

# Wholesale Canadian drug importation programs will fail to protect patients and fail to save money.

## Canada Is Not a Willing Partner

Canada is so opposed to the idea of the U.S. dipping into its supply of prescription drugs that **it has 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.<sup>1</sup> In November 2020, Health Canada and the federal government enacted permanent restrictions on the bulk export of Canadian pharmaceuticals.<sup>2</sup>

**The Canadian drug supply system is geared towards providing for the needs of its 38 million citizens.** Its drug supply is simply not large enough to support the Canadian population and the nine-times-greater American population. Canada relies heavily on importing medication, has limited facilities to produce its own, and has been experiencing crippling drug shortages for years.<sup>3</sup> Additionally, 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>4</sup>

## Savings Are Unsustainable or Nonexistent

In a June 30, 2020 memo, Deloitte reported that the **state of 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>5</sup> Wyoming’s Department of Health (WY-DOH) came to the same conclusion. In a report released in 2020, 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>6</sup> Savings found in the exploitation of price differences are fleeting and generally cause the prices to converge, eliminating any savings.

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<sup>1</sup> Allison Martell, “Canadian Ambassador Says Drug Imports Would Not Lower U.S. Prices,” *Reuters*, November 1, 2019, <https://reut.rs/3l0ePCO>.

<sup>2</sup> Matthew S. Schwartz, “Canada Blocks Export of Medications in Short Supply in Response to Trump Plan,” *National Public Radio*, November 29, 2020, <https://n.pr/38dOM8r>.

<sup>3</sup> “Summary Report,” Drug Shortages Canada, accessed May 10, 2022, <https://bit.ly/3ytjaGz>.

<sup>4</sup> “Report on Prescription Drug Importation,” Department of Health and Human Services, December 2004, <https://bit.ly/3P4Ztum>.

<sup>5</sup> Actuarial Review of Proposed Bill 21.0068.01000, Deloitte, June 30, 2020, <https://bit.ly/3M1yoGD>.

<sup>6</sup> “Prescription Drug Costs in Wyoming,” Wyoming Department of Health, October 1, 2020, <https://bit.ly/399nC2h>.



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States such as Wyoming<sup>7</sup> and Maine<sup>8</sup> have studied bulk Canadian drug importation and found that **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 costs of safety testing.

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>9</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 potential savings.**<sup>10</sup> Dr. Acri also found that if a patient were to receive substandard or counterfeit medicine, **the cost to treat a single adverse medical event could eliminate a drug importation program's putative savings.**<sup>11</sup>

## What History Has Taught Us

The **COVID-19 pandemic showed the world how susceptible it is to counterfeit medical items.** Whenever there was a need or want, counterfeiters were more than happy to take advantage however they could. **The first report of criminals injecting people with a counterfeit vaccine came in early March 2020.**<sup>12</sup> Later the same month, the U.S. Department of Justice (DOJ) received a temporary restraining order against a man selling a counterfeit vaccine on his website.<sup>13</sup> With supply chains disrupted, counterfeit masks even made it into the hands of frontline healthcare workers.<sup>14</sup>

**Canada has not invested in a track-and-trace system** for its prescription drugs so any drug importation scheme would thwart the purposes of track-and-trace. Simply adding an identifier onto a bottle when it enters the

<sup>7</sup> "Wyoming's Dept. of Health Recommends the State Not Attempt a Drug Importation Program," The Partnership for Safe Medicines, October 6, 2020, <https://safedr ug/3ypkwC9>.

<sup>8</sup> "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, <https://safedr ug/ME-Medicaid>.

<sup>9</sup> Text: H.R.1 — 108th Congress (2003-2004), U.S. Congress, December 8, 2003, <https://bit.ly/3ytnoh6>.

<sup>10</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, <https://bit.ly/3sr9ecG>.

<sup>11</sup> Idib.

<sup>12</sup> "Maharashtra: Three Held for Administering Fake Coronavirus Vaccines," *Deccan Herald*, March 12, 2020, <https://bit.ly/3N8pyqv>.

<sup>13</sup> Sarah Coble, "US Court Blocks Website Selling Fake #COVID19 Vaccine," *Info Security Magazine*, March 23, 2020, <https://bit.ly/3kYdWuh>.

<sup>14</sup> Juliet Linderman and Martha Mendoza, "Counterfeit Masks Reaching Frontline Health Workers in US," *AP News*, May 12, 2020, <https://bit.ly/3N4c6UH>.



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country does not give the chain-of-custody or pedigree information to ensure the safety of the medicine contained within it.

**If a serious violation does occur, holding a Canadian vendor responsible will not be easy.** Even if the case warrants the involvement of the DOJ, 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.<sup>15</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>16</sup> No one involved received even a one-day jail sentence. The fines and forfeiture came to just over \$34 million.

A flood of counterfeit prescription drugs, primarily opioid pills, has been taking lives, devastating communities and straining law enforcement agencies throughout the country since 2015.<sup>17</sup> **Drug importation opens the door to more counterfeit and substandard drugs** making their way into the U.S. and harming patients. As the National Sheriff's Association (NSA) stated on March 6, 2020: "NSA has serious concerns about any drug importation proposals — legislative, administrative, or regulatory — that could **jeopardize local law enforcement's ability to protect the public health** and safety of our citizenry."<sup>18</sup>

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<sup>15</sup> [Superseding Indictment](#), U.S. District Court, District of Montana, Butte Division, Case No. 2:14-cr-00027-DLC.

<sup>16</sup> "Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States," U.S. Department of Justice, April 13, 2018, <https://bit.ly/3w1w9h2>.

<sup>17</sup> "Fake Pills Are Ravaging Communities Across the U.S.," The Partnership for Safe Medicines, accessed May 10, 2022, <https://safedr.ug/Fake-Pill-Crisis>.

<sup>18</sup> "Statements Opposing Drug Importation, 2000-," The Partnership for Safe Medicines, accessed May 10, 2022, <https://safedr.ug/ForeignDrugImportation>.



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