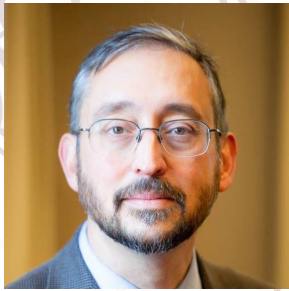


# Canadian Drug Importation

How has it been tried before? What are the challenges?



**Shabbir Imber Safdar**  
Executive Director  
The Partnership for Safe  
Medicines

Academy of Managed Care Pharmacy  
ADAP Advocacy Association  
Alabama Pharmacy Association  
Alaska Pharmacists Association  
American Pharmacists Association  
Arizona Pharmacy Alliance (AzPA)  
Association for Accessible Medicines  
Biotechnology Innovation Organization  
Colorado BioScience Association  
Community Access National Network  
Connecticut Pharmacists Association  
Delaware Pharmacists Society  
Healthcare Distribution Association  
HealthCare Institute of New Jersey  
HealthHIV  
Illinois Pharmacists Association  
Institute for Safe Medication Practices  
International AntiCounterfeiting Coalition  
International Health Facility Diversion  
Association  
Kansas Pharmacists Association

Maine Pharmacy Association  
Maryland Pharmacists Association  
Men's Health Network  
Minnesota Pharmacists Association  
Mississippi Pharmacists Association  
Missouri Pharmacy Association  
National Alliance of State Pharmacy  
Associations  
National Alliance On Mental Illness  
National Association of Boards of  
Pharmacy  
National Association of Chain Drug Stores  
National Association of Drug Diversion  
Investigators  
National Association of Manufacturers  
National Coalition for LGBT Health  
National Consumers League  
National Grange of the Order of Patrons  
of Husbandry  
Nebraska Pharmacists Association

NeedyMeds  
New Hampshire Pharmacists Association  
New Mexico Pharmacists Association  
Ohio Pharmacists Association  
Oklahoma Pharmacists Association  
Oncology Managers of Florida, Inc.  
Pennsylvania Pharmacists Association  
Pharmaceutical Industry  
Labor-Management Association (PILMA)  
Pharmaceutical Researchers and  
Manufacturers of America  
Pharmaceutical Security Institute  
RetireSafe  
Rx Outreach  
Rx Partnership  
Texas Pharmacy Association  
University of New England College of  
Pharmacy  
Virginia Pharmacists Association

# Illinois' Experience With ISaveRX, 2003–2006

A “whitelisted” online pharmacy program of 28 online drug sellers dispensing from Canada, the United Kingdom, Australia, and New Zealand to IL, WI, KS, MO, and VT.

## Select IG findings:

- Operating in violation of federal law with unapproved federal funds.
- Dispensing entities in the program in violation of IL pharmacy practice law.
- 40% of the inspections records (32 of 80) were not completed.
- State did not monitor that only approved pharmacies participated.
- Significant labor costs of \$488,000 for 26 employees (19 months).
- High expenses, incl. \$111,000 for international travel and over \$350,000 for contract management, marketing, and legal services.
- Uptake of the program was small and it was eventually cancelled.



# Minnesota RXConnect, 2004-2010

An online pharmacy regulation program started by Gov. Tim Pawlenty. After launch, the FDA cited a number of patient safety issues, including several found during a pre-announced visit by Minnesota's own inspectors:



- Pharmacy techs, not pharmacists, entering prescriptions.
- Having pharmacists check 100 new prescriptions / hour or refill 300 prescriptions / hour.
- Cold-chain drugs shipped not refrigerated / no historic thermometers in refrigerators.
- Allowing pharmacy techs instead of pharmacists contact U.S. medical providers
- Allowing faxed prescriptions.
- Failed to meet minimum lighting standards as set by MN pharmacy law.
- Uptake of the program was small and it was eventually cancelled.



## MYTH: "WE ARE GETTING THE SAME DRUGS CANADIANS TAKE."



Testing proves they are not getting the same medicine. They are risking ineffective and dangerous drugs from other countries.

From 2013 until 2015, Maine law allowed the importation of foreign prescription drugs from online "pharmacies" associated with licensed retail pharmacies in Canada, the U.K., Australia and New Zealand, exclusively.

However, the cost savings came with some surprising results.

University of New England Professor Kenneth McCall tested three widely used medications from one of these pharmacy websites. He ordered drugs that are available in brand name and generic in the U.S., and received:

- A non-FDA approved generic of Nexium, *esomeprazole* (which treats acid reflux disease)
- A non-FDA approved generic of Celebrex, *celecoxib* (an anti-inflammatory)
- A non-FDA approved generic of Plavix, *clopidogrel* (a blood thinner)



## Maine's program: 2013-2015

Advocates of the Canadian importation promised that the medicines they would receive would come from just over the border in Canada.

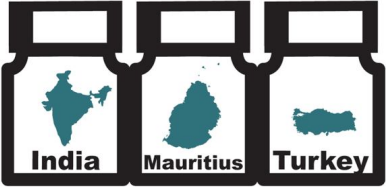
The medicines they received from Canadian vendors did not even touch Canadian soil.



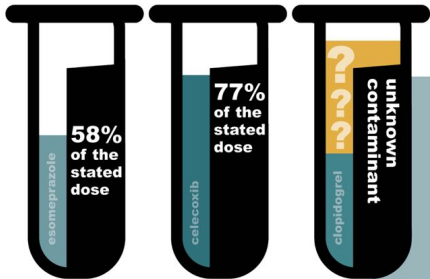
The medicines McCall received came from India, Mauritius and Turkey and none of them were approved medicines in the U.S. or Canada. His tests showed: the esomeprazole was only 58% of the stated dose, the celecoxib was only 77% of the stated dose, and the clopidogrel contained an unknown contaminant. Portland's WGME News performed the same experiment with similar results.



INSTEAD OF COMING FROM CANADA'S DRUG SUPPLY, THESE CAME FROM . . .



ON TESTING THEM, HE FOUND:



**What happens if patients take black market medicine that is weaker than the stated dose?**

Treatment will be ineffective and potentially dangerous. Patients with chronic illnesses such as diabetes and hypertension may get sicker as doses vary between unregulated batches of medicine. Their doctors may presume that treatment is ineffective for that patient instead of realizing that their imported medication is unreliable. When patients take substandard medicines they could suffer serious harm.

To date it is not known how many Mainers were exposed to counterfeit medicines during this time.

# Colorado

Colorado has burned \$3mm in taxpayer money. They don't have a Canadian seller, and they don't have an application into HHS.

They could have saved \$43mm this year if they focused on U.S. generics instead of Canada importation.

Drug	Dose	Colorado Unit Cost (wholesale)	Generic Price	Unit	Generic Unit Cost (retail)	Total Units Used in Colorado	Current CO Price	Money Saved with Generics (retail price)
Advair Diskus	250/50	\$ 4.54	\$ 103.78	60	\$ 1.73	2,844,435	\$ 12,461,754.45	\$ 7,993,810.50
Nuvaring		\$ 154.70	\$ 59.93	1	\$ 59.93	68,578	\$ 10,237,567.86	\$ 6,499,137.06
Advair Diskus	500/50	\$ 5.12	\$ 134.59	60	\$ 2.24	1,455,908	\$ 7,193,348.08	\$ 4,188,404.66
Zytiga	250mg	\$ 86.22	\$ 1,076.31	120	\$ 8.97	50,889	\$ 4,234,059.97	\$ 3,931,175.25
Advair Diskus	100/50	\$ 4.67	\$ 84.69	60	\$ 1.41	872,328	\$ 3,931,190.04	\$ 2,842,480.79
Noxafil	100mg	\$ 67.96	\$ 1,789.48	90	\$ 19.88	40,697	\$ 2,668,974.67	\$ 1,956,585.15
Gleevec	400mg	\$ 334.84	\$ 193.29	30	\$ 6.44	3,539	\$ 1,143,658.53	\$ 1,162,196.98
Copaxone	20mg	\$ 238.08	\$ 1,181.27	30	\$ 39.38	4,703	\$ 1,080,602.09	\$ 934,506.48
Jadenu	360mg	\$ 167.95	\$ 1,628.90	60	\$ 27.15	6,525	\$ 1,057,440.17	\$ 918,730.88
Xeloda	500mg	\$ 45.63	\$ 64.93	84	\$ 0.77	17,758	\$ 782,024.14	\$ 796,623.88
Portia 28	0.03/0.15mg	\$ 0.91	\$ 11.26	28	\$ 0.40	1,562,510	\$ 1,364,918.77	\$ 793,531.86
Yaz 28	3/0.02mg	\$ 4.80	\$ 19.32	28	\$ 0.69	175,582	\$ 814,013.37	\$ 721,642.02
Lamictal	100mg	\$ 11.94	\$ 7.62	30	\$ 0.25	61,573	\$ 709,377.23	\$ 719,542.08
Wellbutrin XL	300mg	\$ 14.47	\$ 17.52	30	\$ 0.58	51,109	\$ 713,493.80	\$ 709,699.57
Afinitor	5mg	\$ 556.65	\$ 5,095.26	28	\$ 181.97	1,443	\$ 775,173.66	\$ 540,658.09
Prograf	1mg	\$ 6.16	\$ 41.65	120	\$ 0.35	84,936	\$ 505,199.29	\$ 493,725.89
Synthroid	100mcg	\$ 1.18	\$ 10.00	90	\$ 0.11	404,717	\$ 459,902.57	\$ 432,597.50
Zomig	5mg	\$ 73.99	\$ 8.47	30	\$ 0.28	5,849	\$ 417,576.74	\$ 431,116.14

Projected 1 year savings from generics in CO  
\$43,860,108.09



# Maine

We recently FOIA'd documents out of Maine's Medicaid program (MaineCare) showing that they would LOSE MONEY buying medicine from Canada because they wouldn't get rebates.

Medicaid (MaineCare) touches 1 in 5 residents. Many private insurers also get rebates.

Drug Name	Generic or Chemical Name	Condition	A Current Net and out-of-pocket rebatable price / unit	B Drug Utilization (2017-2018 utilization)	C Plan Total Net Spend Multiple Column A, plus net price by volume %	D Canadian Price (\$ USD)	E Canadian Price with importation 40% rebate (\$ USD)	F Plan Net Spend Importation with 40% rebate (\$ USD)	G Plan Net Spend with Canadian Price with 40% rebate (\$ USD)	H Plan Savings from Canadian Importation Subtract F - Plan Net Spend with Canadian Price with 40% rebate - from actual Plan Net Spend (C)
ARIPY MAINTENA 150 mg injection post corticosteroids	Aripiprazole	Antipsychotic		6		\$142.14* (1 dose)	\$85.28	\$2,976.02		
ARIPY MAINTENA 150 mg injection post corticosteroids	Aripiprazole	Antipsychotic		49		\$142.14* (1 dose)	\$85.28	\$24,089.09		
ASPIRIN DISKIN 100 mg / 20 mg aspirin/acetaminophen	Flurbiprofen-Salicylate	Asthma/COPO		442		\$16.84* (60 doses)	\$10.10	\$36,430.38		
ASPIRIN DISKIN 200 mg / 40 mg aspirin/acetaminophen	Flurbiprofen-Salicylate	Asthma/COPO		1506		\$16.84* (60 doses)	\$10.10	\$148,529.83		
ASPIRIN DISKIN 100 mg / 20 mg aspirin/acetaminophen	Flurbiprofen-Salicylate	Asthma/COPO		381		\$16.84* (60 doses)	\$10.10	\$3,102.74		
ATOMOXETINE 18 mg capsule Generic	Atomoxetine HCl	ADHD	\$	1,91	7321	\$	13,968.88	\$0.38	\$	5,903.91
ATOMOXETINE 18 mg capsule Generic	Atomoxetine HCl	ADHD	\$	1,44	1705	\$	13,086.44	\$0.43	\$	6,287.37
ATOMOXETINE 21 mg capsule Generic	Atomoxetine HCl	ADHD	\$	1,78	13635	\$	24,248.33	\$0.48	\$	14,746.78
ATOMOXETINE 40 mg capsule Generic	Atomoxetine HCl	ADHD	\$	1,38	10373	\$	25,893.02	\$0.55	\$	10,468.27
ATOMOXETINE 60 mg capsule Generic	Atomoxetine HCl	ADHD	\$	1,38	9842	\$	15,318.34	\$0.61	\$	8,665.05
BICITARY 50 mg/200 mg/20 mg tablet	Bictegravir-Empicitabine Fosfato AP	HIV		14780		\$19.42	\$	\$80,819.33		
SUPPION HYDROCHLORIDE 100 mg extended release (12 hr) tablet Generic	Sufentanil	Smoking Cessation/Antidepressant	\$	0.04	41209	\$	2,384.11	\$0.12	\$	6,049.10
SUPPION HYDROCHLORIDE 100 mg extended release (12 hr) tablet Generic	Sufentanil	Smoking Cessation/Antidepressant	\$	0.08	104715	\$	6,463.84	\$0.17	\$	18,880.46
SUPPION HYDROCHLORIDE 100 mg extended release (12 hr) tablet Generic	Sufentanil	Smoking Cessation/Antidepressant	\$	0.15	213022	\$	12,995.08	\$0.11	\$	39,004.77
SUPPION HYDROCHLORIDE 800 mg extended release (24 hr) tablet Generic	Sufentanil	Smoking Cessation/Antidepressant	\$	0.10	140728	\$	16,325.30	\$0.22	\$	51,141.45
EPCLUSA 400 mg/200 mg tablet	Sofosbuvir-Velparvir	Hepatitis C		1834		\$30.71	\$	\$76,791		\$1,428,624.97
GABAPENTIN 100 mg capsule Generic	Gabapentin	Nerve Pain	\$	0.02	475009	\$	5,383.84	\$0.03	\$	23,516.24
GABAPENTIN 800 mg capsule Generic	Gabapentin	Nerve Pain	\$	0.04	193073	\$	76,734.19	\$0.08	\$	212,513.24

Projected loss if imported:  
**\$927,983.28**

# Florida

The Agency for Health Care Administration published a proposed project for \$30mm over 3 years to run their importation program.

Nobody bid.

# Miami Herald

Florida fails to attract bidders for Canada prescription drug importation program

PHIL GALEWITZ

OCTOBER 23, 2020 01:38 PM



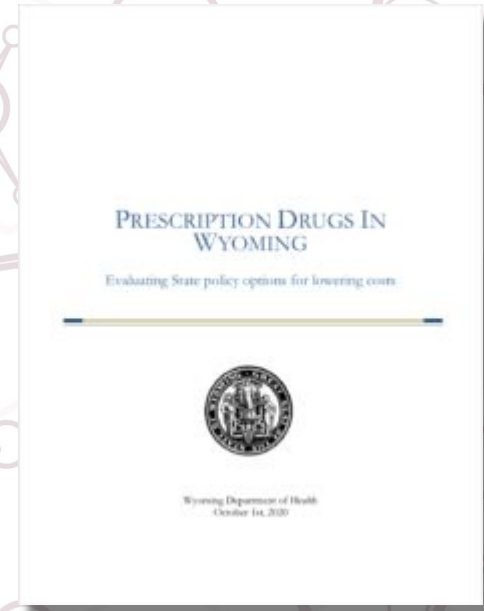
## New Mexico

Six state agencies spent eight months and retained consultant expertise at state expense to develop a Canadian drug importation plan over the objection of Canadians who testified against the plan in February of 2020.

Fifteen days before New Mexico finished their plan, Canada put restrictions on export of medication to the U.S.

# Wyoming

“This [limited state control] makes it virtually impossible to guarantee that consumers will actually see savings, particularly in the case of Canadian drug importation. Basic economics also suggests fundamental problems with this plan that make it unsustainable in the long-run.”



October 10, 2020  
WY Dept. of Health

# North Dakota

“The issues of potentially a very limited supply of imported drugs from Canada, and subsequent price equalization both indicate that little if any potential savings could be realized by the State’s health program.”

**Deloitte.**

Deloitte Consulting LLP  
111 South Wacker Drive  
Chicago, IL 60606  
USA  
Tel: 312 486 0200  
Fax: 877 288 0542  
www.deloitte.com

## Memo

**Date:** June 30, 2020  
**To:** Rep. Mike Lefor, Chairman  
Employee Benefits Programs Committee  
**From:** Josh Johnson and Dan Plante, Deloitte Consulting LLP  
**Subject:** ACTUARIAL REVIEW OF PROPOSED BILL 21.0068.01000

The following summarizes our review of the proposed legislation as it relates to actuarial impact to the Uniform Group Health Insurance Program administered by NDPERS.

### OVERVIEW OF PROPOSED BILL 21.0068.01000

The following is a summary of the relevant proposed amendments:

This bill proposes the requirement that prescription drug benefits under the uniform group insurance program must include coverage for prescription drugs imported from Canada (in compliance with section 804 of the Federal Food, Drug, and Cosmetics Act). Coverage required under this section may allow for a copayment that does not exceed \$25.

The bill also would require NDPERS to provide a report to the sixty-eighth Legislative Assembly regarding the effect of the prescription drug coverage requirement on the system’s health insurance programs, information on the utilization and costs relating to the coverage, and a recommendation regarding whether the coverage should continue.

### ESTIMATED ACTUARIAL IMPACTS

There have been numerous reports issued that indicate that the importation of brand (and, ultimately, generic) prescriptions from Canada will not have an impact on US health care prices. Key points from these reports:

- Canada, with a population about 11% that of the US, does not produce sufficient quantities of drugs to allow for meaningful importation into the US without jeopardizing access for Canadians. Any level of a constricting supply for Canadians would likely increase the cost of Canadian drugs given the continued Canadian demand.
- Canada would potentially oppose any importation plan that would either shrink the Canadian drug supply or raise costs for Canadians.

June 30, 2020



# Has anyone analyzed cost of these programs? Yes.

“While pharmaceutical importation plans are politically attractive, the numbers demonstrate that they fail to deliver cost savings when implemented safely. These schemes can be cheap, or they can be safe, but not both.”

*State pharmaceutical importation programmes: an analysis of cost effectiveness*, Kristina M. L. Acri née Lybecker, Journal of Pharmaceutical Health Services Research, March 18, 2020, Royal Pharmaceutical Society

**JPHSR** Journal of Pharmaceutical Health Services Research



State Pharmaceutical Importation Programs: An Analysis of the Cost Effectiveness

Colorado College Working Paper 2019-02 June 2019

58 Pages • Posted: 19 Jun 2019 • Last revised: 26 Jun 2019

Kristina M.L. Acri née Lybecker

Colorado College - Department of Economics & Business

Date Written: June 12, 2019

#### Abstract

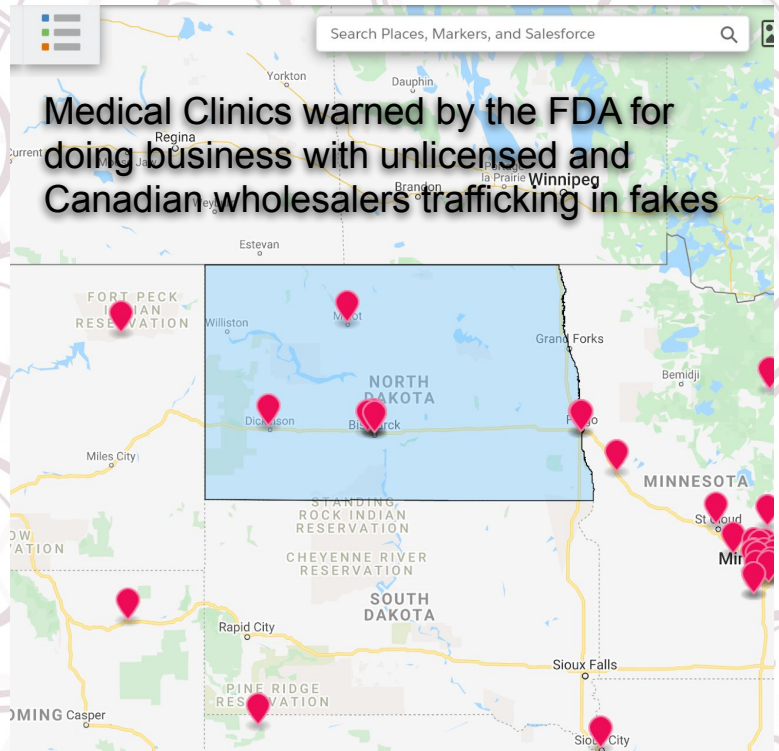
Recently proposed legislation in Colorado, Connecticut, Florida, Maine, Missouri, Oklahoma, Oregon, Utah, Vermont and West Virginia aims to reduce spending on pharmaceuticals by importing them from Canada. To examine the cost effectiveness of importation, this study analyzes 24 drugs from an online Canadian supplier, accounting for the cost savings, the cost of testing, the medical consequences of treatment failure, and the cost of treating an adverse medical event. For a "Representative State", given an adverse medical event, the presumed savings from an online Canadian supplier are exhausted in the treatment of only one patient in the case of Nexium, to 24,318 adverse events for patients in the case of Advair. The analysis shows the cost of testing (99.999% confidence level with 99.999% reliability) exceeds the presumed cost savings in all cases. Pharmaceutical importation plans are politically attractive, but the numbers demonstrate that they fail to deliver cost savings.

**Keywords:** pharmaceutical importation, drug prices, Canadian pharmacy, cost effectiveness

**JEL Classification:** F13, F14, H21, I11, I18, L51, L65

**Suggested Citation:**

# History of counterfeits in North Dakota



Real (top) and fake (bottom) Avastin

## THE DEADLY COUNTERFEIT DRUG TRADE THRIVES IN NORTH DAKOTA

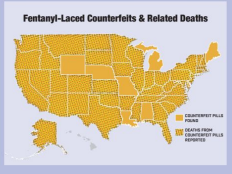
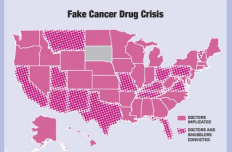
**May 2013:** The FDA warned two doctors to stop purchasing medicine from an unlicensed wholesaler that sold a fake cancer medication.

**March 2020, Grand Forks:** A resident died after taking a counterfeit Xanax made with fentanyl.

**10 NORTH DAKOTA DOCTORS LINKED TO FAKE DRUG RINGS**  
Counterfeit cancer drugs have touched North Dakota as well. 10 different medical practices in North Dakota have been implicated in various black market supply chains associated with counterfeit cancer treatments and other therapies. Families who have lost relatives to cancer will never know if their loved ones were given real medication or fake, and if they died from a lack of treatment.

**THE COUNTRY HAS SEEN AN UPSURGE IN COUNTERFEIT PRESCRIPTION PILLS MASQUERADING AS PAINKILLERS AND XANAX.**  
These pills are disguised as real medications but made with deadly fentanyl or its even deadlier variants, and even a fraction of a single pill can mean death in less than 30 minutes of ingesting it. Fentanyl is a serious threat in North Dakota. Two North Dakotans suffered serious bodily harm after they ingested counterfeit pills made with fentanyl sold by a drug ring operating out of Texas. Between October 2017 and January 2018, five members of a drug ring that sold fake fentanyl pills in North Dakota and Minnesota each received prison sentences ranging from 24 to 65 months. One person in Grand Forks suffered a non-fatal overdose from a pill sold by this drug ring. In March 2020, another Grand Forks resident died after taking a fentanyl-laced counterfeit Xanax pill.

### OPENING THE U.S.'S CLOSED DRUG SUPPLY CHAIN PUTS NORTH DAKOTA LIVES AT RISK OF SERIOUS INJURY OR DEATH.



The Partnership for SAFEMEDICINES®  
© April 2020

# We struggle to extradite Canadian criminals.

## Internet pharmacy pioneer's licence reinstated, just days after it was suspended

Kris Thorkelson's Manitoba licence was pulled on same day his Canada Drugs reached tentative plea deal in U.S.

By Karen Pauls, CBC News | Posted: Dec 21, 2017 5:03 PM CT | Last Updated: Dec 21, 2017 5:14 PM CT



American prosecutors accuse CanadaDrugs.com, its CEO Kris Thorkelson, affiliated companies and associates of selling \$78 U.S. in unapproved and counterfeit cancer drugs to U.S. doctors. (CBC)

A licensed Canadian wholesaler who admitted to trafficking US\$78mm in counterfeit Avastin to U.S. company beat extradition and was allowed to serve six months house arrest.

We cannot outsource regulation of our medicine supply chain to Canadian entities.



## **Canada has no track-and-trace system**

There is no way to track a medicine back to the manufacturing floor if it was made for the Canadian market. There is also no way for the Canadians to do it either.

# Shortage issues

Respective population - 2018



**Breast cancer survivor says Tamoxifen drug shortage is at 'crisis point'**



Pharmacists being asked to limit each patient to 1-month supply of drug, rather than normal 3-month supply



Aly Thomson · CBC News · Posted: Nov 15, 2019 6:00 AM AT | Last Updated: an hour ago



# Canadian action

## Canada Blocks Export Of Medications In Short Supply In Response To Trump Plan

November 29, 2020



Canadian Minister of Health Patty Hajdu, pictured in 2016, announced a new rule in response to a U.S. plan to import drugs from Canada.  
Charly Triballeau/AFP via Getty Images



END OF PRESENTATION