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By Jim Greenwood
July 14, 2017

Importing drugs from other countries undermines safety

The Food and Drug Administration was established to ensure the safety of food and medicines sold in the United States. That original charter seems to be ignored by the advocates of drug importation, who brush aside legitimate safety concerns to advance a political agenda.

Ensuring access to safe and reliable prescription medications is a paramount concern to U.S. drug manufacturers. And many Americans — including [pharmacists and law enforcement officials](#) — want to prevent potentially counterfeit or adulterated foreign drugs from flooding our communities.

STAT's Ed Silverman [recently downplayed](#) the many valid concerns that have been raised about the prospect of opening the United States's prescription drug market to untraceable foreign products. Here's why he is wrong to dismiss the risks.

The debate about drug importation has been underway for decades. Those who support it have never advanced a responsible plan that would provide the same level of health and safety protections that the FDA has delivered for decades. Its rigorous system of rules and protocols ensure that prescription drugs in this country are safe and effective. It protects those high standards by preventing the sale of imported prescription drugs that are not approved for use in the U.S.

This longstanding policy has generated protests from individuals who want Americans to have greater access to lower-cost medicines. This laudable goal is shared by the biopharmaceutical industry, which is championing market-based solutions to advance it.

We cannot, however, ignore the very real safety risks of buying prescription medicines from other countries. The dangers range from seemingly innocuous concerns about the information listed on drug labels to the more

obvious threats posed by counterfeit drugs and a lack of quality control in drug manufacturing in other countries.

In June, former federal judge and FBI director Louis Freeh released the findings of [an extensive investigation](#) into the ways drug importation would affect public health, safety, and law enforcement. According to Freeh, importation would increase the threat of counterfeit drugs entering the U.S., exacerbate our nation's opioid epidemic, and further strain limited law enforcement resources.

Advocates often point to Canada as a potential source of safe drugs. But the Canadian government [has said in the past](#) that it does not, and will not, ensure the safety or effectiveness of drugs that are sent across the border. The FDA [issued a very blunt warning](#) about drugs coming from our neighbor to the north: "Drugs coming to the United States from Canada may be coming from some other country and simply passing through Canada" and these drugs could be "counterfeit, contaminated, or sub-potent, among other things."

Leona Aglukkaq, a former Canadian health minister, affirmed this view in [the Washington Post](#), making it clear that Canada would be a transfer point for drugs made in other countries on their way to the U.S. market. "Allowing Americans to purchase prescription drugs from Canada could have terrible consequences for the citizens of both countries," she wrote.

Four former FDA commissioners, who served during both Republican and Democratic administrations, [also warned Congress](#) in March to reject the idea of drug importation because it could lead to "serious harm" and "undermine American confidence in what has proven to be a highly successful system for assuring drug safety."

If we can't guarantee the safety of medicine imported from a trusted neighbor like Canada, what should we expect of prescription drugs shipped to the U.S. from China, India, and elsewhere? Is this a risk worth taking, especially when the [Department of Health and Human Services](#) and the [Congressional Budget Office](#) have both found it will do almost nothing to actually lower drug costs?

These are serious questions that should not be casually dismissed. This issue is too important to families with a loved one afflicted by a difficult disease; it is too important to patients struggling with debilitating illnesses; and it is too important to seniors who depend on prescription medications to improve their lives.

There are better ways to drive down drug costs. The Council for Affordable Health Coverage [recently encouraged](#) policymakers to start by fostering more competition, streamlining the payment process, and accelerating the

approval process for generic treatments. There are numerous ways to achieve these goals.

For example, Congress and the Trump administration could take steps to reduce barriers to value-based pricing contracts, in which the price paid for a drug is tied to the outcome it produces rather than the volume of it that is sold.

We should also ease restrictions on the information that drug manufacturers may share with payers and providers, such as information on a drug's post-market clinical performance, to help payers and providers make better-informed decisions.

We are fortunate to live in an age of rapid innovation. Researchers are developing breakthrough treatments, and even cures, for a range of once-deadly or debilitating illnesses. These medicines are improving the quality of life for countless individuals.

Let's not take a step back by undermining the basic safety of those groundbreaking treatments. Instead, we should move forward together on responsible solutions that will promote greater access to affordable medicines while still protecting patient safety.

Jim Greenwood is the president and CEO of the Biotechnology Innovation Organization (BIO).

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