs to the U.S.² Agreements between manufacturers and wholesalers/distributors prevent the export of products made for the Canadian market, creating a commercial risk and deterrent to exporting. In addition to these legal and contractual barriers, Canadian wholesalers cite the significant threat to the integrity of Canada's drug supply chain driven by greater drug shortages as another core reason they do not see importation of drugs from Canada as a viable solution to U.S. drug prices

¹ <https://www.drugshortagescanada.ca/rws-search?perform=1>

² <https://www.reuters.com/article/us-usa-healthcare-canada/canadian-drug-distributors-say-no-to-trump-import-plan-idUSKBN1YO24O>

We strongly discourage the U.S. FDA from modifying eligibility requirements to allow Canadian entities outside the licensed wholesaler network to participate as SIPs partners. Allowing alternative suppliers such as pharmacies would shift regulatory oversight from federal to provincial authorities, making it more challenging to monitor and respond to non-compliant behaviour. Furthermore, opening the door to additional sources of Canadian supply could worsen drug shortages in Canada.

#3. We Share FDA's Concerns About Illegal Online Sellers of Prescription Medicines

Third, while we are pleased the FDA has clearly indicated personal importation through online sources is not permitted, we are nonetheless concerned with the proliferation of illegal sites misrepresenting themselves as licensed Canadian pharmacies and exacerbating a situation that is already dangerous and threatening patient safety on both sides of the border.

The U.S. National Association of Boards of Pharmacy currently estimates that roughly 35,000 active online drug sellers are operating, 95% of which are out of compliance with pharmacy practice standards or applicable laws³. Canadian law enforcement cannot protect patients from illegal foreign actors who blatantly disregard Canadian and/or U.S. laws, and operate anonymously or hide offshore while pretending to be Canadian in many cases.

In the case involving CanadaDrugs.com, a rogue site profiled in the FDA's proposed rule, an indictment and ultimate closure of the site only resulted after more than five years of international collaboration between Canadian and U.S. authorities. We therefore encourage the FDA, HHS, Department of Homeland Security and Canadian authorities to remain vigilant and work together to shut down illegal online sellers, recognizing that any effort to encourage more importation of Canadian drugs to the U.S. is likely to increase the dangers posed by these illegal, predatory sites.

#4. As Canadians, We Will Demand Our Government Take Active Measures to Protect Our Drug Supply

Finally, the FDA's proposed amendment to allow importation of drugs in bulk from Canada will not work because Canada's government cannot be expected to allow the safety and security of its prescription medication supply chain to be undermined. We only need to look to the past to understand how scenarios will unfold.

In the early 2000s, the high cost of prescription drugs was a priority issue in the United States. Politicians looked north of the border, promising to import quantities of "cheap" pharmaceuticals from Canada. In response, the Canadian government prepared legislation to explicitly block the export of prescription drugs to the United States. A copy of the proposed legislation is attached to our submission.

This Canadian legislation never passed because the message was loud and clear: Canada's drug supply is not available for U.S. consumers and plans to import medicines from Canada will not succeed in providing lower cost medications for Americans. In 2020, with this issue back on the U.S. agenda, as Canadians we will demand that our government prepare the levers necessary to protect our country's drug supply and access to vital medications.

³ <https://safe.pharmacy/buy-safely/>

In summary, the proposed rule will not work. The rule will not result in lower drug prices for American citizens because Canadian wholesalers are unable to participate and cannot in good conscience take medications out of the hands of Canadian patients.

If the category of eligibility is expanded to include “suppliers” outside of traditional Canadian regulated wholesalers, we fear this will make oversight more challenging, and further exacerbate drug shortages in communities across Canada. Opening the door to additional suppliers could also support the proliferation of illegal online sellers, which will further endanger the U.S. public. Finally, if the U.S. proceeds this unworkable plan to create drug shortages across Canada, as Canadians we will demand our government intervene to protect the health of Canadians by blocking the bulk export of Canadian medicines.

Thank you for the opportunity to share our concerns regarding the proposed rule to import medicines from Canada.

Sincerely,

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Best Medicines Coalition
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