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 regulating the safety of our medicine supply. 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.

The History of Drug Importation

Since the early 2000s, the Secretary of Health & Human Services has had the authority to permit the importation of 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.
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.

- Ingredients 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 percent 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 worldwide are counterfeit

96% of internet drug outlets were found to be operating out of compliance with U.S. pharmacy laws since 2008

+3,600 – the number of websites selling counterfeit medicines and medical devices from which FDA and Interpol seized products in 2018

Learn more at PhRMA.org/Importation.