The Partnership for SAFEMEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

Analysis of Texas H.B. 25: Foreign Drug Importation

Shabbir Imber Safdar, Executive Director, Partnership for Safe Medicines
March 20, 2023

Partnership for Safe Medicines is a twenty-year-old not-for-profit that accepts no corporate members or donations. Our members are other nonprofits and trade associations that represent manufacturers, wholesalers, pharmacists, and patients—everyone that touches medicine from the factory floor to the patient.

We study, educate, and advocate for pharmaceutical supply chain safety focusing on policies that reduce the threat of counterfeits in the American drug supply. That includes regulations around pill presses, training and resources for law enforcement to recognize counterfeit drugs and counterfeit drug traffickers, and policies that weaken or strengthen the supply chain.

H.B. 25 would require Texas' Health and Human Services Commission to design a program for bulk importing prescription medicines under 21 USC 384 of the U.S. Food, Drug, and Cosmetics Act, more commonly known as a Section 804 State Importation Program (SIP). Below, we outline the many reasons this proposal is unsafe and unworkable.

The Legislation Allows Importation From Literally Any Country

Initially, it's worth pointing out that a provision of the legislation allows importation from any country in the world if the federal regulators allow it. This seems unwise, as that would include the country of Mexico, whose criminal cartels are currently flooding America with tens of millions of fake pills containing fentanyl that have killed tens of thousands of Americans in just the last 12 months.

Bulk Canadian Drug Importation Programs Do Not Save Money Once Legally Required Safety Testing Costs Are Factored In

Many states have abandoned bulk Canadian importation plans because they have been unable to demonstrate savings after accounting for the costs of running the program.

Testing costs, which are crucial to protect the public from counterfeits, are a big factor in the economic model of these programs. If you conduct the testing the statute requires, the entire price difference vanishes. Colorado College economist Dr. Kristina Acri modeled the cost of testing some commonly named medicines for importation and found that the cost of required drug safety testing alone eats up all the cost savings. This doesn't include the additional costs of relabeling, repackaging, or inspections.

Bulk Canadian Drug Importation Programs Do Not Save Medicaid Programs Money And Imported Drugs Do Not Qualify For Rebates

Wyoming and Maine found that **340B and Medicaid programs cannot save money with Canadian importation because they already get better pricing than Canadian provinces do**. Maine's Medicaid program estimated that importing Canadian drugs would cost the state $900,000 more per year than existing program costs, and that was before considering the costs of safety testing.

Maine's Medicaid program estimated that importing Canadian drugs would cost the state $900,000 more per year than existing program costs, and that was before considering the costs of safety testing.

Additionally, the Center for Medicare and Medicaid Services has determined that medicines imported from Canada do not qualify for Medicaid rebates, (September 25, 2020).

The Partnership for SAFEMEDICINES.org®

WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

The Partnership for SAFEMEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

Canada Has Blocked Bulk Exports of Its Medicine

Any state seeking to import prescription drugs from within the Canadian drug supply chain would need Canada to be a willing participant. **Canada is not willing or able to inspect medicines or vendors for the purpose of exporting to Texas (or any other U.S. state) because they view bulk exports as a threat to their citizens' access to medicine.**

Canada is so strongly against this program **they have taken steps to block exports with federal regulations**. In 2019, representatives of the Canadian embassy notified the White House they would not cooperate with drug importation programs. In November 2020, Health Canada and the federal government enacted permanent restrictions on the bulk export of Canadian pharmaceuticals. Canada enacted these regulations because they don't make most of their medicine and have been experiencing crippling drug shortages for years.

In addition, the U.S. population of 331 million people is nine times the size of Canada's, and while the state of Texas itself has a smaller population (roughly 30 million), Canada recognizes such a program as that proposed in H.B. 25 has the potential to deplete Canada's supply of prescription medicines within six months of implementation. Canada will act on the perceived threat to its limited drug supply by any U.S. state to protect its own citizens.

Canadian Prescription Drug Importation Breaks FDA's Track-and-Trace

H.B. 25 specifically states that Canadian suppliers and eligible importers participating in an importation program can only import "safe and effective" prescription drugs that "comply with the tracking and tracing requirements" of the Drug Supply Chain Security Act (DSCSA). Unfortunately, **Canada does not have a track-and-trace system for any medical products, meaning any drug imported would automatically break track-and-trace** and, therefore, be in violation of Texas' own legislative requirements.

Asking a potential vendor to add an identifier onto a bottle when it enters the U.S. only gives information as far back as that. Texas would need to trust everyone else in foreign drug supply chains before U.S. protocols are enacted. Canada does not possess its own manufacturing capacity and relies on foreign countries for its supply of drugs, leaving Canada unable to verify the original source before it is transshipped to Texas for consumption.

Because of the enormous number of illegally operating manufacturers around the world, including in the countries both we and Canada buy medicine from, it is not safe to buy from a supply chain that you haven't licensed.

Canadian law enforcement has acknowledged they do not inspect packages meant for the U.S. This means H.B. 25 relies on **trusting in good faith that foreign sellers will not mislead Texans. This leaves them vulnerable to bad actors and exposes them to unnecessary risk of consuming adulterated or counterfeit medicines**.

Further, H.B. 25 directs the state's drug wholesaler to submit track-and-trace information in order to participate in the program, requiring Canada to submit to U.S. oversight and regulation when Canada has already stated they are not willing to do so. Canadian entities also cannot be categorized as Trusted Trading Partners under the DSCSA because they do not possess U.S. State-issued wholesaler or pharmacy licenses.

Given these circumstances, any drugs coming from Canada would be in violation of H.B. 25's own state safety provisions, let alone those of the federal government, and only serves to put Texans at risk.

The Partnership for SAFEMEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

Neither FDA, HHS, Nor the Canadian Government Has Approved Any State's Canadian Drug Importation Program…and It's Costing Them Money

Several states confidently began spending money to implement a bulk Canadian drug importation program in 2019. While much taxpayer money has been spent, no state has received federal approval in the U.S. or Canada, and not a single pill has been imported from Canada.

As of November 2022, Florida had spent 27 million dollars on Canadian drug importation. Yet, its program does not have approval from HHS/FDA to operate, nor do they have the blessing or approval from the Canadian government and not a single unit of medicine has yet to be imported. Florida continues to lose an estimated one million dollars a month while their plan is being reviewed – quickly eating away at any potential savings Florida consumers would see.

Colorado also allocated two million dollars to design and set up a bulk Canadian drug importation program without approval from either the FDA, HHS, or the Canadian government. They have also heard directly from the Canadian consulate that they would not be allowed to export medicine from the Canadian drug supply.

Then, there's New Mexico. In 2021, New Mexico passed a bulk Canadian drug importation bill and spent most of the year working with a task force of five different agencies to design a program to submit for approval to HHS. **Within weeks of New Mexico completing the design of their program, Canada enacted permanent restrictions on bulk export of the Canadian medicine supply.** This year-long project required the participation and time of staff from the Board of Pharmacy, the Commissioner of Insurance, the New Mexico State Health Agency, and many others, only to result in a program design that cannot be implemented.

Past Importation Experiments Show the Difficulty of Regulating Foreign Drug Suppliers

In the past, several states tried and failed to make importation work without federal approval. Illinois' effort, ISaveRx, had trouble enforcing safety standards: a 2006 audit found that 40% of the required inspections of the foreign pharmacies were never completed and pharmacies that had not been approved were filling prescriptions in violation of state law. A similar program in Minnesota was also riddled with safety issues. Both states shuttered their programs when they failed to save enough money to justify the state budget costs.

If a serious violation does occur, holding a Canadian vendor responsible will not be easy. Even if the case warrants the involvement of the U.S. Department of Justice, that does not mean that justice will be easily achieved. For example, CanadaDrugs.com was indicted in November 2014 for selling $78 million worth of unapproved, mislabeled, and counterfeit cancer drugs to doctors across the U.S. The Canadian defendants spent years objecting to the case until a deal was brokered. In April 2018, the CEO of CanadaDrugs.com finally stood in a U.S. courtroom and admitted to the widespread illegal sale of misbranded and counterfeit drugs. No one involved received even a one-day jail sentence. The fines and forfeiture came to just over $34 million.

If Texas pharmacies dispense counterfeits as part of this scheme, they will have enormous financial and legal liability.

Distributing counterfeits (often charged as misbranded medication) violates the Texas Food, Drug, and Cosmetic Act as well as Federal law. However pharmacies that distribute counterfeit medicines also violate trademark law, and these violations have been pursued in recent years by drug manufacturers who extract heavy financial penalties.

These violations are strict liability statutes, so pharmacies that believed they were buying real medicine from an importation program, but instead dispensed counterfeits, would not have any legal safe harbor.

A drug importer or pharmacy that fails to investigate suspicious products acquired through a bulk importation program would be vulnerable to prosecution under the Trademark Act of 1946, also known as the Lanham Act. The legislation allows pharmaceutical companies to sue companies that import products bearing their trademarks if they are different from goods authorized for sale in the United States, including differences in quality control, packaging, and language of labeling. Penalties can be ruinous, topping out at 20 years imprisonment and fines as high as $15 million.

In closing, I know that addressing financial barriers to healthcare is a priority for every elected official and I emphasize with Texas residents. The goal of this bill is a noble one and one that we can all relate to. However, importation is a poor and risky strategy to solve these problems. The safety and efficacy of the U.S. prescription drug supply chain must be preserved – we cannot forfeit safety for convenience.

The flaws in the American healthcare system that create barriers to healthcare were made in America, and we must find American solutions to them.

Sincerely,

Shabbir Imber Safdar
Executive Director, the Partnership for Safe Medicines
www.safemedicines.org

The Partnership for SAFEMEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

Additional Issues with Canadian Drug Importation

Canada Continues to Experience Crippling Drug Shortages

As of March 28, 2022, Canada has over 1,500 drugs listed as currently being in shortage.[1] A report found that between 2017 and 2018, nearly 25 percent of medications in Canada were in shortage.[2] A national survey released in 2018 by the Canadian Pharmacists Association found that one in four Canadians had either personally experienced or knew someone who had experienced a drug shortage in the past three years.[3] The COVID-19 pandemic worsened the prescription drug situation in Canada, which is why they have banned bulk exports.[4]

A Board of Pharmacy (BOP) has Limited Powers

The powers given to Texas' BOP expire at the state's borders. Even if the state's drug importation program gives the BOP the right to inspect foreign facilities, the BOP would be at the mercy of that facility to allow inspections. Inspecting foreign facilities is a time and labor-intensive process, something that the U.S. Food and Drug Administration (FDA) struggles with and lacks the manpower and resources to do effectively and in a timely manner.

Regulating a Foreign Entity is an Impossible Task

Despite no Secretary of HHS previously approving a state drug importation plan, multiple states have continued to try, but have failed. Texas and its Board of Pharmacy will find it impossible to regulate a foreign entity just as previous drug importation programs have.

Minnesota tried to make Canadian drug importation work for seven years. The program, RxConnect, started in 2003 and quickly ran into trouble.[5] Eventually, Minnesota's program was shut down, hardly any medicines were imported (and those that were may have been substandard or fake), and the program did not save any substantial amount of money.

The State of Maine is experiencing similar issues as it attempts (and failing) to run a state-sponsored drug importation program. Personal drug importation was approved by the State, beginning in 2013, however its program was found to be in violation of federal law and likely dispensing counterfeit and substandard medicine illegally shipped into the State.[6] The former head of the Maine Pharmacy Association filed a lawsuit after testing of drugs he purchased showed that none of the drugs contained enough active pharmaceutical ingredients and one of them had an unknown, potentially hazardous contaminate.[7] While Maine's law required the medications to be sourced from a limited set of countries, the medications received still came from unapproved countries (India, Mauritius, and Turkey).[8] In 2015, Maine's law was thrown out and the program ended.

If a serious violation does occur, holding a Canadian vendor responsible will not be easy. Even if the case warrants the involvement of the U.S. Department of Justice, that does not mean that justice will be easily achieved. For example, CanadaDrugs.com was indicted in November 2014 for selling $78 million worth of unapproved, mislabeled, and counterfeit cancer drugs to doctors across the U.S.[9] The Canadian defendants spent years objecting to the case until a deal was brokered. In April 2018, the CEO of CanadaDrugs.com finally stood in a U.S. courtroom and admitted to the widespread illegal sale of

---

[1] Summary Report, Drug Shortages Canada, January 25, 2021.
[2] "Nearly a Quarter of Drugs Marketed in Canada Reported Shortages: Study," *CTV News*, September 1, 2020.
[3] "One in Four Canadians Touched by Drug Shortage in Last 3 Years," Canadian Pharmacists Association.
[4] Brooklyn Neustaeter, "Drug Shortages Could 'Imperil the Lives' of Canadians, Doctors Warn Ottawa," *CTV News*, August 13, 2020.
[5] "Minnesota's Experiment With Drug Importation: RxConnect 2003-2010," The Partnership for Safe Medicines, March 11, 2019.
[6] Jackie Farwell, "Judge Overturns Maine Law Allowing Prescription Drug Imports," *Bangor Daily News*, February 24, 2015.
[7] "MYTH: 'We Are Getting the Same Drugs Canadians Take,'" The Partnership for Safe Medicines.
[8] Ibid.
[9] Superseding Indictment, U.S. District Court, District of Montana, Butte Division, Case No. 2:14-cr-00027-DLC.

misbranded and counterfeit drugs.[10] No one involved received even a one-day jail sentence. The fines and forfeiture came to just over $34 million.

Any Canadian Vendor Would Be Operating in a Legal Gray Area

Health Canada regulates Canadian wholesalers and pharmacies that distribute medications to Canadian citizens and, going back as far as 2004, has said Health Canada "does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future."[11] Coupled with the U.S. Food and Drug Administration's limited to zero say over Canadian pharmacies and wholesalers, any state doing business with a Canadian vendor would be making a leap of faith, and that leap has not worked out very well for other states that tried to do drug importation.

Negotiated Drug Prices by Canada Are Not Transferable

While Canada does have universal healthcare coverage that includes medications when administered in the hospital setting, the same is not true for any prescription drugs taken outside of a hospital.[12] Much like in the U.S., most Canadians have prescription drug coverage through a patchwork of public and/or private insurance plans. Canada's Patented Medicines Prices Review Board sets prices to ensure that brand-name medication is not priced excessively, but those prices are for Canadian citizens receiving care in Canada.[13] There is nothing that can compel any Canadian wholesaler to give those same discounted prices to a U.S. state looking to import cheaper prescription drugs from Canada. This fact was one of the items listed in Deloitte's June 30, 2020, memo to the North Dakota's state Employee Benefits Programs Committee as the committee was debating a drug importation bill.[14]

Canadian Drug Importation Is Not a Sustainable Solution

In the same memo, Deloitte stated that North Dakota would see "little if any potential savings" because of Canada's limited drug supply and the price equalization that would follow even a small percentage of prescription drugs being exported to the U.S.[15] Wyoming's Department of Health (WY-DOH) came to the same conclusion. In a report released in 2020, WY-DOH stated that the concept of sustained savings via the importation of Canadian drugs has a fundamental economic flaw: it relies on a form of arbitrage.[16] Savings found in the exploitation of price differences are fleeting and generally cause the prices to converge, eliminating any savings.

Drug Importation Will Not Help Most Texas Residents

Ninety percent of prescriptions in the U.S. are filled with generic drugs, the vast majority of which cost less than $20.[17] Seventy-seven percent of the money that U.S. patients spend is on the ten percent of prescriptions that are filled with brand-name drugs. So, Texas'' potential pool for citizens who would benefit from drug importation would be limited to people for whom there is not an FDA-approved generic option.

The Costs of Federally Mandated Testing Will Eliminate All Savings

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that any drugs imported be statistically tested to ensure the safety of all imported medicines.[18] Dr. Kristina M.L. Acri examined if it was possible to test cheap drugs into safety, and she found that doing the required amount

---

[10] "Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States," U.S. Department of Justice, April 13, 2018.
[11] Report on Prescription Drug Importation, Department of Health and Human Services, December 2004.
[12] Prescription Drug Insurance Coverage, Government of Canada, last modified December 3, 2020.
[13] Patented Medicines Prices Review Board, Government of Canada.
[14] Actuarial Review of Proposed Bill 21.0068.01000, Deloitte, June 30, 2020.
[15] Ibid.
[16] "Prescription Drug Costs in Wyoming," Wyoming Department of Health, October 1, 2020.
[17] "2018 Generic Drug Access and Savings Report," Association for Accessible Medicines.
[18] Text: H.R.1 — 108th Congress (2003-2004), U.S. Congress, December 8, 2003.

of testing quickly ate up all monies saved.[19] Dr. Acri also found that if a patient were to receive substandard or counterfeit medicine, a single adverse medical event could eliminate a drug importation program's savings anywhere from days to decades.[20]

Fiscal Impact Analysis

The theory that importing drugs from Canada will allow patients to see significant savings is just that: a theory. Many states looking into drug importation have applied a blanket 45 percent increase to the Canadian prices, but no state actually knows if this number is accurate.

While no state has yet to operate an HHS-approved drug importation program, some have tried and there are lessons to be learned from them. Illinois operated a program called i-SaveRx in the mid-2000s. The Office of the Auditor General released a report in 2006 that showed the program was expensive for the state to run:

- Twenty-eight agencies reported that 521 employees provided almost 5,600 hours of assistance at an estimated payroll cost of $488,000.
- Illinois had significant expenditures on the program, including travel, contractual services, marketing, and legal services.[21]

Additionally, no state discussion of importation to date has actually addressed the cost of the testing for counterfeits. Testing alone is sufficient to make almost every importation program financially unworkable. Colorado is one of the states currently pursuing a Canadian drug importation program. In March 2020, the state released a draft of its plan that included a list of potential drugs to import. PSM did an analysis and found that nearly one-third of the drugs on the list already had a generic version on the U.S. market and that the state could save over $43 million just by switching to the generic versions of those drugs.[22] Over a two-year period, Colorado budgeted $3 million of taxpayers' money to get its drug importation program up and running. Only recently did the state submit its plan to HHS, and not one patient has yet to save even a penny on costs.

---

[19] Dr. Kristina M.L. Acri nèe Lybecker, "State Pharmaceutical Importation Programmes: an Analysis of the Cost effectiveness," Journal of Pharmaceutical Health Services Research, March 18, 2020.
[20] Idib.
[21] "Report Digest Management Audit of the Flu Vaccine Procurement and the I-saverx Program," State of Illinois Office of the Auditor General, September 2006.
[22] "Analysis of Draft Colorado Importation Plan," The Partnership for Safe Medicines.