

# FDA's proposed drug importation program is NOT a safe way to reduce drug prices. It puts patients at risk.

Together with pharmacists like you, APhA and NASPA told FDA that patient safety cannot be compromised.

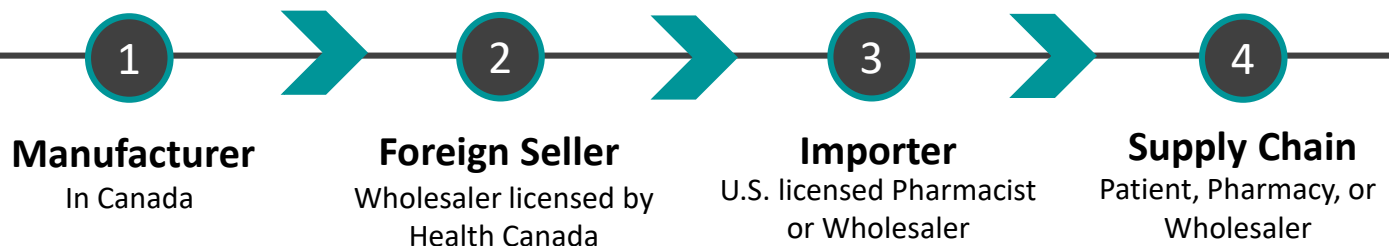
Under the Food, Drug, and Cosmetic Act (FD&C Act), the Secretary of Health and Human Services (HHS) can permit pharmacists and wholesalers to import certain Canadian prescription drugs into the United States under specific conditions—but only if doing so poses no additional risks to public health and safety and results in significant cost savings to consumers.

On December 23, 2019, FDA issued a proposed rule that, if finalized, would create a program for the legal importation of certain drugs from Canada to the United States.

FDA's proposed rule identifies who could participate in the program, which drugs would be excluded, and labeling, track and trace, testing, and other compliance requirements, all of which adds to the ultimate cost of the imported drugs.

The program would undermine the safeguards that are in place to ensure that prescription drugs are manufactured, stored, shipped and dispensed in a safe manner. This would have a negative effect on patient confidence in the safety of their medications.

Under FDA's proposed drug importation program, a state or other nonfederal government entity (with or without a cosponsoring pharmacist, wholesaler, or another state or non-government entity) would submit a proposal for FDA approval that includes specifics about the Canadian drugs for import, foreign seller, importer, testing, labeling, recall procedures, and more.



# What we commented on FDA's proposed drug importation program

## FDA's proposed importation program jeopardizes patient safety.

Decades of federal and state laws have created patient safety and drug supply chain protections to ensure that the drugs that we provide to patients are safe. The proposed program would bypass these protections and create [supply chain vulnerabilities](#). Counterfeit or unsafe drugs could be introduced in these gaps in the supply chain, putting patients at an increased risk.

## FDA's proposed importation program undermines the Drug Supply Chain Security Act (DSCSA), also known as "the track-and-trace law."

Pharmacists and other drug supply chain stakeholders have been working for years to implement DSCSA, which creates 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 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.

## FDA's proposed program would create pharmacy operation disruptions that could introduce barriers to access that may compromise patient safety.

The FDA-approved and Canadian versions would be commingled in the marketplace. With already limited shelf space, and time spent on managing inventory, introducing these foreign products onto the pharmacy shelves would interfere with pharmacy operations. Further, the proposed program would create product selection confusion, with questionable interchangeability between products, and the pharmacist may not know which version of the drug to dispense to patients. [Access to medication could be limited](#) if a patient's plan dictates dispensing one version and a pharmacy only has the other. It would also complicate insurance coverage and reimbursement at the pharmacy.

## FDA's proposed importation program fails to produce significant cost savings to American consumers.

As a result of additional steps in the supply chain, such as relabeling and laboratory testing requirements, it is [highly unlikely that there will be a significant cost savings to consumers](#). The need for additional track-and-trace, recall, and adverse event reporting systems will further increase costs associated with the importation program. Also, most high-cost drugs are excluded from the program. The lack of clarity around unknown, unproven cost savings does not justify jeopardizing U.S. supply chain integrity and patient safety.

