



TEXAS *Pharmacy Association*

Together Pharmacy Advances

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[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:

Thank you for the opportunity to provide comments on the Food and Drug Administration's proposed rule on importation of prescription drugs. The Texas Pharmacy Association (TPA) is writing to request that this proposed rule not be finalized. TPA represents more than 30,000 Texas pharmacists in all practice settings and knows firsthand the obligation to ensure that pharmacists provide safe, effective, high quality, and authentic drugs to their patients. The FDA drug approval process and the secure, closed drug distribution system in the United States provide assurances that enable pharmacists to fulfill this obligation to their patients.

FDA's proposed drug importation program introduces unnecessary risks to patient safety and threatens pharmacists' ability to optimize medication outcomes for their patients, as these products are not distributed with the same safeguards as products distributed in the U.S. The proposed program is also unlikely to result in a significant reduction in the cost of prescription drugs to the American consumer.

The proposed importation program jeopardizes patient safety.

The proposed program bypasses important drug supply chain protections that were created to ensure that the drugs pharmacists 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 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. 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 some drugs 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 pharmacists, we see the negative outcomes of that problem every day. TPA is committed to finding solutions for patients to ensure they have access to the medications they need, and 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.

The proposed importation program contemplates the inclusion of Pharmacy Benefit Managers (PBMs) in the importation supply chain.

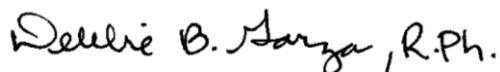
We are very concerned that the proposed program as designed contemplates the inclusion of Pharmacy Benefit Managers (PBMs) in the importation supply chain. PBMs are not currently acting in the best interest of patients. Pharmaceutical costs are a prime concern for Americans; however, implementing this policy is unlikely to bring down prices for most Americans, and it is likely to create dangerous loopholes in the U.S. secure, closed drug supply chain. There are a number of ways prescription drug costs can be addressed that don't require taking risks with the safety of the American drug supply, including:

- Reform the role PBMs play in the supply chain. In West Virginia alone, when PBMs were removed from the state's Medicaid program, they saved \$52 million 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 for the most efficient review of generics for small molecule drugs and biosimilars for biologics. Generics and biosimilars provide competition in the marketplace that will bring down prices.

In conclusion, TPA urges you to not 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 pharmacists' patients and for American consumers in general. Pharmacists live and work on the front lines of health care affordability. We urge you to pursue solutions that will work without sacrificing safety.

Thank you for your time and consideration.

Sincerely,



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