



March 4, 2020

[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 (FDA) proposed rule on importation of prescription drugs. The Michigan Pharmacists Association (MPA) is pleased to submit these comments regarding the Importation of Prescription Drugs Proposed Rule, Docket No. FDA-2019-N-5711. MPA represents 9,000 pharmacists, 15,000 student pharmacists and pharmacy technicians. Our members have an obligation to ensure that they can 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 (U.S.) provides pharmacists with the assurance that enables them to fulfill this obligation to their patients. The FDA's proposed drug importation program introduces unnecessary risks to patient safety and threatens their ability to optimize medication outcomes working with their patients, as these products may not be held to the same production, manufacturing and compounding standards as those 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. We urge the FDA to NOT finalize the rule as currently written. Below, we provide additional information on how this proposed rule can jeopardize patient safety as well as additional concerns associated with the proposed rule.

The proposed importation program jeopardizes patient safety.

The U.S. is the gold standard for the regulation of medication supply. 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 our member pharmacists to dispense to the American population. These same safeguards and gold standards do not exist in Canada. The 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. Without proper oversight designed to protect patient safety, we are allowing counterfeit and/or adulterated products to infiltrate our pharmaceutical supply chain which renders patients vulnerable to life-threatening consequences. 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. Our pharmacists want to be able to reassure their patients that the drugs they are taking are safe, effective, high quality and authentic. We cannot do that if there are drugs that are able to bypass DSCSA protective measures.

The proposed importation program might put the patient at risk of counterfeit drugs

The Pharmaceutical Research and Manufacturers of America (PhRMA) states that 1 in 10 medications worldwide are counterfeit. The U.S. should not outsource the protection of its citizens to a foreign regulator that has not agreed to undertake the same regulatory burden that Americans expect. There has already been one very serious safety breach in the U.S. of a Canadian wholesaler trafficking in counterfeit cancer drugs to American clinics. The lack of jail time in that case and the impossibility of extradition of the criminals from Canada demonstrate our concern that quality is not a guarantee. State importation programs previously attempted in Illinois, Minnesota and Maine all struggled to extend their regulatory authority to Canadian participants. It is important to note that state boards of pharmacy do not operate with enough resources to conduct all the inspections warranted, and in all cases they accept reciprocal inspections from other states not because they want to, but because they have to. U.S. state boards of pharmacy are not resourced or legally empowered to inspect pharmacies or wholesalers in foreign countries. It is even more dangerous to American patients to expect uncooperative foreign regulators to conduct inspections on our behalf.

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

High drug costs are a significant problem for U.S. patients. Our pharmacists witness the negative outcomes associated with medication cost and access on a daily basis and are committed to finding solutions for their patients to ensure access to the medications they need. MPA will continue to advocate for changes that we believe will have a real impact on lowering drug prices. The FDA's proposed importation program is not a workable solution to lowering drug costs with the Congressional Budget Office predicting U.S. pharmaceutical spending would decrease by 1 percent. Most of the highest-cost drugs for American consumers are carved out of the program, such as insulin and other biologics, which further impairs any potential savings. 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. Furthermore, Canada represents only 2 percent of global pharmaceutical consumption compared with the United States' 44 percent, meaning Canada's drug supply would not be adequate to supplement the U.S. drug supply.

Additionally, there is concern that the 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 and are unfairly gaming the system and bankrupting pharmacies. We believe that health care costs, of which pharmaceutical costs are a part, are a prime concern for Americans at nearly all income levels, even those with what many consider good insurance. However, implementing this policy is unlikely to bring down prices for most Americans, and very likely to create dangerous loopholes in the U.S. closed secure drug supply chain.

There are a number of ways these can be addressed that do not require taking risks with the safety of the American drug supply, including:

- Reforming the role PBMs in the supply chain. For example, in West Virginia, PBMs were removed from the state's Medicaid program which saved the state approximately 52 million dollars the very first year the program was in operation.
- Providing transparency for patients to help them better understand their drug costs.
- Providing the FDA with resources to allow for the review of generics for small molecule drugs and biosimilars for biologics in an efficient, yet safe manner. Generics and biosimilars provide competition in the marketplace that will bring down prices.

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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 my patients and for American consumers in general.

Thank you for your time and consideration. Please feel free to contact me with any questions or comments via phone (517) 377-0226 at or email at Larry@MichiganPharmacists.org.

Regards,



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