

HEALTH LAW: PEER-REVIEWED ARTICLE

What Should Prescribers and Policy Makers Know About US Drug Importation?

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Abstract

Drug importation raises several ethical and safety concerns relevant to prescribers and policy makers considering costs and benefits of international medicine importation. This article suggests key points to consider, especially from a policy perspective, when weighing imported medicines' perceived affordability and accessibility against additional resource expenditure needed to assure sufficient regulatory oversight and equitable distribution and to mitigate potential risks of harm to patients.

Federal Drug Importation Regulation

The rising cost of prescription drugs poses affordability challenges for both patients and the federal government, with the United States spending more on prescription drugs per capita than other high-income countries.¹ As prices of certain drugs outpace inflation,² the federal government has attempted to curb this trend by using drug importation as a potential policy lever. Since 2003, the US Food and Drug Administration (FDA) has had the legal authority to allow wholesale importation of prescription drugs from Canada, thanks to the Medicare Prescription Drug, Improvement, and Modernization Act passed by Congress.³ In 2020, the FDA and the Secretary of the US Department of Health and Human Services (HHS) issued a rule to implement this provision, thereby permitting the importation of specific prescription drugs from Canada under Section 804 of the Food, Drug, and Cosmetic Act, known as the Section 804 Importation Program (SIP).^{4,5} The aim of the SIP was to “achieve a significant reduction in the cost of covered products to the American consumer with no additional risk to the public’s health and safety.”⁶ However, drug importation raises several ethical and safety concerns, necessitating that perceived affordability and accessibility of imported medications be weighed against their potential risks to patient safety, lighter regulatory oversight, and potential for inequitable distribution.

SIPs

Implementing a SIP requires SIP sponsors (states) not only to create their own importation program but also to submit it to the FDA for approval prior to proceeding with implementation. A state’s proposal must list specific, eligible prescription drugs for the SIP; identify a Canadian foreign seller to procure directly from manufacturers; and

designate a US importer that will buy the drug directly from the foreign seller.⁴ Since the rule establishing the SIP went into effect, several states—including Vermont, Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas, and Wisconsin—have passed laws allowing them to submit SIP proposals to the FDA for approval, and 6 of them have submitted proposals and are awaiting FDA approval.^{7,8} Designing a state-operated program that can guarantee adherence to FDA standards regarding authenticity, purity, potency, and lack of adulteration⁹ while still achieving cost savings for consumers is a challenge.

Since the rule took effect, only Florida's SIP proposal has been approved by the FDA,¹⁰ casting doubt on the likelihood of such approval in the future. Despite its intent to reduce drug costs without compromising public safety, the rule has aroused concerns about potential risks to public health that have been repeatedly emphasized by the FDA and public health leaders from both political parties.¹¹ Supporters of drug importation argue that circumstances have changed since the authority was granted,⁶ but, unfortunately, risk of counterfeit products entering the supply chain remains.

Counterfeit Drug Risks

The process proposed by the FDA in the 2020 final rule requires the cooperation of Canadian suppliers for drug importation. However, considering that Canada has a population of only 38.9 million,¹² one-tenth that of the United States, the National Association of Pharmacy Regulatory Authorities in Canada deems it improbable for the Canadian pharmaceutical market to absorb the substantial drug demand from the United States.¹³ One study estimated that US importation of 46 Canadian drugs would exhaust supplies for most of them in less than 3 months.¹⁴ Importantly, the combined population of 5 states—Florida,¹⁵ Vermont,¹⁶ Maine,¹⁷ New Mexico,¹⁸ and Colorado¹⁹—that have passed importation legislation exceeds 30 million people, which is more than 80% of Canada's total population. The Canadian government vehemently opposes US federal and state action that encroaches on its drug supply, contending that such policy could exacerbate Canada's chronic **drug shortage problem** and jeopardize the health of Canadians.²⁰ In fiscal year 2019 to 2020, shortages affected nearly a third of all the prescription medicines sold in Canada,²¹ with 2700 drug shortages in fiscal year 2022 to 2023.²² These shortages hit consumers, as a 2018 national survey published by the Canadian Pharmacists Association revealed that 1 in 4 Canadians had either personally experienced or knew someone who had faced a drug shortage in the past 3 years.²³ Canada's drug shortages raise concerns about equity and fairness in the global distribution of pharmaceuticals, as importing countries like the United States could inadvertently reduce the availability of drugs in countries where they are manufactured or originally intended for sale.

In addition to exacerbating drug shortages in Canada, allowing drug importation from Canada could potentially open the way for counterfeit drugs to enter the US market. Canada has acknowledged its inability to monitor the safety of medicines destined for the United States,²⁴ placing the responsibility on American authorities to ensure the safety of imported drugs. US law enforcement^{25,26} has already come out in opposition to drug importation, highlighting that the influx of drugs from other countries would only shift costs and burden to law enforcement while simultaneously increasing the risk of illegitimate products entering the country. While some might believe that limiting imports to drugs manufactured in Canada enhances safety for US consumers, in reality, drugs labeled as *from* Canada could originate from any country and pass through Canada during shipment to the states. Canadian law permits the "transshipment" of

drugs from many countries, including from those with lower regulatory standards.²⁷ These countries might not have a Mutual Recognition Agreement with Canada to ensure reliance on its regulatory system for prescription medicines. Importing drugs from foreign countries thus effectively bypasses the regulatory oversight and approval processes and raises concerns about the government's ability to ensure the safety, efficacy, and proper labeling of imported drugs.

Leading Patients to the Internet

Approval of the drug importation rule has erroneously led consumers to believe they can obtain their medications from online pharmacies, despite the rule explicitly prohibiting it.²⁸ Significantly, 96% of online pharmacies on the National Association of Boards of Pharmacy® Not Recommended List do not require a valid prescription.²⁹ Moreover, the IQVIA Institute for Human Data Science estimated that 12.6% of adverse events from 2017 to 2022 could have been avoided had all drugs purchased from illegal online pharmacies instead been purchased legally.³⁰ These adverse events contributed an additional \$67 billion in costs to the US health system and resulted in an estimated loss of \$34 billion for legitimate pharmaceutical businesses in 2022.³⁰ While the US government can and does take action against illegal online pharmacy operators within its borders, its jurisdiction ends there. Although there have been instances in which foreign jurisdictions collaborated with the United States on enforcement actions, many international criminal internet drug sellers continue to evade capture.^{29,31,32}

An illustrative example of collaborative enforcement is a 2015 case involving Canadadrugs.com. In this particular case, the US Department of Justice brought charges against companies and individuals affiliated with Canadadrugs.com for smuggling \$78 million worth of mislabeled, unapproved, and counterfeit cancer drugs into the United States.^{33,34} To expand its operations to physicians' offices in 2009, the company reportedly utilized subsidiaries based in Barbados and the United Kingdom (UK).³⁵ These subsidiaries, along with the parent company, allegedly shipped illegally imported medicines through the UK to drop shippers situated at 3 US locations. Of the 14 defendants, only 1 was based in the United States.³⁴ To apprehend the remaining 13 defendants located in different countries, law enforcement sought the cooperation of foreign nations through extradition treaties. The company's website closed in 2018,³⁶ and the founder of the company received a relatively lenient sentence,³³ which many perceive as an insignificant consequence for the company's actions.

Cost Savings?

While drug importation can be perceived as a means to address high drug prices and access, it might not necessarily lead to sustainable, long-term solutions and could potentially undermine policy efforts to address pricing and access issues by diverting attention from systemic reforms within the health care system. The rule establishing SIP explicitly states that the potential cost savings from drug importation could not be estimated,⁴ and previously the Congressional Budget Office had concluded that importation policy would "produce at most a modest [cost] reduction."³⁷ The idea of accessing cheaper drugs from Canada might seem straightforward, but the actual importation process incurs additional costs such as packaging, testing, shipping, and compensation for intermediaries, which ultimately add to the price.

Costs and cost savings are also relative. In a 2017 interview, George Karavetsos, the former head of the FDA's Office of Criminal Investigation, emphasized that implementation costs of state importation programs' compliance with FDA standards

would be substantial.³⁸ In particular, he highlighted that the significant budget allocated to FDA enforcement and inspection initiatives would be extremely difficult for a state to replicate and for a state budget to absorb. Moreover, despite US buyers initially being able to obtain Canadian medication at a reduced cost, there is no measure preventing a US importer from marking up the price of the medicine and keeping the surplus instead of passing on the savings. In light of these factors, non-US supply chains for medicines pose challenges and might not be justifiable.

Upshots About Law and Supply Chain Safety

The Drug Supply Chain Security Act (DSCSA),³⁹ enacted in 2013 and still undergoing implementation, establishes stringent requirements for trading partners to enable the tracking and tracing of prescription drugs from manufacturers to distributors and finally to pharmacies. This system enables regulators and trading partners to successfully thwart the infiltration of counterfeit ingredients and drugs into the drug supply. However, drug importation compromises protections outlined in the DSCSA by allowing foreign prescription drug packages alongside FDA-approved products.

While ensuring access to affordable medications remains a global priority for patients, this objective should never compromise patient safety. Policy decisions related to prescription medications and public health should prioritize drugs' quality, safety, and legitimacy. Drug importation as a policy fails to address the root causes of drug pricing and accessibility in the United States and instead introduces new health risks, which directly contradict the evidence-based approach followed by the FDA and the Department of Health and Human Services since 2000.^{40,41} Importing prescription drugs from Canada not only weakens the existing controls in the historically safe pharmaceutical supply chain, but also misleads consumers by wrongly suggesting the safety of drugs sourced from other countries.

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