

I am writing to explain my concerns with and opposition to SB 2209 and SB 2212 that would establish Canadian drug importation. I am Shabbir Imber Safdar, the Executive Director of the Partnership for Safe Medicines, a seventeen-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 take positions almost exclusively on pharmaceutical supply chain safety issues, tightly 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.

SB 2209 and 2212 propose to require the North Dakota Board of Pharmacy and the state's department of health to design a program for prescription medicines imported from Canada under Sec. 804 of the U.S. Food, Drug, and Cosmetics Act. Below we outline the many reasons this proposal is unsafe and unworkable for the North Dakota Board of Pharmacy and the health department.

Lack of Funding or Statutes for Required Screening and Enforcement

The proposed legislation requires that the program created involve carefully screening Canadian suppliers and preventing any imported medicine from leaving the state of North Dakota. However, no funding is identified for enforcement of either of these functions for the Board of Pharmacy (BOP) or state law enforcement. Nor are there any new criminal penalties created for taking these prohibited products out of the state.

A Board of Pharmacy Has Limited Powers

The powers given to North Dakota's 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 that inspection. Inspecting foreign facilities is a time and labor intensive process, something that the U.S. Food and Drug Administration (FDA) struggles with. Dr. Janet Woodcock's testimony for the FDA at a House subcommittee in December 2019 showed this:¹ records showed that in 2016 there were 965 foreign manufacturing facilities licensed by the agency that had never been inspected. Though progress was made, by 2019, there were still 470 that needed inspections.

¹ [Testimony: Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program](#), Janet Woodcock, M.D. for U.S. Food and Drug Administration, December 10, 2019.

Regulating a Foreign Entity Will Be an Impossible Task

Despite no secretary of HHS previously allowing a state to try a drug importation plan, states have tried and they have failed. North Dakota and the state's Board of Pharmacy will find it impossible to regulate a foreign entity 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.²

While Maine is currently attempting to run a state-sponsored drug importation program, the state did allow a personal drug importation program beginning in 2013. Long before a federal judge ruled that the law was in violation of federal law, counterfeit and substandard medicine was being illegally shipped into the state.³ The former head of the Maine Pharmacy Association filed a lawsuit after testing of drugs he purchased showed that all of the drugs did not have enough active pharmaceutical ingredients and one of them had an unknown, potentially hazardous contaminate.⁴ While Maine's law required the medications to be sourced from a limited set of countries, the medications received came from unapproved countries anyway (India, Mauritius, and Turkey.⁵)

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 easy to achieve. 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.⁶ including North Dakota. 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.⁷ 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 Grey Area

Health Canada regulates Canadian wholesalers and pharmacies that distribute medications to Canadian citizens, and going back as far as 2004 it has said Health Canada "does not assure

² "[Minnesota's Experiment With Drug Importation: RxConnect 2003-2010](#)," The Partnership for Safe Medicines, March 11, 2019.

³ Jackie Farwell, "[Judge Overturns Maine Law Allowing Prescription Drug Imports](#)," *Bangor Daily News*, February 24, 2015.

⁴ "[MYTH: 'We Are Getting the Same Drugs Canadians Take](#)," The Partnership for Safe Medicines.

⁵ Idib.

⁶ [Superseding Indictment](#), U.S. District Court, District of Montana, Butte Division, Case No. 2:14-cr-00027-DLC.

⁷ "[Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States](#)," U.S. Department of Justice, April 13, 2018.

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.”⁸ However, the U.S. Food and Drug Administration has 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.

Drug Importation Breaks Track-and-Trace

Given that Canada has not implemented a track-and-trace system for any medical products, any drug importation plan would automatically be breaking track-and-trace. Simply slapping an identifier onto a bottle when it enters the country only gives you information as far back as that. The state would just need to trust everyone else earlier in the supply chain that the medication is what they say it is, it has been handled properly. Additionally, Canadian entities cannot be categorized as Trusted Trading Partners under the DSCSA because they do not possess state-issued wholesaler or pharmacy licenses.

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.⁹ 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.¹⁰ There is nothing that can compel any Canadian wholesaler to give those same discounted prices to a U.S. state looking to import prescription drugs from Canada. This fact was one of the items listed in Deloitte’s June 30, 2020 memo to the state’s Employee Benefits Programs Committee as the committee was debating a drug importation bill.¹¹

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.¹² Wyoming’s Department of Health (WY-DOH) came to the same conclusion. In a report released last year, the 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.¹³ Savings found in the exploitation of

⁸ [Report on Prescription Drug Importation](#), Department of Health and Human Services, December 2004.

⁹ [Prescription Drug Insurance Coverage](#), Government of Canada, last modified December 3, 2020.

¹⁰ [Patented Medicines Prices Review Board](#), Government of Canada.

¹¹ [Actuarial Review of Proposed Bill 21.0068.01000](#), Deloitte, June 30, 2020.

¹² Idib.

¹³ [“Precription Drug Costs in Wyoming”](#), Wyoing Department of Health, October 1, 2020.

price differences are fleeting and generally cause the prices to converge, eliminating any savings.

Drug Importation Will Not Help Most North Dakotans

Ninety percent of prescriptions in the U.S. are filled with generic drugs, the vast majority of which costs less than \$20.¹⁴ 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 North Dakota's potential pool for citizens that would benefit from drug importation would be limited to people for whom there is not an FDA-approved generic option.

Importation programs can only work on paper if they operate at scale and North Dakota does not have the opportunity to do that. However operating a Canadian drug importation program at scale is exactly what has caused Canada to act to refuse cooperation with these programs.

Canada Promises to Protect Its Limited Drug Supply

Any state looking to import prescription drugs from within the Canadian drug supply chain would need Canada to be a willing participant, which it has never been. A bill proposed in 2005 would have allowed the Health Minister to ban the bulk exportation of prescription drugs from Canada to the U.S.¹⁵ In a March 2020 comment submitted to Health and Human Services during the proposed rulemaking comment period, the Government of Canada warned that drug importation "would not provide an effective solution to high drug prices in the U.S."¹⁶ As the federal government continued pressing forward with the issue, Canada imposed an interim order in November 2020 banning the export of prescription drugs that would cause or exacerbate drug shortages in that country.¹⁷ If North Dakota attempts to do its own drug importation program or if the state works in tandem with another or other states, Canada will still protect the drug supply it has secured for its citizens.

Additional Issues to Canadian Drug Importation

Canada Has and Continues to Experience Crippling Drug Shortages

As of January 25, 2021, Canada has over 1,600 drugs listed as currently being in shortage.¹⁸ A report found that between 2017 and 2018, nearly 25 percent of medications in Canada were in

¹⁴ "[2018 Generic Drug Access and Savings Report](#)," Association for Accessible Medicines.

¹⁵ Beth Duff-Brown, "[Health Minister Says Canada Intends to Ban the Export of Bulk Prescription Drugs](#)," *Consumer Watchdog*, June 28, 2005.

¹⁶ "[Government of Canada Comments on the Proposed Rulemaking 'Importation of Prescription Drugs' \(Docket No. FDA-2019-N-5711\)](#)", Government of Canada.

¹⁷ "[Interim Order Respecting Drug Shortages \(Safeguarding the Drug Supply\)](#)", Government of Canada, November 27, 2020.

¹⁸ "[Summary Report](#)", Drug Shortages Canada, January 25, 2021.

shortage.¹⁹ 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.²⁰ The COVID-19 pandemic has worsened the prescription drug situation in Canada.²¹

Drug Importation Will Not Help Medicaid Beneficiaries

While wanting to help constituents lower their prescription drug costs is a laudable goal, drug importation will be of no benefit to the 11 percent of North Dakotans who are on Medicaid due to the discounted prices that the state is already able to get for those citizens.²² So if drug importation cannot help the neediest in the state, who can it help? Despite the negative experiences in its attempt to do personal drug importation, Maine is currently pursuing a Canadian drug importation plan. When MaineCare, Maine's version of Medicaid, examined to see if drug importation would be a benefit for those beneficiaries, the state's analysis showed the state would lose close to \$1 million because of all of the rebates the program already receives.²³

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.²⁴ Dr. Kristina M.L. Acri née Lybecker examined if it was possible to test cheap drugs into safety, and she found that doing the required amount of testing quickly ate up all monies saved.²⁵ 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.²⁶

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% increase to the Canadian, 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

¹⁹ [“Nearly a Quarter of Drugs Marketed in Canada Reported Shortages: Study,”](#) CTV News, September 1, 2020.

²⁰ [“One in Four Canadians Touched by Drug Shortage in Last 3 Years,”](#) Canadian Pharmacists Association.

²¹ Brooklyn Neustaeter, [“Drug Shortages Could 'Imperil the Lives' of Canadians, Doctors Warn Ottawa,”](#) CTV News, August 13, 2020.

²² [“Medicaid in North Dakota,”](#) Henry J. Kaiser Family Foundation, October 2019.

²³ [“Maine's Medicaid Program Analysis Shows the Truth: Importing Medicine from Canada Would Cost More, Not Less,”](#) The Partnership for Safe Medicines, December 1, 2020.

²⁴ [Text: H.R.1 — 108th Congress \(2003-2004\),](#) U.S. Congress, December 8, 2003.

²⁵ Dr. Kristina M.L. Acri née Lybecker, [“State Pharmaceutical Importation Programmes: an Analysis of the Cost-effectiveness,”](#) Journal of Pharmaceutical Health Services Research, March 18, 2020.

²⁶ Idib.

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of the Auditor General released a report in 2006 that showed the program was expensive for the state to run²⁷:

- 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.

Additionally, no state discussion importation to date has actually addressed the cost of testing outlined above. Testing alone is sufficient to make most 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.²⁸ Over a two-year period, Colorado budgeted \$3 million of taxpayers' money to get its drug importation program up and running. The state has still not submitted its plan to HHS and no patient has saved even a single penny. Even Florida, with its \$30 million contract, is struggling to find both a Canadian and a U.S. vendor.²⁹

Drug Importation Will Weaken the Security of the Drug Supply Chain

The U.S. has one of the most secure drug supply chains in the world. Drug importation will only make it less secure, not more. In a 2017 report, former FBI director Louis Freeh warned that drug importation “would deplete and overburden already limited resources. In particular, importation proposals would force law enforcement agencies to make tough prioritization decisions that leave the safety of the U.S. prescription drug supply vulnerable to criminals seeking to harm patients.”³⁰ North Dakota is not immune to this issue. Ten doctors received warning letters between 2012 and 2016 to stop purchasing medications from known black-market suppliers.³¹

There Are Other Safer Ways to Bring Down Prices.

There isn't an elected official today who doesn't hear from their constituents that health care costs are an issue, and pharmaceutical spending, which is less than 20% of overall healthcare

²⁷ [“Report Digest Management Audit of the Flu Vaccine Procurement and the I-saverx Program,”](#) State of Illinois Office of the Auditor General, September 2006.

²⁸ [“Analysis of Draft Colorado Importation Plan,”](#) The Partnership for Safe Medicines.

²⁹ Phil Galewitz, [“Florida Fails to Attract Bidders for Canada Drug Importation Program,”](#) *Kaiser Health News*, October 26, 2020.

³⁰ [“Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement,”](#) Freeh Group International Solutions, LLC.

³¹ [“The Deadly Counterfeit Drug Trade Thrives in North Dakota,”](#) The Partnership for Safe Medicines, April 2020.

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spending, is certainly a piece of the problem. But states are finding other, safer ways to address these costs. California is aggregating its spending across different healthcare programs to achieve volume discounts. Louisiana has negotiated a “Netflix” subscription model, which will allow the state to treat hepatitis C at a fixed cost. West Virginia kicked their PBM out of their Medicaid program to use a pass-through entity and saved \$52 million in their first year.

Canadian drug importation sounds like a good idea. However, history shows that previous drug importation programs, such as in Illinois and Minnesota, revealed patient safety issues and programs with operational costs that exceeded customer savings. Implementing this program in North Dakota is likely to consume state money without producing an operation program due to Canada’s statement of non-cooperation.

If North Dakota’s program were to somehow become fully operational, the program would rely on an existing black market of poorly regulated and counterfeit drugs. This bill incentives gray market wholesalers to ship counterfeit or substandard medicine into American that is expensive to detect and even more expensive for patients if we fail to detect it. North Dakota could help more people access healthcare by funding programs with less risk.