

The Dangers of Drug Importation

A Threat to Patients' Health and Safety

Ensuring patients have access to needed medicines is critical, but the importation of unapproved medicines, from Canada or elsewhere in the world, poses a serious risk to public health.

The U.S. Food and Drug Administration (FDA) is the gold standard when it comes to reviewing and approving drugs. Medicines that enter the United States through importation will not be subject to these same strong standards and, as a result, counterfeit, substandard or diverted, repackaged and adulterated drugs could be introduced into our secure drug supply chain.

Two Decades of Drug Importation

Since the early 2000s, the Secretary of Health & Human Services has had limited authority to permit the importation of some drugs from Canada, but only if the Secretary could certify the imports would pose no additional risk to public health and safety and would generate cost-savings that could be passed on to American consumers.

To date, not a single Secretary from both Democratic and Republican administrations has been able to make these certifications. Even in 2020, despite claims to the contrary, the Secretary was no more able to certify than his predecessors and questionably circumvented the statute by punting the responsibility to state governments.

Learn more at PhRMA.org/Importation

As of April 2022



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Why Importation Is Bad for Patients

Foreign governments will not and cannot ensure the prescription drugs entering the United States from abroad are safe and effective.

- The Canadian government has said it cannot and will not guarantee the safety of medicines imported to the United States through Canada.

Counterfeiters are becoming increasingly sophisticated in large-scale illegal manufacturing of fake products that look like the real drug, posing a significant health and safety risk to patients.

- Toxins that have been found in counterfeit medicines include: fentanyl, mercury, lead, aluminum, arsenic, rat poison, antifreeze, floor wax, house paint, road paint and paint thinner.
- Incidences of counterfeit drugs such as counterfeit cancer drugs and synthetic opioids pose serious public health threats.

Importation is not an effective approach to reducing drug costs.

- The resources required to ensure the safety and efficacy of any drugs being imported from or passing through other countries into the United States, e.g., for FDA inspections and law enforcement, would outweigh any potential savings.
- The Congressional Budget Office estimates a mere 1% reduction in drug spending under importation, and there is no guarantee patients would see any of the potential savings.

Counterfeit Drugs: A Growing Problem

1 in 10 medicines in low- and middle-income countries are substandard or falsified.

95% of internet drug outlets have been found to be operating out of compliance with federal and state pharmacy laws and practice standards.

9 million fraudulent medical devices and illicit pharmaceuticals were seized by Interpol in June 2021.

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