



california pharmacists association

March 6, 2020

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:

On behalf of the California Pharmacists Association (CPhA), I would like to thank you for the opportunity to provide comments on the Food and Drug Administration's proposed rule on importation of prescription drugs. CPhA represents pharmacists, pharmacy technicians, and student pharmacists from all practice settings in the state of California.

As you know, pharmacists play a vital role in ensuring access to safe, effective, high quality, and authentic drugs to improve the health of the patients they serve. The FDA drug approval process and the secure, closed drug distribution system in the United States provide assurances that enable each pharmacist to fulfill this obligation to their patients. FDA's proposed drug importation program introduces unnecessary risks to patient safety and threatens the pharmacist's ability to optimize patient outcomes, as these products are not distributed with the same safeguards as those products distributed in the US. Based on the evaluation of several pharmacy organizations, the cost of prescriptions drugs to the American consumer will not be significantly lowered. 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 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 me, 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.

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

High drug costs are a significant issue for American consumers and our pharmacist members see the negative outcomes of that issue every day. CPhA, along with the national pharmacy associations, 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 true 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 imported 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 would outweigh any cost savings realized from purchasing the drugs from Canadian rather than U.S.-based sellers or distributors.

For the reasons mentioned above, the California Pharmacists Association urges that the FDA 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 the patients our pharmacists serve and for American consumers in general.

Thank you for your time and consideration. If you have any questions or require additional information, please contact me by emailing rvaidya@cpha.com or calling 916.779.1400.

Sincerely,



Rajan Vaidya, PharmD

Director, Pharmacy Practice & Policy

California Pharmacists Association