

4 facts on why drug importation is bad for patients

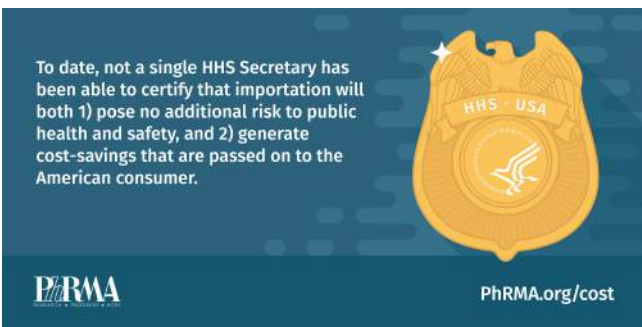
Ensuring patients have access to needed medicines is critical, but importing medicines, whether from Canada or elsewhere in the world, is the wrong answer.

Due to the U.S. Food and Drug Administration’s (FDA) comprehensive drug approval process, medicines on the U.S. market are widely regarded as the safest in the world. The U.S.’s relatively closed distribution system plays a critical role in helping to keep the global proliferation of counterfeit medicines from infiltrating the U.S. prescription medicine system.

The [World Health Organization](#) (WHO) estimates 10 percent of medicines worldwide – and up to 50 percent of the drugs consumed in developing nations – are counterfeit. Without proper FDA oversight and enforcement of laws designed to protect patient safety –which importation undermines– these products could infiltrate the U.S. pharmaceutical supply chain, with life threatening consequences. Under both democratic and republican administrations, the [FDA](#) has stated it cannot assure the safety of imported medicines from foreign countries and they would present a risk to public health.

Importation is often viewed as a means to lower drug costs, but these proposals ignore key facts about how importation impacts patient safety and access to new, innovative treatments. Consider the following four facts:

The Medicare Modernization Act (MMA), enacted in 2003, created the U.S. Department of Health and Human Services (HHS) Task Force on Drug Importation and mandated it report to Congress on the safety of drug importation. It included a [provision](#) that could lead to the importation of drugs from [Canada](#), but only after Secretarial certification to Congress that such imports would not threaten the health and safety of the American public and would generate cost savings for the consumer. To date, the federal government has been unable to do that.



1. To date, not a single Secretary of the U.S. Department of Health and Human Services (HHS) has been able to certify that importation will both 1) pose no additional risk to public health and safety, and 2) generate cost-savings that are passed on to American consumers.

2. Foreign governments will not ensure that prescription drugs entering the U.S. from abroad are safe and effective.

Foreign governments are not in the position to monitor and regulate medicines that are intended for the U.S. market. For example, the Canadian government is on record saying that while it regulates medicines manufactured for its citizens, it cannot be expected to ensure the safety of medicines that are shipped through Canada for export to the U.S. or other countries. In fact, many drugs that pass through Canada to patients in the U.S. may not actually originate in Canada, but instead can come from places with [lax regulatory systems](#), like Bulgaria and Pakistan. Also, given that drugs imported from abroad will effectively lack oversight by any health authority, there is a high likelihood such drugs are mishandled (e.g., proper temperature control is not maintained, which causes rotting, counterfeit, or display deceptive or incorrect packaging and labeling).

3. There is no guarantee any potential savings generated from the importation of medicines will be passed on to the patient.

HHS stated in 2004, “total savings to drug buyers from legalized commercial importation would be one to two percent of total drug spending,” and the [Congressional Budget Office](#) determined in 2005 that importation would reduce drug spending by “roughly 1 percent.” 3



4. Counterfeiters are becoming increasingly sophisticated with their technology and pose a significant health and safety risk to patients.

It has become very easy for counterfeiters to make bottles and packages look genuine, but the reality is they are often filled with laced, adulterated or fake pills that are dangerous to patients. Recent examples of threats to the U.S. pharmaceutical supply chain include:

- [Newly unsealed federal indictment](#) charges a major Canadian online pharmacy and a number of other related entities and people with conspiring to allegedly smuggle mislabeled and unapproved prescription medicines into the U.S.

- In June 2015, the FDA and Interpol [announced the seizure](#) of illegal medicines and medical devices from “more than 1,050 websites.” Many claimed to be approved generic versions of branded drugs.

- An [October 2014 National Association of Boards of Pharmacy \(NABP\)](#) survey of online drug sellers revealed that 96 percent of over 10,000 internet drug outlets “were operating out of compliance with U.S. pharmacy laws and practice standards. Within that 96 percent, NABP found that 88 percent of drug sellers did not require a valid prescription, 12 percent dispensed controlled substances and 91 percent appeared to have affiliations with rogue networks of internet drug outlets.”