

DRUG IMPORTATION

Issue Background

The Food and Drug Administration (FDA) was created to ensure food and medicines sold in the United States are safe for consumers. Today, the FDA's regulatory and enforcement policies are recognized globally as the "gold standard" for safety and efficacy. Some have proposed that to address the cost of prescription drugs, the U.S. should import medicines manufactured in foreign countries, like Canada and China. However, trusted law enforcement and health officials have expressed strong concerns with importing drugs from foreign countries that do not meet the gold standard for health and safety.

Judge Louis Freeh, former director of the Federal Bureau of Investigation (FBI), has warned that legalized drug importation would expose patients to counterfeit or adulterated drugs. He has also said it would strain law enforcement resources and exacerbate the opioid epidemic. According to the National Sheriffs Association, drug importation 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, other first responders."

Additionally, in March 2017, a bipartisan group of former FDA commissioners warned Congress that importation is "likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products." They also noted that importation "will not achieve the aim of [lowering costs]," a view that has been largely reaffirmed by both the nonpartisan Congressional Budget Office and the U.S. Department of Health and Human Services.

Furthermore, drug importation would impose artificial foreign price controls on America's highly innovative drug development ecosystem, which produces more new drugs than the rest of the world combined. Disrupting that successful ecosystem of biomedical innovation would be devastating to future drug discovery.

Policy Position

The United States is the standard-bearer for ensuring drug safety and efficacy, as well as the world leader in innovative drug development. Importing medicines from foreign countries would undermine public health and do little to reduce prescription drug costs. Policymakers should reject proposals that would endanger the well-being of patients, families and communities or stifle the discovery of new cures and treatments. Instead, policymakers should seek to strengthen a system that encourages biomedical innovation and gives patients peace of mind knowing the medicines they need are safe and effective.

Key Points

- ✓ 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.**
- ✓ Former FDA Commissioner Robert Califf has testified 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 global market for counterfeit drugs is estimated to be as large as **\$75 billion a year.**
- ✓ **96 percent of online drug retailers** are operating out of compliance with U.S. health and safety standards.
- ✓ Any improved access or cost savings for consumers resulting from importation are likely to be minimal — estimates suggest this number would be **less than 1 percent.**