

Executive Summary

Colorado's legislature and Governor passed a bill in 2019 to prepare a plan to import select medicine from Canada. The Canadian federal government, Canadian patient advocates, and U.S. safety advocates objected. They argued that Canadian drug importation wasn't implementable for a number of obvious reasons:

- The country of Canada, which doesn't produce the majority of its own medicine supply, does not have the inventory to supply even a fraction of U.S. demand. Therefore, the Canadian federal government and Canadian stakeholders, including wholesales and patients would not be on board and would block it.
- There are safer and cheaper ways to save money on medicines, such as switching to generics.
- The cost and complexity of testing made the program impossible to save money.

In March of this year the Colorado Department of Health released a draft of the proposed importation plan as part of their comments to the FDA on the draft regulations. It is clear that they are seeking shortcuts on safety checks required by the federal government. They are requesting the ability to contract with:

- Canadian vendors who don't buy their medicine directly from manufacturers, a critical promise made last year during the debate over this legislation.
- Testing vendors that aren't regulated by the U.S. FDA (Food and Drug Administration).
- Medicine relabeling, repacking, and testing vendors who are on foreign soil, where the U.S. FDA and the Department of Justice don't have legal authority and can only access criminals via extradition.

Contrary to promises last year that this program would save money across Colorado, the Department of Health has admitted in filings to the Federal government that no money can be saved for the state's Medicaid population because the program already enjoys discounts that are better than even a foreign country.

Additionally, after being promised that these medicines would be protected by track-and-trace just like our medicines today, the Department of Health has admitted that these medicines would only acquire track-and-trace protection once they enter the United States, leaving the trail of ownership in Canada "on the honor" of the vendor in Canada.

It's clear that this program can't work as designed or promised by backers last year. The responsible thing to do now is to suspend all work on the importation plan and cease burning state budget dollars.

How did we get here?

Last year, supporters of importation in Colorado assured the state that Canadian drug importation would be safe and save Colorado tens of millions of dollars. Since then, the state has appropriated millions of Colorado tax dollars and hired consultants and employees to implement an importation program. In March, they published their plan to import medicine from Canada.

The problem

In the plan, state officials admit that what we were sold as easy last year is actually very difficult. The easy and safe project to import drugs from Canada won't work as passed unless the federal government relaxes its safety standards *even more than it already has*. And yet, state officials continue to burn Colorado state budget money that could be providing critical healthcare services to Coloradans instead.

Here are some depressing things we learned about the money pit that is the Colorado drug importation program. If you care about safety or state tax dollars, you should urge your elected officials to suspend the implementation of the drug importation program, furlough the employees and consultants working on it, and preserve whatever remains of the \$3mm in state budget money allocated to this program.

Colorado wants to import brand name drugs to save money without considering cheaper generic drugs already available in Colorado.

PSM studied the list of medicines the state wants to import from Canada, and nearly a third of them are available in the U.S. as generics—affordable alternatives to brand name medications that have gone off-patent. We found that Colorado's drug list includes many medicines that have cheaper and safe generics available.

For example, the state's own numbers say they could save money by buying Advair Diskus from Canada, which provides relief for asthma and COPD patients. What they fail to mention is that by purchasing the generic version of the product, they could save \$7.9mm per year on that product alone.¹ A generic was approved by the FDA in January 2019 and is on the market right now.

¹ Based on their estimated in-state usage of 2,844,435 units of Advair Diskus 250/50 per year.

The state also says they use 3,539 units of the cancer medication Gleevec per year and want to buy it from Canada to save money. But since 2016 there have been generics approved by the FDA for Gleevec, and if the state were to buy one of those generics, they would save over \$1mm.²

All in all, we totaled up all the generics available for medicine that the state of Colorado wants to import from Canada (which we know isn't going to happen) and we found a savings of more than \$43mm.³

² Based on Colorado's reported usage of 3,539 units of Gleevec 400mg per year.

³ We discovered these savings by comparing GoodRX retail prices to the wholesale prices Colorado listed in their draft proposal. We suspect that the wholesale price of generics would increase the annual savings for Colorado beyond \$43mm.

Analysis of Colorado Draft Importation Plan - Partnership for Safe Medicines
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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

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Cuprimine	250mg	\$ 262.15	\$ 1,557.00	30	\$ 52.57	1,938	\$ 490,376.98	\$ 406,166.04
Synthroid	75mcg	\$ 1.17	\$ 10.00	90	\$ 0.11	377,769	\$ 425,850.79	\$ 400,015.40
Synthroid	112mcg	\$ 1.19	\$ 10.00	90	\$ 0.11	341,012	\$ 390,846.51	\$ 367,914.06
Synthroid	50mcg	\$ 1.18	\$ 10.00	90	\$ 0.11	340,286	\$ 386,852.91	\$ 363,727.92
Synthroid	125mcg	\$ 1.19	\$ 10.00	90	\$ 0.11	332,880	\$ 382,517.94	\$ 359,140.53
Lamictal	150mg	\$ 11.95	\$ 7.80	30	\$ 0.26	29,777	\$ 343,325.24	\$ 348,093.13
Synthroid	88mcg	\$ 1.19	\$ 10.00	90	\$ 0.11	320,991	\$ 370,033.79	\$ 346,313.62
Uloric	80mg	\$ 10.89	\$ 58.80	30	\$ 1.96	37,234	\$ 391,254.07	\$ 332,499.62
Vivelle-Do t	0.05mg	\$ 16.05	\$ 35.55	8	\$ 4.44	28,086	\$ 434,890.82	\$ 325,973.14
Lumigan	0.01%	\$ 71.16	\$ 38.02	1	\$ 38.02	9,661	\$ 663,446.01	\$ 320,165.54
Yasmin 28	3/0.03 mg	\$ 3.96	\$ 19.85	28	\$ 0.71	92,271	\$ 352,188.73	\$ 299,979.61
Vesicare	10mg	\$ 11.42	\$ 21.63	30	\$ 0.72	27,543	\$ 303,631.42	\$ 294,682.56
Revatio	20mg	\$ 48.29	\$ 10.41	30	\$ 0.35	6,092	\$ 283,925.45	\$ 292,050.48
Vivelle-Do t	0.1mg	\$ 16.08	\$ 35.30	8	\$ 4.41	24,275	\$ 376,669.13	\$ 283,228.56
EpiPen	0.3mg/ 0.3mL	\$ 267.30	\$ 124.64	2	\$ 62.32	1,275	\$ 328,919.36	\$ 261,349.50
Wellbutri n XL	150mg	\$ 13.83	\$ 13.31	30	\$ 0.44	18,807	\$ 251,064.84	\$ 251,756.77
Diclegis Dr	10/10m g	\$ 6.80	\$ 106.32	60	\$ 1.77	44,644	\$ 292,812.44	\$ 224,470.03
Sabril	500mg	\$ 140.15	\$ 3,644.86	120	\$ 30.38	1,800	\$ 243,433.36	\$ 197,586.00
Finacea	15%	\$ 6.83	\$ 46.95	30	\$ 1.57	37,403	\$ 246,372.15	\$ 196,926.80
EpiPen Jr	0.15mg /0.3mL	\$ 259.19	\$ 124.64	2	\$ 62.32	988	\$ 247,029.00	\$ 194,507.56
Vivelle-Do t	0.0375 mg	\$ 16.01	\$ 34.49	8	\$ 4.31	16,431	\$ 253,778.57	\$ 192,222.16
Kepra	500mg	\$ 7.50	\$ 9.00	60	\$ 0.15	25,337	\$ 183,368.65	\$ 186,226.95
Relpax	40mg	\$ 52.36	\$ 27.17	6	\$ 4.53	3,662	\$ 185,034.52	\$ 175,153.46
Vivelle-Do t	0.075m g	\$ 16.10	\$ 35.60	8	\$ 4.45	14,757	\$ 229,257.81	\$ 171,919.05
Apri 28 Day	.15mg	\$ 0.41	\$ 7.00	28	\$ 0.25	1,051,330	\$ 416,437.27	\$ 168,212.80

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Sensipar	30mg	\$ 24.75	\$ 147.06	30	\$ 4.90	8,450	\$ 201,859.69	\$ 167,732.50
Climara	0.05mg /day	\$ 12.93	\$ 26.67	4	\$ 6.67	26,680	\$ 332,810.12	\$ 167,083.50
Gleevec	100mg	\$ 94.13	\$ 43.14	30	\$ 1.44	1,615	\$ 146,727.02	\$ 149,697.58
Vimovo	500/20 mg	\$ 41.80	\$ 810.80	60	\$ 13.51	5,169	\$ 208,535.30	\$ 146,213.78
Sensipar	60mg	\$ 51.94	\$ 285.14	30	\$ 9.50	3,060	\$ 153,385.53	\$ 129,866.40
Climara	0.025m g/day	\$ 12.79	\$ 29.99	4	\$ 7.50	13,806	\$ 170,394.76	\$ 73,068.26
					Total Savings with U.S. Generics:			\$ 43,860,108.09

And that means Colorado wouldn't have to pay someone to test medication for safety, or repackage the medicines, or conduct special inspections of Canadian wholesale vendors, or expend additional state budget funds.

Would Coloradans have supported this program last year if they knew the state could save money by switching to cheaper, available, generic medications?

Advocates of importation promised the medicines we buy would be protected by track-and-trace, just like the medicines we use today. Now the state has explained that isn't going to happen.

During the debate on the bill, advocates of Canadian importation promised medicine would be protected by track-and-trace. Safety advocates and Canadians insisted it wasn't true because Canada has no track-and-trace system. Medicine made for America is manufactured with a serialized tracker number on the factory floor, but medicine made for Canada does not.

What Colorado's plan revealed is that advocates have finally admitted that their claims were untrue. The proposed plan admits that medicines bought from the Canadian market will have a unique number attached to it after Canadian vendors handled it, which is not track-and-trace.

Would Coloradans have supported this plan if they knew that their medicine was not going to be protected by track-and-trace just like medicine made for the American market?

Colorado's Department of Health Care Policy and Financing doesn't care about harming Canadian patients. Colorado is proceeding with its plan despite the outright opposition of the Canadian federal government.

Colorado listed 31 different drugs they want to import that Health Canada's [drug shortage tracker](#) says have been in shortage or close to imminent shortage since 2017, including Advair inhalers; EpiPens, which provide emergency relief for life-threatening allergic reactions; and Lamictal, which prevents seizures. None of these medications are optional for the Canadian patients that take them, and emptying the limited supply in Canada of them, even for a few months, would significantly harm them.

In the next chart, we show those medications that have been monitored for shortage by Health Canada, the date of the most recent shortage report, and the number of shortage incidents tracked by Health Canada.

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Drug	Strength	Most Recent Filing	Number of Reports
Advair Diskus	100/50	12/28/2019	1
Anoro Ellipta	62.5-25 mcg	2/8/2019	1
Apri 28 Day	.15mg	10/24/2019	3
Cuprimine	250mg	12/22/2018	2
Dificid	200mg	1/11/2019	3
Dulera	100/5mg	6/7/2017	1
Dulera	200/5mg	1/25/2020	7
EpiPen	0.3mg/0.3mL	9/25/2019	6
EpiPen Jr	0.15mg/0.3mL	2/20/2019	2
Farxiga	5mg	4/16/2019	1
Finacea	15%	9/3/2020	3
Incruse Ellipta	62.5mcg	2/6/2020	2
Isentress	400mg	2/24/2018	1
Januvia	100mg	10/11/2017	2
Lamictal	150mg	3/16/2018	1
Lamictal	100mg	5/26/2018	1
Lumigan	0.01%	10/5/2017	1
Nuvaring		2/4/2020	9
Portia 28	0.03/0.15mg	10/10/2019	1
Premarin Cream	0.625mg/g	12/19/2018	5
Relpax		7/31/2019	1
	40mg		
Retin-A	0.03%	9/10/2019	7
Revatio	20mg	3/18/2017	1
Serevent diskus	50mcg	2/15/2019	2
Synthroid	100mcg	11/24/2017	1
Synthroid	125mcg	12/18/2017	2
Synthroid	112mcg	1/30/2020	2
Tradjenta		11/8/2017	2
	5mg		
Wellbutrin XL	300mg	2/3/2019	3
Wellbutrin XL	150mg	2/3/2019	3
Xigduo	5/1000mg	1/15/2019	1

Colorado officials said they've been in touch with the Canadian authorities, but they fail to acknowledge that the official Canadian position on importing their drugs is clear opposition. The Canadian federal government is the chief regulator of all pharmaceutical wholesalers in Canada. Here's what they said on March 9, 2020 about the federal program which would allow Colorado to import medicine from Canada:

The Canadian drug market and manufacturing capacity are too small to meet the demands of both Canadian and American consumers for prescription drugs...Canada opposes the proposed rule... as it is not an effective approach to reduce drug prices in the U.S. and could exacerbate drug shortages in Canada, putting the health of Canadians at risk.⁴

Would Coloradans have supported this program last year if they knew the Canadian federal government had promised to act to stop it?

Colorado wants to put repackaging, relabeling, and testing vendors on foreign soil where the FDA's legal authority is limited.

Federal importation regulations require that all the repackaging and relabeling services necessary to make Canadian drugs safe for use in the U.S. must be conducted on U.S. soil by FDA-regulated vendors. This is because the U.S. Department of Justice has learned over the last decade that it is challenging,⁵ and sometimes impossible to extradite counterfeit criminals from Canada.⁶

At no time during the debate last year did proponents of this legislation warn that these vendors would be located on foreign soil, in a country with a history of challenging extradition for medical crime.

⁴ Comment from Government of Canada on the Food and Drug Administration (FDA) Proposed Rule: Importation of Prescription Drugs, <https://www.regulations.gov/document?D=FDA-2019-N-5711-1208>.

⁵ In 2015, Canadian companies [TC Medical Group and SB Medical](#), Inc pleaded guilty to selling misbranded prescription pharmaceuticals, [including counterfeit Botox](#), to U.S. medical practices. The company paid \$75 million in fines and forfeitures, but prosecuting individuals proved difficult. Four of the six individuals who were indicted for falsifying customs forms, repackaging medications to make them look as if they had been FDA-approved or improperly storing sensitive cold-chain injectable medications walked away with probation.

⁶ CanadaDrugs.com, associated companies, and individuals were [indicted](#) in 2014 for selling American medical practices [\\$78 million in non-FDA approved drugs, some of which were counterfeit](#). The case ended in [2018 plea deals](#) that led to \$34 million in fines and forfeitures, but U.S. officials were never able to extradite Canadian citizens for prosecution. CEO [Kris Thorkelson](#) agreed to a six-month house arrest followed by four and a half years probation and a small fine. Six additional individuals had all charges against them dismissed.

Would Coloradans have supported this plan last year if they were told that the vendors managing critical functions were to be located on foreign soil, where the FDA has no legal authority?

Colorado has deeply underestimated the cost of safety-testing imported medicines.

When SB19-005 was passed in 2019, supporters of the bill were clear these medicines would be tested. And the language in the act was clear that “each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation.”⁷ Colorado College economics professor Dr. Kristina Acri née Lybecker has estimated the cost of testing medications imported from Canada.⁸ By her estimate, testing the 2,844,435 units of Advair diskus 250/50 that Colorado wants to buy from Canada would cost \$4,100 for a single sample and a statistically valid sample tested to 99.99% confidence and reliability would require testing 92,099 samples at a cost of \$377mm.⁹ In the best-case scenario, Colorado would save \$7.7mm buying them from Canada, a figure that is dwarfed by the cost of testing. Saving \$7.9mm by buying generic Advair Diskus from the United States’ existing, regulated drug supply makes a lot more fiscal sense, especially when you consider that no additional testing will be required.

Would Coloradans have supported this proposal last year if they knew the cost of testing would obliterate any savings?

Colorado promised us the medicines they imported would be tested to FDA standards but in this draft proposal they back away from having FDA-certified labs conduct those tests on U.S. soil.

The FDA concluded that to effectively regulate imported medicines, they needed to be tested for authenticity by a qualified laboratory in the United States with an FDA inspection history.¹⁰ In the legislation Colorado passed in 2019, the bill stated that “all testing required...must be conducted in a qualified laboratory that meets the standards under the federal act.”¹¹

In the ensuing months, Colorado officials have decided that those standards are unnecessarily rigorous, and are lobbying the federal government to weaken them, rather than admitting to the Colorado public that they can only save money by lowering safety standards.

Would Coloradans have supported this bill knowing that testing would be done by foreign labs not regulated or legally inspectable by the FDA on foreign soil?

⁷ CO SB 19-005 (2019) p. 5 clause (I)(A) and (I)(B).

⁸ Dr. Acri also submitted testimony to this effect when this bill was being discussed last year, including her testing calculations.

⁹ \$377,605,900 to be exact.

¹⁰ Proposed Rule, Importation of Prescription Drugs, page 42.

¹¹ CO SB 19-005 (2019), p.5, Clause (3).

Coloradans need to ask some important questions of their legislature

- Why is the Colorado Department of Health Care Policy and Financing happy to spend taxpayer money implementing a plan that violates the limitations of federal law for importation and is clearly not unimplementable in a way that saves money and meets the safety promises made last year?
- How is that a responsible use of three million dollars of state funds?
- Everyone knows the Canadian importation plan is not going to work. The wholesalers and pharmacists in Canada know it. The Canadian federal government knows it. And now it's clear the Colorado Department of Health knows it too. Why are we still pursuing it?

The responsible thing to do right now would be to immediately stop spending money implementing a plan that Colorado's Department of Health Care Policy and Financing has admitted is too flawed to be implemented.