



# Importation



Some people argue the importation of drugs would help save consumers money. What they often miss is how importation threatens patient safety and would impact access to new, innovative treatments. Under both Democratic and Republican administrations, no Secretary of Health and Human Services has certified that importation of medicines from foreign countries would be safe or result in savings for American patients. And in a recent [letter](#)<sup>i</sup>, four former Food and Drug Administration (FDA) commissioners wrote, “importation represents a complex and risky approach [...] that is likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation’s medical products.” Below are four key facts regarding the implications of importation of unapproved drugs:

**1. Opening our borders to imported drugs could increase the flow of counterfeit drugs into the United States, harming patients.**

The World Health Organization estimates [up to 10 percent](#)<sup>ii</sup> of medicines worldwide – and up to 50 percent of medicines consumed in some developing countries – are counterfeit. Without proper FDA oversight and enforcement of laws that protect patient safety, these products could infiltrate the U.S. pharmaceutical supply, with life-threatening consequences. In the European Union (EU), where parallel trade is sanctioned, the European Commission [seized 34 million counterfeit pills](#)<sup>iii</sup>, including antibiotics, cancer, cholesterol, and anti-malaria medicines across the EU over a two-month period in 2009. Just in June of this year, [Europol seized thousands of cartons of counterfeit medicines](#)<sup>iv</sup> in Spain that were set to be distributed throughout Europe.

**2. The risk from the counterfeit drug trade is growing.**

It is becoming increasingly easy for counterfeiters to make packages and bottles that look genuine, but often contain laced, adulterated, or fake medicines. Data from the Pharmaceutical Security Institute showed that drug counterfeiting [increased 122 percent](#)<sup>v</sup> between 2005 and 2010. Recent threats to the U.S. drug supply from counterfeiters include a [conspiracy between one of the largest Canadian online pharmacies and counterparts in the U.S.](#)<sup>vi</sup> to smuggle mislabeled and unapproved drugs into the United States. Meanwhile, according to the [National Association of Boards of Pharmacy](#)<sup>vii</sup> (NABP), “more than 96% of online pharmacies websites are operating illegally, failing to comply with applicable laws and safety standards” and “89% of illegal online pharmacies do not require a valid prescription.” NABP found these illegal online pharmacies often distribute products that “contain too much, too little or no active ingredient; are manufactured in unsafe conditions; and/or contain materials such as floor wax, mercury, concrete, chalk, boric acid, road tar, antifreeze, and other potentially deadly poisons.”

### 3. Foreign drugs could enter the U.S. drug supply without any oversight or regulation, posing significant health and safety risks to patients.

Foreign governments are not in the position to monitor and regulate medicines that are intended for the U.S. market. For example, as a former Health Minister for Canada recently highlighted, while the Canadian government regulates medicines manufactured for its citizens, it cannot be expected to ensure the safety of medicines that are shipped through Canada to the United States or other countries. In fact, many drugs that pass through Canada to patients in the United States may not actually originate in Canada, but instead can come from places with lax regulatory systems, like Pakistan. Such drugs could be mishandled (e.g., proper temperature control is not maintained), adulterated, counterfeit, or display deceptive or incorrect packaging and labeling.

### 4. There is no guarantee that importing drugs will actually save consumers money.

Both the [Department of Health and Human Services](#)<sup>viii</sup> (HHS) and the [Congressional Budget Office](#)<sup>ix</sup> (CBO) have stated that savings from importation would be limited. HHS has stated total savings would be 1 to 2 percent of total drug spending, and the CBO determined that importation would reduce drug spending by “roughly 1 percent.” Furthermore, researchers found that any potential savings generated from the importation of unapproved medicines would likely not be passed on to patients. In a peer-reviewed [study](#)<sup>x</sup> of previously introduced importation legislation, researchers from the University of Pennsylvania and Arizona State University found that “intermediaries may capture a significant share of any savings that are available” and that consumers are “likely to realize even smaller savings, because they lack the leverage relative to pharmacies, especially if supply of imported drugs is limited or sporadic.”

Importation is not the answer. There are many other, safe alternatives available to patients who are unable to afford their medicines. For example, the Partnership for Prescription Assistance (PPA) ([www.pparx.org](http://www.pparx.org) or 1-888-4PPA-NOW) offers a single point of access to more than 475 public and private patient assistance programs, including more than 200 programs offered by pharmaceutical companies. Other ways consumers can potentially save include: asking for generic versions of medicines, shopping around at different pharmacies to get the best deal, participating in state prescription assistance programs, and enrolling eligible seniors in the Medicare prescription drug program (Medicare Part D).

<sup>i</sup> Dr. Mark. McClellan and Dr. Robert Califf, “Counterfeit Medicines: an update on estimates 15 November 2006”, Duke Margolis Center for Health Policy. March 17, 2017.

<https://healthpolicy.duke.edu/news/former-fda-commissioners-letter-opposes-re-importation>

<sup>ii</sup> International Medical Products Anti-Counterfeiting Taskforce, “Counterfeit Medicines: an update on estimate 15 November 2006”, World Health Organization. November 2006.

<http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>

<sup>iii</sup> “Growing threat from counterfeit medicines”. *Bulletin of the World Health Organization*, Volume 88, Number 4. April 2010. <http://who.int/bulletin/volumes/88/4/10-020410/en/>

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<sup>v</sup> Tim K. Mackey et al. "Counterfeit Drug Penetration into Global Legitimate Medicine Supply Chains: A Global Assessment." *The American Journal of Tropical Medicine and Hygiene* 92. June 3, 2015. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4455087/>

<sup>vi</sup> Dan Mangan, "Canada pharmacy charged in \$78M drug export scheme." CNBC. August 19, 2015. <http://www.cnn.com/2015/08/19/canada-pharmacy-charged-in-78m-drug-export-scheme.html>

<sup>vii</sup> "About Online Pharmacies and Canadian Pharmacy Websites." Alliance for Safe Online Pharmacies. 2017. [http://buysaferx.pharmacy/for-the-media/about-online-pharmacies-and-canadian-pharmacy-websites/-\\_ftn3](http://buysaferx.pharmacy/for-the-media/about-online-pharmacies-and-canadian-pharmacy-websites/-_ftn3)

<sup>viii</sup> Dr. Richard H. Carmona, et al. "Report on Prescription Drug Importation." U.S. Department of Health and Human Services Task Force on Drug Importation. December 2004. <https://archive.hhs.gov/importtaskforce/Report1220.pdf>

<sup>ix</sup> CBO Cost Estimate for FTC Reauthorization Act of 2005 (S. 1392). Congressional Budget Office. September 8, 2015. <https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/costestimate/s13920.pdf>

<sup>x</sup> Patricia M. Danzon et al. "Commercial Importation of Prescription Drugs in the United States: Short-Run Implications." *Journal of Health Politics, Policy and Law*, Vol. 36, No. 2. April 2011. [https://faculty.wharton.upenn.edu/wp-content/uploads/2012/04/2011\\_DanzonJohnsonLongFurukawa\\_2011\\_CommercialImportationOfPrescriptionDrugsInTheUnitedStates\\_Short-RunImplications\\_JOfHealthPoliticsPolicyAndLaw36.2\\_April2011.pdf](https://faculty.wharton.upenn.edu/wp-content/uploads/2012/04/2011_DanzonJohnsonLongFurukawa_2011_CommercialImportationOfPrescriptionDrugsInTheUnitedStates_Short-RunImplications_JOfHealthPoliticsPolicyAndLaw36.2_April2011.pdf)

