ALABAMA PHARMACY
ASSOCIATION
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February 28, 2020

[Submitted electronically via https://www.regulations.gov]

Stephen M. Hahn, MD
Commissioner
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Importation of Prescription Drugs Proposed Rule, Docket No. FDA–2019–N–5711

Dear Commissioner Hahn:

We write today to express our opposition to the proposed draft regulations to import Canadian medication into the United States. Our concerns are not with the legitimate Canadian drug supply, but with:

- the unworkability of the proposal given the obvious size difference between Canada and U.S. populations, the current Canadian drug shortage problem, and the stated non-cooperation from Canadian stakeholders;
- the unlikelihood it will save money for American patients because of the enormous cost and the lack of clear commitments to cost savings;
- the unacceptable risks of relaxing Track and Trace standards; and
- the history of and prevalence of counterfeits previously trafficked by Canadian operators and the difficulty of handing over our safety to uncooperative foreign entities.

Additionally, we are very concerned that the program as designed contemplates the inclusion of Pharmacy Benefit Managers (PBMs) in the importation supply chain. PBMs are not currently acting in the best interest of patients and are unfairly gaming the system and bankrupting pharmacies.

We believe that health care costs, of which pharmaceutical costs are a part, are a prime concern for Americans at nearly all income levels, even those with what many consider good insurance. However, implementing this policy is unlikely to bring down prices for most Americans, and very likely to create dangerous loopholes in the U.S. closed secure drug supply chain.

There are a number of ways these can be addressed that don't require taking risks with the safety of the American drug supply, including:

- Reforming the role PBMs play in the supply chain: In West Virginia when PBMs were removed from the state's Medicaid program they saved $52mm the very first year the program was in operation.

- Provide transparency for patients to help them better understand their costs.
- Resource the FDA to allow them most efficiently review generics for small molecule drugs and biosimilars for biologics. Generics and biosimilars provide competition in the marketplace that will bring down prices.

The following issues with the current proposal cause us to be greatly concerned that in the best scenario, no medicine will be imported in any quantity that brings down prices for Americans.

In the worst-case scenario, it will create a demand for Canadian medicines at a price point that doesn't exist that will give rise to a black market of counterfeits.

This proposal is unworkable because of the U.S.- Canadian population difference, existing Canadian shortages, and non-cooperation of Canadian stakeholders.

Given the facts that Canada manufactures very little of its own medicine and therefore does not control its own drug supply, the current alarming state of Canada's existing drug shortage problem, and the stated opposition to Canadian drug importation by the Canadian government, patient advocates, and healthcare professionals across all disciplines, it seems entirely unlikely that an American program of Canadian wholesale drug importation could ever be implemented.

A program that has so many impediments is not going to bring down prices for American patients.

The unlikelihood a program will save money for American patients and the enormous costs means patient safety will be and is currently being compromised to make importation work.

Four previous FDA commissioners appointed by both Republican and Democratic administrations have said that it is unlikely that one could save money by importing medicine from another country's drug supply. The level of additional screening and chemical testing, the additional vetting of vendors, and the costs of additional repackaging and relabeling all incur costs that make Canadian drug importation less profitable than proponents suggest.

Additionally, we note that all biologics including insulin are not allowed to be imported under this program, meaning there are many American patients who will not be helped by this program.

The law the regulation is based upon[1] requires that importation be done if and only if it "result[s] in a significant reduction in the cost of covered products to the American consumer". However, the draft guidelines completely ignore this requirement, saying that HHS is "unable to estimate … the savings to U.S. consumers who may participate in such programs."

This requirement to document cost savings for importation is part of long-standing federal law, and this draft regulation has failed to address it. For this reason alone, this draft regulation is insufficient to be considered and should be withdrawn.

Relaxing standards for supply chain safety is not an acceptable tradeoff for lower prices.

Today the Drug Supply Chain Security Act (DSCSA) requires traceability from the manufacturing floor through the pharmacy shelf.

The original federal law this draft regulation is implementing requires that this program only be enacted if the Secretary certifies that it will "pose no additional risk to the public's health and safety." Because

[1] 2003 Medicare Modernization Act

Canada has no Track and Trace system, the proposed regulations will involve a federal waiver for DSCSA requirements for medicines imported from Canada.

We think it is self-evident that if you have to give a waiver for compliance with Track and Trace, we have sacrificed safety and safety should never be traded off for cost.

The history of and prevalence of counterfeits previously trafficked by Canadian operators even those with wholesale licenses, the difficulty of regulating foreign entities by state boards of pharmacy, and the lack of a Canadian Track and Trace system.

The proposed regulations suggest that the possession of a Canadian-issued wholesale license is a sufficient proxy for American patient safety. America should not outsource the protection of its citizens to a foreign regulator that has not agreed to undertake this burden, has refused to cooperate with this program, and owes no allegiance to American patients.

There has already been one very serious safety breach in America of a Canadian wholesaler trafficking in counterfeit cancer drugs to American clinics. The lack of jail time in that case and the impossibility of extradition of the criminals from Canada demonstrates our concern that Americans cannot be protected.

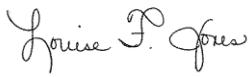
State importation programs previously attempted in Illinois, Minnesota, and Maine all struggled to extend their regulatory authority to Canadian participants.

There is no state board of pharmacy we know of that operates with enough resources to conduct all the inspections they feel are warranted, and in all cases they accept reciprocal inspections from other states not because they want to, but because they have to. US state boards of pharmacy are not resourced or legally empowered to inspect pharmacies or wholesalers in foreign countries. It is even more dangerous to American patients to expect uncooperative foreign regulators to conduct inspections on our behalf.

We agree with you that addressing health care costs is a critical and priority issue for every American right now. This program seems very unlikely to bring down drug prices for Americans and very likely to create safety issues.

Pharmacists live and work on the front lines of health care affordability. We urge you to pursue solutions that will work without sacrificing safety.

Sincerely,



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