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March 09, 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

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

The Canadian Pharmacists Association (CPhA) appreciates the opportunity to respond 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. As the national voice of Canada's 43,000 pharmacists, we are committed to pharmacy practice excellence and optimal health outcomes for patients through safe and effective drug therapy. As such, we are strongly opposed to the proposed rule to allow for the U.S. importation of drugs from Canada as it will negatively impact patient safety and outcomes on both sides of the border.

Canada's limited and unstable drug supply

The Canadian drug supply is designed to meet the demands of a population of 36 million, and it is allocated set quantities of pharmaceuticals based on historical estimated national requirements by global manufacturers. The combined populations of the states of Florida, Colorado and Vermont alone make up close to the entire population of Canada. Should the proposed rule be passed, the number of drugs that could enter the U.S. from the Canadian market through Section 804 Implementation Programs (SIPs) would be wholly insufficient to meet the needs of the U.S. population. The diversion of the Canadian drug supply would also be devastating to the Canadian patient population reliant on these products; the effects of which would aggravate drug shortages and increase drug costs.

Canada has been struggling with drug shortages, recalls and discontinuations for many years, and experts believe that low drug prices, especially for generic drugs, are an important causal factor of these supply issues.^{1,2} With close to

¹ U.S. Food and Drug Administration. Drug Shortages: Root Causes and Potential Solutions. 2019.

<https://www.fda.gov/media/131130/download>

² Duffin, J. Do practice guidelines cause drug shortages? The historical example of β -blockers. *CMAJ* 2019 September 16;191:E1029-31. doi: 10.1503/cmaj.190289



2,000 drugs currently listed on the national drug shortage database and an average of five new shortages reported every day, pharmacists are devoting considerable time and resources to help their patients access the medications they need. A recent poll by Angus Reid found that 40% of Canadian households have had difficulty obtaining prescribed medications because of supply issues.³ Findings from a CPhA survey found that in 2018, 67% of pharmacists dealt with shortages daily or multiple times a day.⁴ With a U.S. population nine times the size of the Canadian population, we are deeply concerned that SIPs will only exacerbate the problem of drug shortages in Canada.

Canadian wholesaler/distributor participation

Canadian licensed wholesalers and suppliers share our concerns about Canada's drug supply issues. Through the Canadian Association for Pharmacy Distribution Management and other industry groups, Canada's wholesalers have made it clear that they will not participate in the FDA's Importation Program and put the Canadian drug supply at risk. Further, Canadian distributors are bound by supply agreements with international drug manufacturers that prohibit them from reselling a drug product outside of Canada that is intended for the Canadian market, thus making the proposal highly impractical.

The lack of support from wholesalers and their contractual obligations are clear signals that the importation rule will not achieve its aim of bringing lower cost drugs to the American market. However, there are considerable risks to consider should the FDA attempt to relax the rule to allow unlicensed suppliers from Canada to export drugs to the U.S. Such a move would risk opening up the supply chain to products that have not been approved or authorized for sale by Health Canada as well as counterfeit and potentially substandard medications by unscrupulous suppliers who are operating outside of the legitimate supply chain and not regulated by Canadian authorities.

Illegal online sale of drugs

While the FDA's drug importation plan does not include personal importation, we are concerned that its implementation will result in the expansion of illegal sales of unapproved, substandard or counterfeit drugs from online dealers claiming to be legitimate Canadian online pharmacies.

According to the National Association of Boards of Pharmacy, up to 96% of "pharmacies" operating online are illegal and unsafe.⁵ While there are legitimate online Canadian pharmacies that are regulated by Health Canada, any drug

³ Angus Reid Institute. As Trump calls for prescription drug imports from Canada, most north of the 49th call that bad medicine. Oct 2019.

<http://angusreid.org/cross-border-pharma/>

⁴ Canadian Pharmacists Association. CPhA Drug shortages and recalls survey 2018. <https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/CPhADrugShortagesandRecallsSurvey2018.pdf>

⁵ National Association of Boards of Pharmacy. Letter to United States Congress Stating Position on Canadian Online Pharmacies Dispensing to US Patients. Feb 2017. <https://nabp.pharmacy/wp-content/uploads/2016/07/Letter-to-Congress-re-Canadian-Online-Pharmacies-2-10-17-final.pdf>



shipped from a Canadian online pharmacy to the U.S. is not subject to the regulatory authority of Health Canada or the FDA.⁶ Most online “pharmacies” claiming to be based in Canada are in fact criminal networks, promising Americans low-cost Canadian drugs. Quite often, these drugs are actually fake and originate from foreign countries outside Canada. These products pose a real danger to patients as they look legitimate but often contain little or no real medication and are instead filled with dangerous materials such as poison and heavy metals.^{7,8,9}

We fear that wholesale drug importation will result in a proliferation of illegal online drug sellers whose products will pose a significant threat to the health and safety of U.S. citizens. Drug importation will enable organizations to take further advantage of Americans who may not know that personal drug importation is not covered by the rule or who have not benefited from lower cost medications because of the unwillingness of manufacturers and Canadian wholesalers to participate in the program.

Illegal online drug sellers are extremely difficult to detect and control because of their sophistication and the large number in operation.¹⁰ By rejecting the FDA’s drug importation plan, the U.S. government can prevent policies that will create a more favourable environment for these illegal networks to thrive and prey on Americans.

No impact on drug costs and supply chain risks

The FDA’s proposed drug importation rule requires SIP sponsors to demonstrate that drugs being imported pose no additional risk to public safety and that it will result in significant cost savings for Americans. We believe the proposed rule will fail on both counts.

We have already pointed to the lack of support from manufacturers and Canadian distributors to participate in SIPs and the likely rise in online drug sellers should the rule be passed. Other challenges and risks to the drug supply include the proposed rule’s failure to comply with the track and trace system outlined in the Drug Supply Chain Security Act (DSCSA). While we are confident in the safety and security of the Canadian drug supply chain for drug distribution within Canada, our country does not have a compatible system to ensure that drugs entering the U.S. are compliant with the DSCSA. This will expose the cross-border drug supply chain to vulnerabilities.

⁶ Consumer Reports. How do I know if an online pharmacy is legitimate? Oct 2011. <https://www.consumerreports.org/cro/news/2011/10/save-money-by-ordering-drugs-from-canada-not-so-fast/index.htm>

⁷ National Association of Boards of Pharmacy. Buy Safely. 2020. <https://safe.pharmacy/buy-safely/>

⁸ The Partnership for Safe Medicines. Counterfeit Drugs in America: Crimes, Victims and Solutions. Fact Pack, 2nd edition. 2017. https://www.safemedicines.org/wp-content/uploads/PSM_FP2_footnotes_secure-1.pdf

⁹ Alliance for Safe Online Pharmacies. FAQs on Canadian Internet Pharmacies Selling To U.S. Residents. 2020. <https://buysaferx.pharmacy/public-awareness-campaigns/drug-importation/faqs/>

¹⁰ Guerra C., Mackey, T.K. USA Criminal and Civil Prosecutions Associated with Illicit Online Pharmacies: Legal Analysis and Global Implications. *Medicine Access @ Point of Care*. Jan 2017, doi:10.5301/maapoc.0000020.



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In fact, the proposed rule calls for many touchpoints for any given drug on its journey to American patients, from the foreign seller to the importer to the laboratory and repackager. Each of these touchpoints represents an opportunity for bad actors to access and manipulate the drug supply en route to the U.S. Even if the supply remains uncompromised, each touchpoint is also an added cost, and these costs will likely cancel out any savings that could potentially be achieved by importing lower cost drugs from Canada.

Conclusion

CPhA is part of an alliance of Canadian health and drug safety organizations who are vehemently opposed to U.S. drug importation from Canada. Drug manufacturers, Canadian wholesalers and the Canadian government have also stated that they are opposed to U.S. drug importation and will prioritize the safety and security of Canada's supply chain. Without the support and participation of these key stakeholders, U.S. drug importation from Canada will simply not work.

We have also outlined how SIPs, if implemented, will exacerbate drug shortages in Canada and undermine the security of the drug supply to U.S. citizens. These effects will not only lead to patient harms and higher drug prices for both Canadians and Americans but they will also result in Americans receiving substandard or counterfeit drugs either through online sellers or through the importation program itself.

Health organizations, patient groups and citizens across Canada have been vocal in their opposition to U.S. importation plans. Together we will ensure that the Canadian government enacts the policies needed to protect our fragile drug supply from diversion.

Thank you for considering our comments on the FDA's proposed rule to allow for the importation of prescription drugs from Canada.

Sincerely,

Glen Doucet
Chief Executive Officer