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

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. The stated purpose of the proposed rule is to lower prices and reduce out of pocket costs for American patients. In our submission, the proposed rule will not only fail to achieve these outcomes but will also create unintended consequences that we have concluded render the proposal unworkable and therefore will not be beneficial to American patients. In fact it merely delays solving the underlying problem that is at the heart of the issue for American patients. There are four main reasons why this proposal is not feasible.

#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 – let alone one with a population 10 times its size – without creating significant access or quality issues for Canadians.

There is a mistaken impression that manufacturers will merely increase the supply if drugs manufactured or imported into Canada at the request of Canadian customers. This is absolutely incorrect. Once the supply allocated to Canada has been exhausted drug shortages occur.

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. Exacerbating the problem, droves of U.S. patients currently enter 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 who present in their pharmacies in need of life-saving medicines. Put simply, Canada's health system cannot withstand further external pressures on our drug supply. To help illustrate our argument, we have enclosed a series of stories featuring individual Canadians and the challenges that drug shortages pose to their daily lives.

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

#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). This will also be unworkable since Canadian wholesalers also recognize the significant threat to the integrity of Canada's drug supply chain driven by greater drug shortages. They have expressed strongly that they do not intend to add to this problem for patients in Canada.

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

Third, we laud the FDA for prohibiting personal importation through online pharmacies to protect U.S. patients, since unfortunately illegal sites do exist, thereby threatening patient safety on both sides of the border. History has shown that we must all be vigilant about these nefarious practices.

.#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 the potential consequences if we do not act.

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 but 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 governments prepare the levers necessary to protect our country's drug supply and access to medications.

In summary, the proposed rule is impractical and unworkable, a stop gap measure at best that could never achieve the goals it is attempting to achieve or solve the underlying problem of U.S. access to affordable drugs. Canada simply cannot supply the American drug market in any meaningful or sustainable way. Canadians will resist attempts to redirect our precious and already very limited supply of drugs allocated by manufacturers for the Canadian market. 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 with the proposed rule.

Sincerely,



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