Drug Importation from Canada Increases Patient Risk with No Guarantee of Lower Prices

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Drug pricing is once again being debated in Washington and in state capitals. One of the proposals on the table – importation of medicines from Canada – poses dangerous patient risks. This proposal is intended to reduce the price Americans pay for medicines. But the risks to patient safety far outweigh any cost savings – which are likely to be minimal anyway. That is why four former commissioners of the U.S. Food and Drug Administration (FDA) sent a letter to Congress on March 16 cautioning against such an approach.

Patient safety concerns are real

Two patient safety issues are especially concerning. First, a staggering 85 percent of drugs sold from "Canadian" pharmacy websites to U.S. patients are not actually from Canada, according to the FDA.

Instead, these drugs often come from countries that lack basic quality assurance and compliance systems. Second, drugs exported from Canada that are not intended for the U.S. market – regardless of where they were made — are not inspected for safety and quality by Canadian authorities before they are shipped to the U.S. These two issues represent a dangerous risk to patients from falsified and substandard drugs. Patients could be harmed by taking drugs that are dangerous or simply do not work.

Risk of medication errors

Foreign drug names and labeling differences of foreign-sourced drugs can drive serious medication errors. Imagine the risk to an elderly patient who is suddenly unable to locate instructions on a diabetes or heart medication. Imported medicines might also come in a different dosage form (such as capsule, tablet, or other dosage forms) disrupting treatment regimens and creating confusion for patients. These differences also present risks to busy healthcare professionals who are accustomed to U.S. standards for drug labels and dosage forms.

There is no comprehensive system to safeguard imported drugs

There is no system in place to assure the safety and quality of medicine that was not intended for the U.S. market if is exported to the U.S. from Canada. Canadian regulators focus on — and are only resourced to regulate — drugs dispensed to Canadians, not on drugs that are exported to the U.S. That is not so surprising, actually. Could you imagine the U.S. Congress authorizing new proposals to spend money protecting Canadian patients?

In 2013, Congress enacted the Drug Quality and Security Act that authorized a national, interoperable prescription drug track and trace system to help FDA act upon safety concerns. Importing medicines that do not comply with this system would increase the risk of patients buying falsified or substandard drugs. An entirely new bureaucracy would need to be established to ensure safe online drug sales from overseas. It's unclear how it would even be feasible to create a nationwide monitoring and inspection system of drugs imported from Canada.

Market forces run counter to drug importation
The importation proposals being discussed are not economically sustainable, in terms of price and product availability — and they do not even promise significant overall cost savings. That's because lower cost generics already cost less in the U.S. than in other developed countries. And since they make up almost 90 percent of U.S. drug sales, importing more would not reduce costs in a meaningful way. In addition, generics are typically offered at very low margins so the opportunities for savings here are limited.

Basic economics indicate that brand name drug makers from the U.S. would have no incentive to ship products to Canada in order for the same drugs to be subsequently imported back to the U.S. and sold at a lower price. Additionally, Canada does not have the manufacturing or supply chain capacity to supply even a small percentage of the U.S. market (the U.S. is nearly 10 times as populous as Canada). Shipping more drug products to the U.S. would risk serious drug shortages for the Canadian population and would certainly be politically unsustainable for Canadians.

Better solutions are available
It is widely recognized that our systems and standards in the U.S. have yielded the safest and most consistent high-quality drug supply in the world. We too often take this for granted. This is why countries from around the world seek FDA's advice and work with U.S. Pharmacopeia (USP), a global U.S.-based nonprofit organization that convenes independent experts in science, medicine, pharmacy and public health to set quality standards for medicines.

Importing drugs from Canada, through wholesalers and online pharmacies, will not solve our problems, and can even exacerbate them because they pose potential danger to patients and because the system would be economically unsustainable.

We should look closer to home for solutions that can increase access to affordable high quality medicines. A good place to start is with policies that speed access to, and competition among, generic medicines. This will reduce treatment costs for individuals, reduce the financial burden on the overall healthcare system, and free up resources that could be used to address unmet patient needs.

The U.S. Pharmacopeial Convention (USP) is a global health organization that improves lives through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

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