



## THE RISKS OF PRESCRIPTION DRUG IMPORTATION AND COUNTERFEIT DRUGS

As the nation's pioneer consumer organization, the [National Consumers League](#) (NCL) strongly supports consumer access to safe, effective, and affordable prescription drugs. However, given NCL's long-standing focus on health policy and fraud issues, we are concerned that pending prescription drug importation proposals will open the U.S. market to a flood of counterfeit and/or substandard drugs, putting patient health and safety at risk. HHS and FDA agree that the risks of importation outweigh any potential cost-saving benefits. "[Over the last 17 years](#), every HHS Secretary and FDA Commissioner has refused to certify the safety of prescription drug importation," said NCL Executive Director Sally Greenberg.

**Counterfeit drugs are a significant public health threat.** The World Health Organization (WHO) estimates that 10 percent of medicines worldwide are counterfeit, including up to half of the drugs consumed in developing nations. Counterfeit drugs may contain the wrong active ingredient, the wrong amount of the active ingredient, no active ingredient, harmful ingredients, or even poisons such as mercury, road tar, or antifreeze. Fortunately, the U.S. has a closed drug distribution system, along with a comprehensive FDA review, approval, and regulatory process that works to protect American consumers from the threat of counterfeit drugs.

**Allowing prescription drug importation from Canada and other countries would likely lead to an explosion of new online pharmacies hoping to lure consumers with the promise of low prices.** We know, however, that it is very difficult for consumers to distinguish between safe and legitimate online pharmacy websites and thousands of others selling counterfeit, adulterated, and unapproved drugs. According to the Alliance for Safe Online Pharmacies (ASOP Global, of which NCL is an Observer Member), [65](#) percent of online search results for prescription drugs lead U.S. consumers to illegal and unsafe websites. Furthermore, it is difficult – if not impossible – for law enforcement to take action against these illegal online pharmacies, especially if they are based overseas. Allowing prescription drug importation will only exacerbate these patient safety risks.

**NCL is also concerned that there is no way to ensure that drugs purporting to come from Canada actually come from Canada.** Canada has said that it will not certify the integrity and safety of drugs exported from Canada into the U.S. According to an FDA report, "FDA evaluation of non-FDA-approved imported drugs revealed that while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85 percent of such drugs were actually from different countries." The [National Association of Boards of Pharmacy \(NABP\)](#) shares NCL's concerns and has cautioned that "sending consumers online to look for Health Canada-approved medicines is reckless, as US patients are likely to receive unapproved, substandard, and counterfeit drugs from unknown foreign sources, posing a serious risk to patient safety."

Prescription drug importation undermines the *Drug Supply Chain Security Act* (DSCSA) safety goals, because product would be sold into the U.S. system without the necessary product identifiers that will enable electronic tracing of products throughout the drug supply chain (see 2/28/17 [letter](#) from the Pew Charitable Trusts to Senator Sanders). The U.S. government would not be able to enforce DSCSA requirements as to foreign manufacturers, wholesalers, or dispensers. In addition, there is no way to verify that foreign sellers are buying only from FDA-registered foreign facilities. There is great profit potential for bad actors to purchase from illegal sources and sell to the U.S. market, thus threatening the health of our nation's consumers.

**"While ensuring access to affordable prescription drugs is a goal shared by all, prescription drug importation is too risky," said NCL Health Policy Director Karin Bolte.** As former FDA Commissioner Dr. Robert Califf has [stated](#): "Authorizing importation would compromise the closed drug distribution system in the United States and undermine these [safety] laws, thus making it easier for unapproved drugs, which may include counterfeit or other substandard drugs, to reach American patients putting their treatment at risk. FDA is concerned that the risks of unapproved products from foreign sources outweigh any potential cost savings."

"The National Consumers League urges Congress to reject prescription drug importation proposals and find other ways to ensure consumer access to the safe, effective, and affordable drugs they need to maintain their health," said Bolte.