March 6, 2020

[Submitted electronically to www.regulations.gov]

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

RE: DOCKET NO. FDA-2019-N-5711, "Importation of Prescription Drugs"

Dear Commissioner Hahn:

Thank you for the opportunity to provide comments on the Food and Drug Administration's proposed rule on the wholesale importation of prescription drugs. The National Alliance of State Pharmacy Associations (NASPA) believes the proposed drug importation program introduces unnecessary risks to patient safety and is unlikely to result in a significant reduction in the cost of prescription drugs to the American consumer. We are writing to express our opposition to the proposed rule and to request that the proposed rule not be finalized.

NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

Risk to Patient Safety

The proposed program bypasses important drug supply chain protections that were created to ensure that the drugs we provide to patients are safe. It creates drug supply chain gaps and vulnerabilities where counterfeits and other unsafe drugs could be introduced. This program would undermine the Drug Supply Chain Security Act (DSCSA), which ensures a closed supply chain to track and trace prescription drugs as they move from manufacturer to distributor to pharmacist. These same safeguards do not exist in Canada. FDA's proposed rule creates a patchwork of interim supply chain measures that introduce gaps and loopholes in the supply chain as drugs are distributed from Canada into the United States. Pharmacies have invested time and money to put DSCSA systems in place, and the proposed rule creates a disincentive for further investment and compliance, especially for those pharmacies who are already financially constrained.

Lack of Actual Cost Savings

High drug costs are a significant problem for American consumers, but FDA's proposed importation program is not a workable solution to lowering drug costs. Most of the highest-cost drugs for American consumers are carved out of the program, such as insulin and other biologics. For the drugs that are included in the proposed program, the additional costs associated with relabeling, testing, complying with the DSCSA workaround, and developing recall and adverse event reporting systems for the imported drugs would outweigh any cost savings realized from purchasing the drugs from Canadian

rather than U.S.-based sellers or distributors. In addition, the vast population difference between the United States and Canada, Canada's existing struggle with drug shortages, and the stated opposition by the Canadian government and other Canadian entities needed to implement such a program all point to Canadian drug importation being an unworkable solution to high drug costs in the United States.

In conclusion, NASPA urges you not to finalize the proposed rule on importation of prescription drugs. The risk to patient safety, combined with the lack of cost savings, makes this proposal an unworkable solution for American patients and consumers.

Sincerely,

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