

The Risks of Parallel Trade of Prescription Medicines between Canada and the United States

By Canada Institute Staff

For every complex problem there is a solution which is clear, simple and wrong.

– H.L. Mencken

Overview

The importation of prescription medicines in large quantities from Canada into the United States has become a hot topic, with several proposals in the United States at both the federal and state levels to open up the market to allow bulk shipment imports. This special report examines the issue primarily through the lens of trade policy, highlighting the risks posed to consumers and regulators on both sides of the border if such proposals are allowed to move forward.

Although currently illegal, American politicians across the political spectrum are pushing to make cross-border sales legal in response to high drug prices in the United States.¹ Already Canadian decisionmakers are sounding the alarm over American plans to open up bulk shipments.²

It is important to distinguish between the common place practice of individuals purchasing medicines for their own individual needs (by crossing the border in person or through online pharmacies) versus proposals to allow importation for the entire American market (roughly ten times the size of Canada's). Concerning the former, this practice is not new. In the early 2000s, many Americans, especially older adults, crossed into Canada to purchase prescription medicines or ordered them online. Concerns were raised then about potential

1 Sarah Owerhohle and Alexander Panetta, «[Canadian shelves 'would run dry' if U.S. imports drugs](#),» *POLITICO*, (February 21, 2019).
2 Allison Martell, «[Exclusive: Canada warns U.S. against drug import plans, citing shortage concerns](#),» *Reuters*, (July 18, 2019).

shortages in Canada.³

The U.S. Food and Drug Administration (FDA) has a policy explaining that it typically doesn't object to the personal import of pharmaceutical medicines under certain circumstances (e.g. when the medicine treats a condition where effective treatment is not available in the United States, or when there is no commercial supply of the drug in the United States).⁴

Different regulatory and funding regimes for pharmaceuticals lead to differences in pharmaceutical prices. Though pharmaceutical prices are difficult to compare across jurisdictions for a number of reasons (e.g. not all countries have the same drugs, different dosage amounts, different consumption levels, variable confidential discounts across payers, etc.), prices in the United States are generally higher than in comparable countries.⁵ A 2015 study conducted for Reuters uncovered that U.S. prices for the world's 20 top-selling medicines were, on average, three times higher than in Britain and were consistently higher than in other European markets.⁶ In North America, single-source patented prescription medicines in Canada are often much lower in price than the same products in the United States.

At the time of writing, in the United States there are five federal bills in Congress each with the aim of facilitating pharmaceutical drug imports from Canada (and other countries in some cases). 13 states are either considering or moving ahead with their own legislation. Some of these bills focus on allowing wholesalers and pharmacies to import, others are narrower and cover individual purchases only.

The Risks of Parallel Trade

Parallel trade refers to instances when a good that is sold in one jurisdiction for a low price is re-exported to another jurisdiction where it sells for a higher price. While this may seem to solve a problem by providing a lower cost solution to the individual in the high-cost jurisdiction, in practice it can lead to unintended consequences particularly when undertaken on a large scale.

Recent experience in the European Union illuminates the negative implications of parallel trade in the context of pharmaceutical medicines. In 2018, Italy faced continued drug shortages that were attributed to the fact that the drugs were being diverted to Northern Europe where they could fetch higher prices.⁷ Greece too has had several instances of national drug shortages linked to parallel trade.⁸ In instances where companies limit the distribution of a particular type of medicine, this can lead to shortages and public health crises if the limited supply of product

3 Nigel S.B. Rawson and Louise Binder, «[Importation of drugs into the United States from Canada](#),» (June 19, 2017).

4 U.S. Food & Drug Administration (FDA), «[Is it legal for me to personally import drugs?](#),» (March 28, 2018).

5 John R. Graham, «[Prescription Drug Prices in Canada and the United States—Part 4](#),» *Fraser Institute*, (September 2003).

6 Ben Hirschler, «[Exclusive: Transatlantic divide: how U.S. pays three times more for drugs](#),» *Reuters*, (October 12, 2016).

7 *APM Health Europe*, «[Parallel trading most likely cause of Italy's continuing drug shortages](#),» (July 13, 2018).

8 Annalisa Merelli, «[Greece's next big problem: medicine shortages](#),» *Quartz*, (July 7, 2015).

is exported to higher-value jurisdictions.⁹

A study into the reasons behind medicine shortages in Finland determined that the three most common reasons are: the small size of the market, sudden or fluctuating demand, and small stock sizes.¹⁰ Considering this in the North American context, it is easy to see how a sudden increase in U.S. demand could overwhelm the Canadian system.

For Canada, as the lower cost jurisdiction in the equation, the risks are real. Manufacturers assess a number of factors when making supply and price decisions for a particular market, and population is an important consideration. Large-scale U.S. imports of Canadian drugs would not likely not be factored into inventory supply decisions by major pharmaceutical companies, thus putting Canadians at risk of finding empty shelves for the medicines they are seeking. As former Canadian Minister of Health Leona Aglukkak stated “I am greatly concerned that excess demand from American consumers would siphon off Canada’s domestic supply of essential drugs, particularly for Canadians in remote communities...”¹¹

Intertwined with supply impacts are implications for Canadian prices. Stephen Gliberman of Western Washington University notes that “if Americans were legally allowed to import prescription drugs from Canada, it would certainly drive up the cost of those drugs for Canadians.”¹² U.S. spending on prescription drugs is more than 10 times the amount Canada spends.

The Canadian system – with regulatory oversight from the federal and provincial governments, pharmacy colleges and pharmacy regulators, and well-established distribution models – provides an orderly management system to meet the prescription medicine needs of Canadians. It was not designed with the idea of Canada acting as a shopping centre for non-domestic prescription drug demands. Regulators in both countries fear that an expanded role for online pharmacies could increase the incentives for nefarious actors to push illegal or ineffective drugs into the Canadian supply chain.

Intellectual Property Regimes and Parallel Trade

Another risk from the trade policy perspective is the protection of patents and other intellectual property (IP). Patents are territorial rights, and Canada and the United States maintain separate IP regimes with certain distinct terms and conditions. Potential differences in periods of protection for patents and other IP could lead to increased instances of infringement. Among other issues, high volumes of U.S. demand, as well as high volumes of drugs passing through Canada

9 Joan Costa-i-Font, «[Parallel trade in medicinal drugs is putting the welfare of EU patients at risk](#),» *The London School of Economics and Political Science*, (March 20, 2015).

10 Kati Heiskanen, Riitta Ahonen, Risto Kanerva, Pekka Karttunen, and Johanna Timonen, «[The reasons behind medicine shortages from the perspective of pharmaceutical companies and pharmaceutical wholesalers in Finland](#),» U.S. National Library of Medicine National Institutes of Health, (June 27, 2018).

11 Leona Aglukkaq, «[Dear Bernie Sanders : Canada is not the United States’ drugstore](#),» *The Washington Post*, (May 12, 2017).

12 *The Fraser Institute*, «[Americans want prescription drugs from Canada](#),» (April 18, 2019).

from third-country sources, creates unmanageable demand on regulators and inspectors, increasing the likelihood of counterfeit medicines entering the supply chain in both countries.

While Canada and the United States share many regulatory similarities and aligned standards, at present the Canadian system is designed to inspect drugs for its own citizens. With a U.S. population ten times the size of Canada's, Canadian authorities "wouldn't have the ability or resources to inspect medicines destined for the United States."¹³

The U.S. FDA strongly discourages the importation of drugs from Canada, because they can't ensure they are safe. The FDA's capacity to monitor and administer a large-scale importation program is limited and the possibility of fraud is high.¹⁴ In 2017, the FDA determined that 85 percent of the drugs sold by supposedly Canadian pharmacies originated from 27 countries other than Canada.¹⁵

National health care systems develop in a particular context based on a country's public policy priorities and a considerable investment of taxpayer dollars. National and sub-national health systems have unique norms, standards, and procedures and it is not feasible for one country to simply tap into one channel of another country's health care services. Especially when one country is so much larger, the influx of imported demand could topple the smaller country's system (Canada's population is roughly comparable to that of California's).

Canada and the United States are each other's largest trading partners in goods and services. Most of this trade is governed by the North American Free Trade Agreement (NAFTA) and its soon-to-be successor agreement the United States-Mexico-Canada Agreement (USMCA), using principles consistent with the World Trade Organization (WTO). Most global trade agreements contain provisions that encourage liberalized trade but also provide exceptions so that countries are not compelled to trade if doing so would violate some fundamental public policy objective. The WTO articulates these [exceptions](#) as those that are necessary for the protection of human, plant and animal life or health.

NAFTA similarly allows countries to take various protective actions in the interest of public health. USMCA goes even further, containing [specific language](#) enshrining a country's access to medicines. While these rules will generally be used to ensure that patent protections are not overly restrictive, they also reinforce Canada's right to take action to ensure that Canadians prescription medicine inventories are not depleted.

The United States and Canada have different health care systems but the two are not incompatible. There are steps the two countries can take that avoid the risks of the importation schemes outlined in this briefing note. There are important opportunities for collaboration between the two countries to bring new drugs to

13 Aglukkaq, (2017).

14 Oweremohle and Panetta, (2019).

15 U.S. Food and Drug Administration, «[FDA Operation Reveals Many Drugs Promoted as 'Canadian' Products Really Originate From Other Countries.](#)» (December 16, 2005).

market faster, fund research and development, and share information with the aim of strengthening overall quality of health care in both countries.¹⁶

A final point that is often lost in U.S. characterizations of the issue is that there is virtually no support for drug re-exportation proposals in Canada. Aside from a few prospective licensees who could benefit financially from re-exportation schemes, there are no constituencies of support among Canada's drug manufacturers, regulators, health care providers or Canadian voters and consumers. For this reason, it is highly unlikely the political or institutional resources (funded by taxpayer dollars) will be used to expedite the changes proposed by the United States.

Summary

It is hard to watch news stories that show chronically ill Americans crossing the Canadian border by bus to purchase needed medications and not think there must be some way to make allowances for certain individuals. However, opening up the process for just a few is not fair to those who need medicines and can't make the trip to Canada. PhRMA, the main group representing pharmaceutical manufacturers in the United States argues that even limited importation would "circumvent the robust safety requirements we have in United States, posing a serious public health risk and jeopardizing our secure medicine system."¹⁷

What's more, dealing with the problem on an individual or even wholesale basis doesn't address core questions of how best to provide affordable medicines for everyone who needs them. Looking the other way while essentially creating a black market system to import medicines from Canada to the United States only increases the opportunities for fraudulent practices and the spread of fake pharmaceuticals.¹⁸

The rationale for seeking less expensive drugs is understandable but legalizing importation to wholesalers and pharmacies in the United States is at best a band-aid solution, and at worst a policy direction that could hurt both Americans and Canadians.

16 Aglukkaq, (2017).

17 Laurie McGinely, «[Trump administration to explore drug imports to counter price hikes](#),» *The Washington Post*, (July 19, 2018).

18 Ibid.

The Canada Institute

-  wilsoncenter.org/canada
-  canada@wilsoncenter.org
-  facebook.com/Canada.Institute
-  [@CanadaInstitute](https://twitter.com/CanadaInstitute)
-  202.691.4070

Woodrow Wilson International Center for Scholars
One Woodrow Wilson Plaza
1300 Pennsylvania Avenue NW
Washington, DC 20004-3027

