



March 2, 2020

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

The Canadian Society of Hospital Pharmacists (CSHP) represents pharmacy professionals working in hospitals and other collaborative healthcare settings who seek excellence in patient care through the advancement of safe and effective medication use. CSHP has 3,200 members and supporters representing pharmacists, pharmacy technicians, hospital pharmacy residents, students and industry representatives. Established in 1948, CSHP conducts national advocacy with the federal government, education, information sharing, promotion of best practices, conferences, facilitation of research, and recognition of excellence. The Society publishes the Canadian Journal of Hospital Pharmacy, conducts the Hospital Pharmacy in Canada Survey, and accredits pharmacy residency programs across Canada.

We have a longstanding relationship with ASHP (American Society of Health-System Pharmacists) and work alongside them to advance hospital pharmacy practice and share best practices within North America. Like them, CSHP is opposed 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 from Canada.

CSHP acknowledges the stated purpose of the proposed rule to lower prices and reduce out of pocket costs for American patients and empathize with the hardship these realities cause for Americans. However, the proposed rule will not achieve these outcomes, and will in fact create several unintended consequences for both our countries.

Allowing the importation of drugs from Canada into the United States is a simplistic and unworkable solution to what is a complex global system involving multiple regulatory systems within and across countries, active ingredient sourcing, manufacturing systems, industry consolidation, business decisions, globalized supply chain management, the rise of generic drugs and consolidated purchasing models, among many others. The proposed rule does not address the root cause of American domestic concerns and will likely result in increased drug shortages in Canada.

The Canadian medicine supply is not sufficient to support both Canadian and U.S. consumers. Canada is allocated certain quantities of pharmaceuticals, based on estimated national requirements, by manufacturers with global supply chains. The Canadian industry, health system, and governments do not have the capacity to address the increased demand that would come from a direct supply relationship between Canada and U.S. states. The supply simply does not and will not exist within Canada to meet the demand of a market that is ten times the size of our own.

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This is especially true given the rise in drug shortages in Canada in the past several years. Canada's pharmaceutical supply system is designed and carefully managed to serve its population of approximately 36 million and is subject to national price negotiation and regulation. A recent report published by C.D. Howe Institute found 250 drug shortages per month in 2017 and routine shortages of 700 to 1000 medicines at any given time.

Our members working in hospitals and collaborative healthcare settings across the country tell us that the administrative and human resource burden of shortages has direct consequences on patient outcomes. Instead of doing clinical work with patients, pharmacists spent inordinate amounts of time sourcing scarce drugs from neighbouring facilities or alternate suppliers, determining appropriate therapeutic substitutes, repackaging for correct dosages, counselling patients on shortages and communicating with other healthcare team professionals.

Should the U.S. proceed with any initiatives to import drugs from Canada, Canadian supply will quickly be at risk of significant depletion and the ability of Canadian patients to access needed medication will decline even further. CSHP is concerned that uncertainty already surrounding drug shortages will heighten and result in additional stockpiling by institutions, difficult ethical decisions on medicine allotment, sub-optimal reactions to substitute drugs, and anxiety among patients about possible scarcity of their medications.

For these reasons, we are deeply concerned by the implications of any U.S. federal rule and state plans that would allow for the draining of Canada's medicine supply to the United States. Along with other national healthcare organizations, CSHP has requested that Health Canada intervene as necessary to ensure continuity in the Canadian drug supply; exercise to the fullest extent possible existing laws and regulations in place to protect the Canadian drug supply from leaving our borders, and to identify measures that can be taken to address any current gaps in Canadian statute should importation legislation be adopted. Thanks to a survey conducted by the Canadian Pharmacists Association showing two-third support of Canadians polled for government intervention to limit or stop the US from importing prescription medicines from Canada, we are confident that action will be taken at the federal level.

Thank you for the opportunity to share our concerns with the proposed rule.

Sincerely,

A handwritten signature in black ink, appearing to be 'T. Mysak', with a horizontal line extending to the right.

Tania Mysak, BSP, PharmD  
President, CSHP