

### 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.

<1%

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/



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



## THE REAL COSTS OF DRUG IMPORTATION

# 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

## Leading Law Enforcement Officials Oppose Drug Importation

IT [T]he National Sheriffs' Association opposes the passage of legislative drug importation proposals which would jeopardize law enforcement's ability to protect the public health; threaten the safety of our drug supply; and endanger law enforcement officers, their canines, and other first responders across America."

- The National Sheriff's Association July 2017

#### In June 2017, Former FBI Director Louis Freeh released a report entitled, "Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement," which found that:

- Drug importation would increase the threat of illegitimate products entering the U.S., fueling criminal organizations' activities and profits.
- Drug importation proposals would worsen the opioid crisis a crisis that has already grown substantially worse due to the powerful opioid fentanyl and fentanyl analogue-laced counterfeit pills being produced by illegal drug trafficking organizations, including in China, and reaching the U.S. through Canada and Mexico.
- Already overburdened law enforcement and regulatory capacity would be unable to ensure a safe prescription drug supply under importation.

### 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, according to a former Canadian government official, "The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada to the United States..."\*

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.

\*Diane C. Gorman, Former Assistant Deputy Minister of Health Canada, May 2003, Letter to the Washington Post