Canadian Health Policy Journal
information and ideas for better healthcare

State importation programs are unrealistic: diverting prescription drugs to American consumers would rapidly deplete the Canadian drug supply

Brett J Skinner

ABSTRACT

Summary: Importation of Canadian drugs as a means of controlling or reducing the cost of providing prescription drugs to Americans has been a recurring political issue for more than 20 years. Differences in Canadian regulated prices and American market prices for patented medicines creates an opportunity for regulatory arbitrage whereby Americans purchase prescription drugs that were intended to be sold from multinational manufacturers through Canadian wholesale distributors and retail pharmacies to Canadian consumers. As of 28 AUG 2024, seven states — Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont — have passed legislation stating their intention to establish State drug importation programs. Five States — Colorado, Florida, Maine, New Hampshire and New Mexico — have submitted proposals to the FDA. In January 2024, Florida's proposal was the first to receive FDA approval. Despite the policy intentions of these proposals, the rapid depletion of the Canadian drug supply from U.S. arbitrage-related prescription drug imports will cause the Canadian government to ban the export of drugs that were intended to be sold on the Canadian market. This reality shows the futility of efforts by American proponents to legalize and facilitate arbitrage-related prescription drug imports of prescription drugs from Canada. This study estimates the impact that U.S. arbitrage-related prescription drug imports will have on the Canadian supply of a sample of medicines that are likely to be targeted by American States represented by the prescription drugs listed for arbitrage-related prescription drug imports by the States of Colorado and Florida. The analysis demonstrates how long it will take to exhaust the entire Canadian supply of these drugs under the full weight of consumer demand from the United States.

Authors credentials and affiliations: Brett J Skinner PhD, is the Founder and CEO of Canadian Health Policy Institute (CHPI) and the Editor of Canadian Health Policy Journal.

Disclosure: Funding for the study was received from Innovative Medicines Canada and the Pharmaceutical Research and Manufacturers of America.

Acknowledgements: the French language version of this paper was translated by Yanick Labrie.

Status: Peer reviewed.

Submitted: 10 SEP 2024 | **Published**: 28 OCT 2024

Citation: Skinner, Brett J. (2024). State importation programs are unrealistic: diverting prescription drugs to American consumers would rapidly deplete the Canadian drug supply. *Canadian Health Policy*, OCT 2024. https://doi.org/10.54194/PGGO7479. canadianhealthpolicy.com.

POLICY ISSUE

Canadian prices for patented medicines (aka. innovative branded prescription drugs) are regulated by the federal government and are significantly lower than American market prices on average. [PMPRB 2024] The difference in drug prices between the markets creates an economic incentive for regulatory arbitrage, whereby Americans import prescription drugs that were originally intended to be sold in Canada to Canadian patients. However, arbitrage-related importation (generally referred to as "importation") on a commercial scale has not been legally permitted in the United States due to concerns of the U.S. Food and Drug administration (FDA) about its capacity to ensure the safety and effectiveness of products sold through foreign resale channels. Recent policy changes in the United States have approved legal pathways to allow the commercial scale resale importation of prescription drugs from Canada.

In 2020 the U.S. Department of Health and Human Services (HHS) established the Section 804 Importation Program (SIP) to facilitate arbitrage related prescription drug imports from Canada. On October 1, 2020, HHS issued the final rule to implement section 804(b-h) of the Federal Food, Drug, and Cosmetic Act to allow importation of certain prescription drugs from Canada. Under this final rule, "States and Indian Tribes" may submit importation program proposals to the FDA for review and authorization. The final rule requires the sponsor to demonstrate that their importation program will pose no additional risk to the public's health and safety and will result in a significant reduction in costs to the American consumer. [FDA 2022, HHS 2024].

As of 28 AUG 2024, seven states — Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont — have passed legislation to establish State drug importation programs. TABLE 1 shows the status of these programs. Five States — Colorado, Florida, Maine, New Hampshire and New Mexico — have submitted proposals to the FDA. In January 2024, Florida's proposal was the first to receive FDA approval. [NCSL 2024]

TABLE 1. Status of prescription drug importation in the seven States that have legislated programs as of 28 AUG 2024.

STATE	PROGRAM STATUS
Colorado	SIP submitted to FDA in 2022 and was denied. Resubmitted FEB 2024. Revised SIP submitted AUG 2024.
Florida	SIP submitted to FDA in 2020. FDA authorized in JAN 2024.
Maine	SIP submitted to FDA in 2020. Awaiting FDA approval.
New Hampshire	SIP submitted to FDA in 2021 and was denied.
New Mexico	SIP submitted to FDA in 2020. Returned by the FDA for unresolved deficiencies in 2021.
Texas	Texas has not yet submitted an SIP proposal to FDA.
Vermont	Concept paper submitted to HHS and Office of Management and Budget in 2020.

SOURCE: [NCSL] National Conference of State Legislatures. (2024).

PRESCRIPTION DRUGS STUDIED

This study estimates the impact that U.S. arbitrage-related prescription drug imports will have on the Canadian supply of a sample of medicines that are likely to be targeted by American States represented by the prescription drugs listed for arbitrage-related prescription drug imports by the States of Colorado and Florida. The analysis demonstrates how long it will take to exhaust the entire Canadian supply of these drugs under the full weight of consumer demand from the United States.

Prescription drugs that were listed under the State importation plans in Colorado and Florida were identified from the proposal documents submitted by each State to the FDA [Florida 20 OCT 2023, Colorado 07 FEB 2024].

IQVIA MIDAS pharmaceutical quarterly value (in USD) and volume sales data (in Standard Units) for 27 brands in the period January to December 2023 was used for this study. IQVIA MIDAS is an IQVIA proprietary information service which integrates IQVIA's national audits into a globally consistent view of the pharmaceutical market, and provides estimated product volumes of registered medicines, trends and market share through retail and non-retail channels.

Data were available by equivalent definition at the national level in both Canada and the United States. State level data is not available in IQVIA MIDAS data. All the drugs studied were authorized for marketing by Health Canada before 2023 and the study assumes the volumes reflect a full year of sales from January 1 to December 31, 2023.

TABLE 2 shows a summary count of the prescription drugs identified for importation. In Colorado, the State government approved 18 branded drugs across 24 dosage strengths. The corresponding numbers for Florida were 14 branded drugs across 24 dosage strengths. Combining both State lists there were 27 distinct branded drugs, with five drugs being common to both lists, and 22 drugs being exclusive to one State or the other.

TABLE 2. Summary count of Florida and Colorado list of prescription drugs from the State importation proposals.

STATUS	NUMBER OF BRANDED DRUGS
Listed in Colorado	18
Listed in Florida	14
Total Distinct	27
Common to 2-States	5
Exclusive to 1-State	22

SOURCES: The State of Florida; The Colorado Department of Healthcare Policy and Financing.

MARKET SIZE

Current (July 1, 2023) population data from Statistics Canada (national) were used to calculate and compare the size of the United States and Canadian markets. TABLE 3 summarizes the population data at the State level for the seven states that have legislated their intention to establish an SIP, and at the national level for the United States and Canada.

The population of Florida was 22.6 million in 2023 or 6.8% of the entire United States population of almost 335 million. Corresponding population numbers for Colorado were 5.9 million or 1.8% of the national population, Maine and New Hampshire 1.4 million (0.4%) each, New Mexico 2.1 million (0.6%), Texas 30.5 million (9.1%), and Vermont 0.6 million (0.2%). The combined populations of these seven states total almost 65 million or 19.3% of the American national population. Comparable population numbers from Canada were nearly 41 million or 12% of the United States population.

TABLE 3. Population comparison, July 1, 2023.

JURISDICTION	POPULATION	PERCENT OF U.S.
United States	334,914,895	100.0%
Florida	22,610,726	6.8%
Colorado	5,877,610	1.8%
Maine	1,395,722	0.4%
New Hampshire	1,402,054	0.4%
New Mexico	2,114,371	0.6%
Texas	30,503,301	9.1%
Vermont	647,464	0.2%
7 States Total	64,551,248	19.3%
Canada	40,097,761	12.0%

SOURCES: U.S. Census Bureau; Statistics Canada.

The population of the seven States exceeds the entire population of Canada by 62%. At the national level, American consumers outnumber Canadian consumers by a ratio of more than 8 to 1.

TABLE 4 shows the drugs that are listed for the Colorado and Florida State importation programs. For each of the 27 drugs, data on the quantity of standard dosage units sold in Canada, the United States, and estimates for the seven States are shown. Two (RAVICTI and TRIKAFTA) of the 27 listed drugs showed no Canadian sales in 2023 and were therefore deemed not to be available in Canada during the study. Volumes of standard units sold in 2023 are presented in thousands.

Canada had volumes ranging from 17 thousand standard dosage units sold in 2023 for the brand drug SYMTUZA to over 124 million standard dosage units sold for JANUVIA. Corresponding volumes in the United States were more than 10 million for SYMTUZA and over 364 million for JANUVIA.

RAPID DEPLETION OF CANADIAN DRUG SUPPLY

To illustrate the magnitude of the threat to Canada's medicine supplies from drug reimport policies in the United States, the full national weight of the potential demand for these drugs from American consumers is applied. The analysis assumes the daily demand from Americans for Canadian sourced drugs is equally weighted to the average per day. Sales to consumers

would normally be expected to fluctuate daily. The analysis excludes concurrent Canadian demand because the price premium paid by American buyers would incentivize Canadian retailers and wholesalers to divert the entire drug supply.

TABLE 4 displays the calculated data for the number of days to exhaust the Canadian stock of the 27 brand drugs identified in the Colorado and Florida State importation plans. The aggregate results showed that the number of days to exhaust the normal Canadian stock of the 25 drugs that were available in Canada, ranged from one day for SYMTUZA to 219 days for OZEMPIC.

If all 50 States had implemented a program (as of January 1, 2023) to import the same 27 patented drugs listed in the State importation plans of Florida and Colorado, 72 percent (18 of 25 drugs available in Canada) would experience supply exhaustion in about two months or less. About 40 percent (10) would be exhausted in 2.5 weeks or less. On average across all 25 drugs, the supply of these medicines would be depleted in 57 days. The results are illustrated in CHART 1.

MANUFACTURERS' RESPONSE

The rationale for state importation programs is based on a false assumption that manufacturers will passively increase supply to the Canadian market to accommodate arbitrage-related demand from U.S. consumers. Manufacturers estimate the potential demand for their products prior to launching in any market, and post marketing sales data provide historical trends. Increases in demand for their products that vary significantly from the Canadian norms would quickly be identified as arbitrage-related drug imports. Individual manufacturers would likely limit the supply of their products to match their estimates of Canadian demand because arbitrage undermines international price differentiation. Diversion of the Canadian drug supply to Americans via importation will therefore result in equivalent shortages for Canadian patients.

CANADIAN POLICY RESPONSE

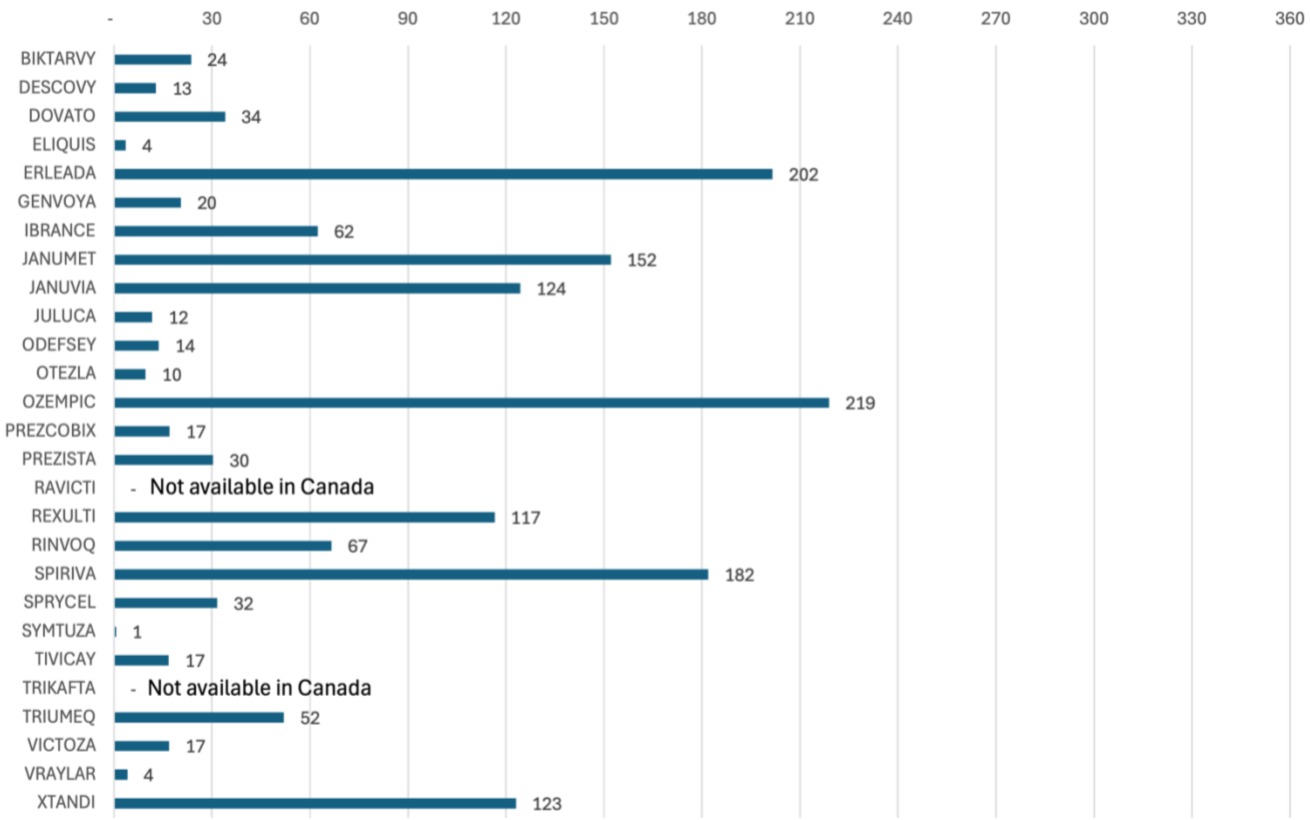
Proponents of State importation programs have also failed to take into consideration the Canadian policy response. The rapid depletion of the Canadian drug supply from U.S. arbitrage-related prescription drug imports will force Canadian governments to ban the export of drugs that were

TABLE 4. Standard dosage units sold in 2023 [n X 1,000]; Number of days to exhaust Canadian stocks.

BRAND DRUG	CANADA	UNITED STATES	DAYS TO EXHAUST CANADIAN STOCKS
BIKTARVY	7,596	117,519	24
DESCOVY	2,129	60,763	13
DOVATO	1,795	19,276	34
ELIQUIS	4,768	487,624	4
ERLEADA	5,938	10,750	202
GENVOYA	1,140	20,354	20
IBRANCE	976	5,710	62
JANUMET	90,299	216,739	152
JANUVIA	124,009	364,044	124
JULUCA	238	7,436	12
ODEFSEY	473	12,604	14
OTEZLA	1,531	57,858	10
OZEMPIC	8,633	14,393	219
PREZCOBIX	1,829	39,110	17
PREZISTA	558	6,725	30
RAVICTI	not available	35	not available
REXULTI	12,897	40,394	117
RINVOQ	3,522	19,297	67
SPIRIVA	73,847	148,176	182
SPRYCEL	230	2,652	32
SYMTUZA	17	10,027	1
TIVICAY	1,093	23,769	17
TRIKAFTA	not available	284	not available
TRIUMEQ	2,435	17,103	52
VICTOZA	411	8,901	17
VRAYLAR	918	81,792	4
XTANDI	6,236	18,503	123

Source: Author's analysis based on IQVIA MIDAS® quarterly volume sales data for calendar year 2023, reflecting estimates of real-world activity.

CHART 1. Days to exhaust Canadian supply under the full national weight of U.S. consumer demand - for the 27 drugs eligible for State importation programs in Florida or Colorado.



Source: Author's analysis based on IQVIA MIDAS® quarterly volume sales data for calendar year 2023, reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.

originally intended for the Canadian market; and to act pre-emptively to prevent events from moving faster than the legislative or regulatory process can respond.

Indeed, in response to the FDA's approval of Florida's drug importation plan, Health Canada issued a statement clarifying the government of Canada's policy.

Paraphrased quote from January 2024 Government of Canada media release:

> *"The Government of Canada is taking all necessary action to safeguard the drug supply and ensure Canadians have access to the prescription drugs they need… Regulations have been implemented under the (Canadian) Food and Drugs Act to prohibit certain drugs intended for the Canadian market from being sold for consumption outside of Canada if that sale could cause, or worsen, a drug shortage in Canada. This includes all drugs that are listed for bulk importation to the U.S., including those identified in Florida's bulk importation plan, or any other U.S. state's future importation programs. Health Canada is actively monitoring the Canadian drug supply and continues to ensure that Canadians have access to the drugs that they need. The Department has informed regulated parties of their obligations under Canadian regulations, including the requirement to not distribute a drug to another person for consumption or use outside Canada unless the person holding the licence has reasonable grounds to believe that the distribution will not cause or worsen a shortage of the drug in Canada and has retained detailed records of the information relied upon to make that determination. The Department will not hesitate to take immediate action to address non-compliance, ranging from requesting a plan for corrective measures, issuing a public advisory or other forms of communication, to taking action on the licenses of regulated parties who contravene the export prohibition if warranted." [Health Canada 2024]*

SUPPLY CHAIN EROSION OF PRICE SAVINGS

Regulatory arbitrage depends on another false assumption that American buyers would pay the same prices as Canadian buyers because Canadian prices for patented prescription drugs are capped by regulation. Under arbitrage-related demand from State importation programs the price gap between Canadian and American drug products would mostly disappear. Price mark-ups imposed by actors in the supply chain would erode the anticipated savings. This is because there is no regulatory control of prices on sales from Canadian manufacturers, wholesale distributors or retail pharmacies to American buyers.

The Canadian government only regulates the ceiling prices of prescription drugs that are under active patent protection, and the target of regulation is the manufacturer's list price. Canada does not regulate wholesale or retail pharmacy price mark-ups. Federal, provincial and territorial governments do impose caps on price mark-ups and pharmacy dispensing fees on prescriptions reimbursed by the public drug plan in their respective jurisdictions, but mark-ups and fees are subject to market pricing on private sales.

Further, Canada's price controls only apply to domestic transactions, i.e., prescriptions sold to Canadians within Canada. There is no legislation or regulation preventing market pricing on exports, or on wholesale or retail sales, or pharmacy dispensing fees pertaining to sales to non-Canadian buyers or pertaining to sales of Canadian sourced products where the transaction takes place outside of Canada.

Realistically, it is almost certain that Americans would be charged prices that are only marginally below American prices but well above Canadian regulated prices. Prices paid by importers must be higher than the Canadian regulated price ceiling to incentivize Canadian wholesalers and pharmacies to prioritize sales to Americans. The profit motive would incentivize Canadian suppliers to capture as much of the price difference as the market could bear.

CONCLUSION

The findings of the study are consistent with previous research. [Shepherd 2010, 2018, 2019; Skinner 2019] It is not possible to supply Americans with prescription drugs through arbitrage-related importation from Canada. At the national level, American consumers outnumber Canadian consumers by a ratio of more than 8 to 1. Under an hypothetical 2023 scenario, U.S. demand would deplete the Canadian stock of the medicines in this study within 57 days on average.

Manufacturers will not over-supply the Canadian market to accommodate arbitrage related importation. The Canadian government stated it will take all measures including banning exports in response to State-scale importation. Even in the absence of the counter actions from manufacturers and the Canadian government, it is very unlikely that the State importation programs will be able to generate the significant savings to consumers required by the FDA for approval of their programs because of supply chain erosion of the price differential.

Proponents of State importation programs are acting on the incorrect notion that pharmaceutical companies are price gouging American consumers. The truth is less convenient: Americans tend to pay the highest prices in the world for patented prescription drugs partly because other countries are taking a free ride on the global cost of pharmaceutical innovation. Price controls undermine the 'fair share' distribution of R&D costs that would occur under market pricing. In the absence of price controls, average prices in each market would naturally adjust to match local price-income elasticity, with the result that international prices would rise relative to American prices.

The Canadian experience with price controls strongly suggests that the 'free ride' on the cost of pharmaceutical innovation comes with its own costs in terms of reduced availability of new drugs. The data show that two drugs (RAVICTI, TRIKAFTA) were not available in Canada during the 2023 study period. Data from another study showed that Canada was a low priority market for new drug launches. The number of new drug applications submitted in Canada from 2018 to 2023 was only 54% of the number launched in the United States during the same period. [CHPI 2024]

Despite being presented by some as a market-based policy, State drug importation programs are not consistent with free-trade and are more accurately identified as regulatory arbitrage induced by price regulation in other countries. The most effective way for Americans to reduce the cost of innovative medicines is to require trading partners to remove anti-free trade policies like price regulation.

REFERENCES

Canadian Health Policy Institute (CHPI) (2024). Waiting for new medicines in Canada, Europe, and the United States 2018-2023. Canadian Health Policy, APR 2024. ISSN 2562-9492 https://doi.org/10.54194/QQVC3893, canadianhealthpolicy.com.

Colorado (2024). The Colorado State Importation Program: Section 804 Importation Plan. The Colorado Department of Healthcare Policy and Financing (February 7, 2024).

Florida (2023). The State of Florida's Section 804 Importation Program (SIP) Proposal for the Importation of Prescription Drugs from Canada. October 20, 2023.

Health Canada. (January 8, 2024). Statement from Health Canada on FDA decision on Florida bulk drug importation plan.

[NCSL] National Conference of State Legislatures. (2024). https://www.ncsl.org/health/state-drug-wholesale-importation-programs.

Patented Medicine Prices Review Board (PMPRB). (2024)

Shepherd M. (2019). New pathways for U.S. importation threaten Canadian prescription drug supply. Canadian Health Policy, September 2019. canadianhealthpolicy.com. | Shepherd M (2018) U.S. Drug Importation: Impact on Canada's Prescription Drug Supply. Health Econ Outcome Res Open Access 4: 146. | Shepherd M. The Effect of U.S. Pharmaceutical Drug Importation on the Canadian Pharmaceutical Supply. Canadian Pharmaceutical Journal, Vol 143, No.5, September/October 2010, 226-232.

Skinner, Brett J. (2019). Potential impact of U.S. demand on the Canadian supply of 46 prescription drugs. Canadian Health Policy, September 2019. canadianhealthpolicy.com.

Statistics Canada (February 2024). Table 17-10-0005-01 Population estimates on July 1, by age and gender.

U.S. Census Bureau, Population Division (December 2023). Annual Estimates of the Resident Population for the United States, Regions, States, District of Columbia, and Puerto Rico: April 1, 2020 to July 1, 2023 (NST-EST2023-POP).

U.S. Congress. (2017). Improving Access to Affordable Prescription Drugs Act, H 1776, 115th Cong, 1st Sess (2017-1018). Affordable and Safe Prescription Drug Importation Act, H 1245, 115th Cong, 1st Sess (2017-1018). Affordable and Safe Prescription Drug Importation Act, S 469, 115th Cong, 1st Sess (2017-1018).

U.S. Food and Drug Administration (FDA). (2022). Importation of Prescription Drugs Final Rule - Questions and Answers Guidance for Industry.

U.S. Department of Health and Human Services (HHS) (2020). Food and Drug Administration. 21 CFR Parts 1 and 251 [Docket No. FDA-2019-N-5711] RIN 0910-AI45. Importation of Prescription Drugs. https://www.hhs.gov/sites/default/files/importation-final-rule.pdf.]