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Comment from Maryland Pharmacists Association

The is a Comment on the **Food and Drug Administration** (FDA) Proposed Rule: **Importation of Prescription Drugs**

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Submitter Information

Submitter's Representative:
Aliyah N. Horton, CAE

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Comment

ATTN: DOCKET FDA-2019-N-5711

Dear Commissioner Hahn:

Thank you for the opportunity to provide comments on the Food and Drug Administration's proposed rule on importation of prescription drugs.

I am the Executive Director of the Maryland Pharmacists Association (MPhA). MPhA's mission is to strengthen the profession of pharmacy, advocate for Maryland pharmacists and promote excellence in pharmacy practice. Our members have an obligation to ensure that they provide safe, effective, high quality, and authentic drugs to patients in our state. The FDA drug approval process and the secure, closed drug distribution system in the United States (US) provide assurances that enable maryland pharmacists to fulfill that obligation to their patients. FDA's proposed drug importation program introduces unnecessary risks to patient safety and threatens their ability to optimize medication outcomes, as these products are not distributed with the same safeguards as those products distributed in the US. The proposed program is also unlikely to result in a significant reduction in the cost of prescription drugs to the American consumer. I am writing to request that this proposed rule not be finalized.

The proposed importation program jeopardizes patient safety.

The proposed program bypasses important drug supply chain protections that were created to ensure that the drugs provided 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 and to the 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 U.S. 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. Maryland Pharmacists want to be able to reassure their patients that the drugs they are taking are safe, effective, high quality, and authentic. They cannot do that if there are drugs that are able to bypass DSCSA protective measures.

The proposed importation program is unlikely to produce significant cost savings to American consumers.

High drug costs are a significant problem for American consumers, and as a pharmacists organization, we see the negative outcomes of that problem every day. We are committed to finding solutions for Maryland patients to ensure they have access to the medications they need, and we will continue to advocate for changes that we believe will have a real impact on lowering drug prices. 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.

We are already dealing with issues related to the lack of regulation and track and trace for physician dispensing. It has created critical safety gaps that have impacted Maryland patient. This rule will obliterate the safety nets we do have in place.

In conclusion, I urge 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 Marylanders.