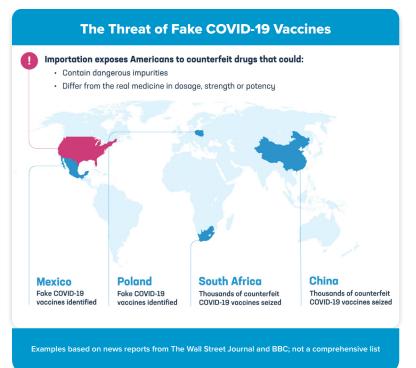
## Why Drug Importation Is Bad For Americans

When governments or individuals circumvent the regulatory gold standard of the FDA's review and approval process to acquire unapproved prescription drugs from other countries outside of the United States' secure drug distribution system - commonly referred to as importation – both individuals and the health care system suffer negative consequences. Without proper Food and Drug Administration (FDA) oversight and enforcement of laws designed to protect patient safety, which importation schemes undermine, there is increased potential for counterfeit, substandard or adulterated products to infiltrate the U.S. pharmaceutical supply chain, putting lives in harm's way.



Counterfeits may look like real medicines, but they can contain dangerous impurities like mercury, lead and fentanyl. They may differ from the real thing in dosage or strength, or their potency may be degraded. Unfortunately patients around the world, including in the United States, have died through online purchases<sup>1</sup> of contaminated fake medicines or the lack of a doctor or pharmacist supervising the use of medicines acquired online. The only vaccine or medicine you should take is one prescribed by your health care provider and dispensed by a U.S. licensed pharmacist.

Counterfeiting is a problem that never goes away. Most recently, for example, the COVID-19 pandemic created new opportunities<sup>2</sup> for criminal counterfeiters to take advantage of unwitting patients seeking prescription treatments and vaccines. Counterfeiters seized on the fact that people around the world were eager to receive a vaccine. Fake COVID-19 shots were identified in Mexico and Poland,<sup>3</sup> with one batch of "vaccines" containing anti-wrinkle cream. Police in China and South Africa seized thousands of doses of counterfeit COVID-19<sup>4</sup> vaccines in 2021. The pandemic created a new space for criminals to take advantage of people, and criminal organizations are getting smarter and using social media to target potential victims.

In 2021, both the Drug Enforcement Administration (DEA) and Department of Justice (DOJ) issued alerts on the threat of counterfeit medicines. The DEA issued a warning<sup>5</sup> about the rising number of counterfeit drugs containing a synthetic opioid in the United States. The DOJ caught a scheme<sup>6</sup> that sold millions of dollars' worth of dangerous prescription medications that were illegal to be sold in the United States. These imported drugs circumvented the FDA and involved fake companies and websites. These recent alerts reinforce that we should not be undermining the closed, FDA-regulated drug distribution system.

Despite this, personal and wholesale importation schemes are under consideration by some policymakers, which would make it easier for criminals to transport adulterated or counterfeit vaccines to unsuspecting consumers in the United States. In October 2020, the FDA published a final rule permitting commercial importation of certain drugs from Canada, the legality of which is the subject of a pending lawsuit brought by PhRMA, the Partnership for Safe Medicines and the Counsel for Affordable Health Care in U.S. District for the District of Columbia.

We must work to lower what patients pay for their medicines AND make sure patients are getting the medicines they need safely. There's a way to do both, but importing unsafe drugs isn't the answer. Learn more at PhRMA.org/BetterWay.

## Sources

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