

Testimony of Shabbir Imber Safdar  
Executive Director, Partnership for Safe Medicines  
February 8, 2022 - HB 478 (Opposed)  
House Health, Welfare, and Institutions Committee

Members of the committee, I am writing to explain my concerns with and opposition to HB 478 that would establish a bulk Canadian drug importation program in the state of Virginia. I am Shabbir Imber Safdar, the Executive Director of the Partnership for Safe Medicines, an eighteen-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 on pharmaceutical supply chain safety issues 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.

**HB 478 proposes to require the Secretary of Health and Human Services to design a program for bulk importing prescription medicines 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.**

## A Bulk Canadian Drug Importation Program Will Fail Because Canada Has Acted To Block Bulk Exports Of Its Drug Supply Due To Crippling Drug Shortages

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. During the Trump Administration representatives of the Canadian consulate notified the White House they would not cooperate with drug importation programs and in November 2020, Health Canada and the federal government enacted permanent restrictions on the bulk export of Canadian pharmaceuticals.<sup>1</sup> Canada enacted these regulations because they don't make most of their medicine and have been experiencing crippling drug shortages for years.<sup>2</sup>

No Canadian drug importation program in Virginia can succeed because the Canadian government has prohibited their export.

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<sup>1</sup> BBC: Canada bans mass exports of prescription drugs, <https://www.bbc.com/news/world-us-canada-55119428>

<sup>2</sup> Website Drug Shortages Canada, <https://www.drugshortagescanada.ca/rws-search?perform=1>

## A Bulk Canadian Drug Importation Program Will Fail Because It Cannot Save Money For Medicaid Patients

Many states have studied bulk Canadian importation and found it difficult to establish how it can save money after counting up the costs of running the program. Colorado College economist Dr. Kristina Acri modeled the cost of testing for some commonly named medicines to import and found that the cost of required drug safety testing alone eats up all the cost savings.<sup>3</sup>

More importantly, states such as Wyoming<sup>4</sup> and Maine<sup>5</sup> have studied bulk Canadian drug importation and found that Medicaid programs cannot save money with it 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 costs of safety testing.

There are currently over 500,000 Virginia patients on Medicaid. The state could not save money on their prescription drug costs with this program.

## No State Has Received Permission To Operate A Canadian Drug Importation Program By HHS, 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, and not a single pill has been imported from Canada.

Florida has contracted with a wholesale vendor in Texas to act as an importer of medicine and set up a warehouse for storage. To date the state has spent nine million dollars to put the program in place and has appropriated thirty million more. The warehouse remains empty, Florida does not have federal approval, and the Canadian government has since enacted export restrictions.

Colorado allocated two million dollars to design and set up a bulk Canadian drug importation program. They have been told by the Canadian consulate that they would not be allowed to

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<sup>3</sup> "State Pharmaceutical Importation Programmes: An Analysis Of The Cost-Effectiveness", Royal Pharmaceutical Journal 18 March 2020, <https://onlinelibrary.wiley.com/doi/full/10.1111/jphs.12349>

<sup>4</sup> "Prescription Drugs In Wyoming: Evaluating State Policy Options For Lowering Costs", <https://www.safemedicines.org/2020/10/wyomings-dept-of-health-recommends-the-state-not-attempt-a-drug-importation-program.html>

<sup>5</sup> "Maine's Medicaid Program Analysis Shows The Truth: Importing Medicine From Canada Would Cost More, Not Less", <https://www.safemedicines.org/2020/12/me-medicaid-program-analysis.html>

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export medicine from the Canadian drug supply. The staffers hired continue designing the program on paper today, but they do not have federal approval.

New Mexico passed a bulk Canadian drug importation bill and spent most of 2021 working with a task force of five different agencies to design a program to submit for approval to HHS. Within weeks of submitting the application, Canada enacted permanent restrictions on bulk export of the Canadian medicine supply. This year-long project required the participation and time from staff from the Board of Pharmacy, the Commissioner of Insurance, New Mexico State Health Agency, and many others.

I know that addressing financial barriers to healthcare are a priority for every elected official, however bulk Canadian drug importation cannot be implemented today and is therefore not a viable solution.

## Additional Issues with 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.<sup>6</sup> A report found that between 2017 and 2018, nearly 25 percent of medications in Canada were in shortage.<sup>7</sup> 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.<sup>8</sup> The COVID-19 pandemic has worsened the prescription drug situation in Canada, which is why they have banned bulk exports.<sup>9</sup>

### A Board of Pharmacy (BOP) Has Limited Powers

The powers given to Virginia'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.

### Regulating a Foreign Entity is 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. Virginia 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.<sup>10</sup>

While Maine is currently attempting (and failing) 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

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<sup>6</sup> [Summary Report](#), Drug Shortages Canada, January 25, 2021.

<sup>7</sup> ["Nearly a Quarter of Drugs Marketed in Canada Reported Shortages: Study,"](#) CTV News, September 1, 2020.

<sup>8</sup> ["One in Four Canadians Touched by Drug Shortage in Last 3 Years,"](#) Canadian Pharmacists Association.

<sup>9</sup> Brooklyn Neustaeter, ["Drug Shortages Could 'Imperil the Lives' of Canadians, Doctors Warn Ottawa,"](#) CTV News, August 13, 2020.

<sup>10</sup> ["Minnesota's Experiment With Drug Importation: RxConnect 2003-2010,"](#) The Partnership for Safe Medicines, March 11, 2019.

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substandard medicine was being illegally shipped into the state.<sup>11</sup> 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 contaminant.<sup>12</sup> 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).<sup>13</sup>

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., including Virginia.<sup>14</sup> 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.<sup>15</sup> 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 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.”<sup>16</sup> 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 adding 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

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<sup>11</sup> Jackie Farwell, “[Judge Overturns Maine Law Allowing Prescription Drug Imports](#),” *Bangor Daily News*, February 24, 2015.

<sup>12</sup> “[MYTH: 'We Are Getting the Same Drugs Canadians Take'](#),” The Partnership for Safe Medicines.

<sup>13</sup> *Ibid.*

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

<sup>15</sup> “[Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States](#),” U.S. Department of Justice, April 13, 2018.

<sup>16</sup> [Report on Prescription Drug Importation](#), Department of Health and Human Services, December 2004.

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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.<sup>17</sup> 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.<sup>18</sup> 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 North Dakota's state Employee Benefits Programs Committee as the committee was debating a drug importation bill.<sup>19</sup>

## 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.<sup>20</sup> 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.<sup>21</sup> 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 Virginians

Ninety percent of prescriptions in the U.S. are filled with generic drugs, the vast majority of which cost less than \$20.<sup>22</sup> 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 Virginia'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.

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<sup>17</sup> [Prescription Drug Insurance Coverage](#), Government of Canada, last modified December 3, 2020.

<sup>18</sup> [Patented Medicines Prices Review Board](#), Government of Canada.

<sup>19</sup> [Actuarial Review of Proposed Bill 21.0068.01000](#), Deloitte, June 30, 2020.

<sup>20</sup> Ibid.

<sup>21</sup> ["Prescription Drug Costs in Wyoming"](#), Wyoming Department of Health, October 1, 2020.

<sup>22</sup> ["2018 Generic Drug Access and Savings Report"](#), Association for Accessible Medicines.

## 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.<sup>23</sup> Dr. Kristina M.L. Acri 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.<sup>24</sup> 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.<sup>25</sup>

### 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.<sup>26</sup>

Additionally, no state discussion of importation to date has actually addressed the cost of the testing for counterfeits. 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

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<sup>23</sup> [Text: H.R.1 — 108th Congress \(2003-2004\)](#), U.S. Congress, December 8, 2003.

<sup>24</sup> 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.

<sup>25</sup> Idib.

<sup>26</sup> "[Report Digest Management Audit of the Flu Vaccine Procurement and the I-saverx Program](#)," State of Illinois Office of the Auditor General, September 2006.

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generic versions of those drugs.<sup>27</sup> 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.

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<sup>27</sup> [“Analysis of Draft Colorado Importation Plan,”](#) The Partnership for Safe Medicines.