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Dr. Steven Hahn, Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
White Oak, MD

Re: Docket FDA2019-N-5711

On behalf of the New Jersey Pharmacists Association (NJPhA), I submit the following comments to express my concern about the proposed draft regulations to import Canadian medication into the United States. At issue is not the *legitimate* Canadian drug supply, but with:

- the population size difference between Canada and the U.S., the current Canadian drug shortage problem, and the stated non-cooperation from Canadian stakeholders;
  - Given the fact that Canada manufactures very little of its own medicine and therefore does not control its drug supply, the current state of Canada's existing drug shortage problem, and the importation opposition expressed by the Canadian government, patient advocates, and others raises real feasibility concerns.
- the unlikelihood that cost savings for American patients will be realized given the lack of clear commitments to cost savings;
  - Four previous FDA commissioners (both Republican and Democratic administration appointees) 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 will make Canadian drug importation less profitable than proponents suggest.
  - A requirement to document cost savings from 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 For this reason alone, this draft regulation is insufficient to be considered and should be withdrawn.
- the risks related to relaxing Track and Trace standards; the original federal law this draft regulation implements requires that a program *only* be enacted if the Secretary certifies that it will "pose no additional risk to the public's health and safety." Because Canada has no Track and Trace system, the proposed

regulations will involve a federal waiver for DSCSA requirements for medicines imported from Canada. Inherently, waivers relax requirements and, in this case, it will jeopardize safety through the process. Clearly, safety should not be sacrificed for cost savings, especially purported savings that can't be documented.

- the history of and prevalence of counterfeits previously trafficked by Canadian operators.
  - The proposed regulations suggest that the possession of a Canadian-issued wholesale license sufficiently safeguards American patients through a foreign regulator that has not agreed to undertake this burden, has refused to cooperate with this program, and owes no allegiance to *our* patients.

    A very serious safety breach occurred when a Canadian wholesaler, trafficking in counterfeit cancer drugs, distributed them to American clinics. Jail time was not imposed in the case, and the impossible Canadian extradition processes should heighten patient safety concerns among all U.S. officials.
- the imprudence of transferring safety to difficult foreign entities.
  - It is ludicrous to expect uncooperative foreign regulators to conduct inspections on our behalf.

Additionally, a program that contemplates the inclusion of Pharmacy Benefit Managers (PBMs) in the importation supply chain, is unwise. Multiple state and federal legislative proposals to regulate these entities, and frequent stories across news media platforms should be enough to give pause to such a consideration. The American public can attest to the uncertainty PBMs impose on the health care system in this country.

We believe that health care costs, to which the cost of drugs contribute, are a prime concern for Americans at nearly all income levels, even those with what many consider *good insurance*. However, implementing this proposal 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 that will give rise to a black market of counterfeits.

The following points can address cost containment concerns without 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 first year the program was in operation.
- Provide transparency for patients to help them understand their costs.
- Encourage expedited reviews of small molecule drugs and biosimilars that would provide competition in the marketplace and bring down prices.

NJPhA agrees wholeheartedly that addressing health care costs is critical and a priority issue for every American. The proposal, however, is ill-conceived, and will likely compromise the safety of medication in American to the detriment of patient health and treatment. Please reconsider the enactment of this proposal.

Sincerely,

Elise M.Barry, MS, CFRE
Chief Executive Officer