

## THE REAL COSTS OF DRUG IMPORTATION

### MYTH

If we allow widespread importation of cheaper drugs from other developed countries such as Canada, patients will be able to keep more of their hard-earned money in their pockets without compromising the safety of our drug supply.

### FACT

Unfortunately, that's not the reality. Such a move would likely expose patients to counterfeit, adulterated, or unapproved drugs, and any savings would mostly wind up as profits for middlemen, not lower prices for patients. Here are the untold costs of drug importation...

- ▶ A bipartisan group of four former FDA Commissioners recently wrote in a warning to Congress: "...importation represents a complex and risky approach — one that the evidence shows will not achieve the aim [of lowering costs], and that is likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products."
- ▶ Any improved access or cost savings resulting from importation are likely to be minimal — with most savings winding up as profits for middlemen.

Source: <https://www.surgeongeneral.gov/news/testimony/t01262005.html>



ESTIMATED SAVINGS  
FROM DRUG  
IMPORTATION



LESS THAN ONE PERCENT  
WOULD GO DIRECTLY TO  
PATIENTS

- ▶ The global counterfeit medicine market could be as high as \$75 billion a year.

Source: <http://www.who.int/bulletin/volumes/88/4/10-020410/en/>

**\$75 Billion**

ESTIMATED SIZE OF GLOBAL  
COUNTERFEIT DRUG MARKET

- ▶ Online drug pharmacies are increasing the risk of counterfeit drugs making their way to U.S. patients.

Source: <https://nabp.pharmacy/denying-consumers-access-patient-care-common-among-rogue-internet-drug-outlets-notes-nabp/>



PROPORTION OF ONLINE DRUG RETAILERS  
OPERATING OUT OF COMPLIANCE WITH U.S.  
HEALTH & SAFETY STANDARDS

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### U.S. Is Standard-Bearer for Ensuring Drug Safety and Efficacy

**“ [Importation] could lead to a host of unintended consequences and undesirable effects, including serious harm stemming from the use of adulterated, substandard, or counterfeit drugs. It could also undermine American confidence in what has proven to be a highly successful system for assuring drug safety.”**

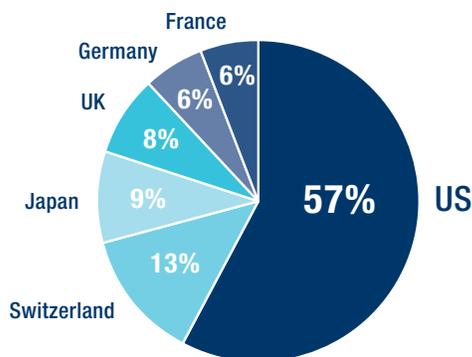
— Robert Califf, Margaret Hamburg,  
Mark McClellan, and Andrew Von Eschenbach

Four former FDA Commissioners (serving in both  
Democratic and Republican Administrations)

March 17, 2017 letter

### The United States Leads the World in Innovative Drug Development. Let's Keep It That Way.

#### Where are new drugs coming from?



Source: <http://www.drugcostfacts.org/drug-pricing-regulations>

Safety considerations aside, importation is nothing more than a backdoor mechanism to import artificial foreign price controls on America's highly innovative drug development ecosystem. Disrupting that successful ecosystem would be devastating to future drug discovery. In fact, one study found that, if the United States had adopted European-style price controls on pharmaceutical drugs from 1986 to 2004, we would have produced 117 fewer new medicines and cures. Shortages are the inevitable result of price controls. Can we really afford a shortage of new treatments and cures?

### It's Canada... how dangerous can it really be?



Many people assume that if drugs are imported from other highly-developed countries like Canada, such supplies would pose little to no safety risks. After all, we don't read regular news reports about Canadian patients being harmed by drugs purchased at Canadian pharmacies. So what's the big deal?

While Canadian regulators ensure the safety and authenticity of medicines entering their market that are intended for use by patients in Canada, they do not apply those standards for medicines intended for export only.

In fact, the Canadian government has stated, "Health Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future."\*

And former FDA Commissioner Robert Califf has testified that, "FDA evaluation revealed that, while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85% of such drugs were actually from different countries."

Given that drugs imported from abroad will effectively lack oversight by any health authority, there is a high likelihood that such drugs — if not counterfeit — could nonetheless be mishandled (e.g., proper temperature control not maintained, causing spoilage) or could display deceptive or incorrect packaging and labeling.

\*Department of Health and Human Services, HHS Task Force on Drug Importation, December 2004, page 61, <https://archive.hhs.gov/importtaskforce/Report1220.pdf>