HINJ
HealthCare Institute of New Jersey
ADVANCING GLOBAL HEALTH • LEADING NEW JERSEY'S ECONOMY

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March 4, 2020

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Proposed Rule: Importation of Prescription Drugs
Docket No. FDA-2019-N-5711

Dear Sir or Madam:

The HealthCare Institute of New Jersey (HINJ) submits these comments in response to the above-referenced Proposed Rule issued by the Food and Drug Administration (FDA) on December 23, 2019, regarding the importation of prescription drugs from Canada.

HINJ is a trade association that represents the research-based biopharmaceutical and medical technology community in New Jersey. We are committed to advocating for an innovation environment – both in New Jersey and nationally – that allows life sciences companies to research and bring to market the next generation of medicines, medical devices and technologies that advance global health, treatments and cures for the world's patient community, and pursuing measures to ensure that patients have access to those medicines, medical devices and technologies.

On behalf of HINJ's member companies, we strongly oppose the Proposed Rule regarding importation of prescription drugs from Canada. The perceived potential benefits of such an approach continue to be far outweighed by the many significant risks it presents. As numerous commentators have noted, there are many reasons summarized below reinforcing why this has not been permitted to date, and should not start now; if anything, those reasons are even more powerful today.

- Even if this plan were deemed feasible, it is noteworthy that Canadian stakeholders (distributors, patient and healthcare advocates) and the Canadian federal government oppose it. The Canadian market, which is only one-ninth the size of the U.S., is far too small to support its own citizenry as well as the U.S., and the Canadian market itself is reportedly suffering drug shortages.
- Any anticipated savings would be offset by the high costs associated with testing requirements for imported medicines.

- Past importation experiments by several states (Illinois and Minnesota) have exposed the risks associated with such programs in terms of oversight of the Canadian sources of the medicines. This situation would be compounded by the inadequacy of available resources to enable U.S. regulators to evaluate the legitimacy of imported medicines.
- Importation would create major public safety concerns and counteract advances in the efforts of American law enforcement authorities and life sciences companies to strengthen our supply chain. Of paramount importance are the well-known – and real – risks associated with counterfeit medicines that can harm or kill patients, whose welfare is our highest priority. Importation would only increase these risks, particularly given the resource limitations of regulators described above. There have been reported instances where even licensed Canadian drug sellers have sold counterfeit medicines to Americans.

We all share the goal of lowering Americans' health care costs; however, in our view, there are more pragmatic proposals to achieve this that are worthy of close consideration in lieu of a high-risk, low-reward approach of importing medicines from Canada. They include:

- Ensuring that pharmacy benefit managers (PBMs) pass on savings directly to patients.
- Capping patient out-of-pocket costs.
- Encouraging a value-based payment model.
- Causing other countries to pay their fair share of the enormous costs of R&D and associated clinical trials.
- Taking a serious look at the need for a comprehensive benefit plan redesign that more accurately reflects the realities of our modernized health care system.

The foregoing reasons compellingly demonstrate why the importation of prescription drugs from Canada into the U.S. continues to lack any rational basis. Accordingly, we urge that this Proposed Rule not be adopted.

Thank you for the opportunity to share our concerns and for your consideration of our comments.

Respectfully,

Dean J. Paranicas
President and Chief Executive Officer