



April 7, 2021

Members of the House Health & Insurance Committee

Re: Sb 21-123, Expand Canadian Import Program

NFIB Position: SUPPORT

This letter presents the comments of NFIB Colorado concerning Sb 21-123, the Expansion of Canadian Import of Prescription Drugs.

NFIB is an incorporated nonprofit association with nearly 300,000 members across America. NFIB Colorado represents approximately 7,000 of those members. NFIB protects and advances the ability of Americans to own, operate, and grow their businesses and, in particular, ensures that the governments of the United States and the fifty states hear the voice of small business as the formulate public policy.

Small and independent business owners often assist or encourage their employees to obtain affordable, flexible, and predictable health insurance coverage, including prescription drug coverage, and appropriate access to medical care and medicines for themselves and their families.

Greater competition in the marketplace for safe and effective drugs should give consumers better prices in that marketplace. For the benefit of small and independent business owners and their employees, NFIB supports greater competition in the market for safe and effective drugs, including by opening that market to competition from prescription drugs imported from Canada.

NFIB appreciates that the Sponsors are committed to expanding small businesses and their employees access to high-quality, safe and effective, affordable medicines.

Please vote YES on Sb21-123.

Tony Gagliardi, State Director
NFIB Colorado
303-831-6099



Written Testimony in Opposition to Senate Bill 123
Submitted by Emily Roberts, Vice President, Colorado BioScience Association
House Health & Insurance Committee
April 7, 2021

Chairwoman Lontine and Members of the Committee, thank you for the opportunity to submit written testimony on Senate Bill 123. My name is Emily Roberts, and I am testifying on behalf of the Colorado BioScience Association (CBSA).

CBSA respectfully opposes Senate Bill 123, which would expand the Canadian drug importation program to other countries.

CBSA represents over 720 life sciences organizations and 32,000 employees across the state that drive global innovations, products, and services to improve and save lives. Our members play a crucial role in the development of breakthrough technologies and therapies that are leading to improved patient outcomes and reduced health care costs. Many of our members are also leading in the fight against COVID-19, researching and developing innovative treatments and adapting technologies to address emerging needs during the pandemic.

CBSA is committed to ensuring patients have access to the medicines they need, but we oppose programs to import prescription drugs from foreign countries. Such programs would jeopardize patient safety by opening up the closed drug supply chain and increase the risk of counterfeit or adulterated drugs infiltrating the U.S. supply. Additionally, implementing a drug importation program will do very little to lower prescription drug costs for Coloradans.

First, there is inherent risk to patient safety when introducing foreign imports into the U.S., making it easier for counterfeit medicines to enter the supply chain. Over the past 15 years, key government officials and experts have stressed these concerns. In fact, a few years ago a bipartisan group of former FDA commissioners sent a warning letter to Congress cautioning lawmakers against importation proposals. In the letter they stated: *"We believe that such importation represents a complex and risky approach – one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products."*¹ These concerns about patient safety should not be ignored.

Secondly, importation will not save Colorado patients money. The Congressional Budget Office (CBO) estimates that a national importation scheme would reduce prescription drug costs in the U.S. by just 1%, and that does not consider the costs of new regulatory schemes to ensure the safety and quality of imported drugs.²

Lastly, two years ago the Colorado state legislature passed SB19-005 to create a Canadian drug importation program, which requires the state to submit an application for approval to HHS. To date, the state has already spent millions of dollars on the program without any data to support whether it

¹McGinley, Laura. (2017, March 17.) Four Former FDA Commissioners Denounce Drug Importation, Citing Dangers to Consumers. *Washington Post*. Retrieved from <http://www.washingtonpost.com>.

² Congressional Budget Office, "Cost Estimate: S.1392 FTC Reauthorization Act of 2005," September 8, 2005.

is feasible.³ The program also requires *voluntary* participation from Canadian and U.S. wholesalers, however, the industry association representing U.S. wholesalers remains opposed to drug importation, and the Canadian government has recently taken steps to protect their country's drug supply amid renewed U.S. interest in drug importation proposals. Without the willing participation of key vendors and the Canadian government, it is hard to see how the program could be operationalized.

While we appreciate the intent of this legislation and share the goal of improving the affordability of medicines, we do not believe drug importation will achieve that goal. We hope to work with members of the General Assembly to advance other policies that will lower out-of-pocket costs for patients right away, including sharing manufacturer rebates and discounts with patients at the pharmacy counter. By passing through rebates to the patient taking the medication, we can significantly lower out-of-pocket costs and improve medication adherence, particularly for those with chronic diseases.

In light of these concerns, we ask you to oppose Senate Bill 123. Thank you.

³ Colorado Legislature. https://leg.colorado.gov/sites/default/files/fy2021-22_hcphrg1.pdf.

Thank you Madame Chair, and members of the committee. My name is Jennifer Roberts and I am a volunteer advocate with the Colorado Cross Disability Coalition. I am excited to support Senate Bill 123.

I use four medicines to control my asthma. Paying cash for two of these would cost more than \$15,000 a year. I have taken Advair for almost 20 years. It is an inhaler that costs \$13 a day. The other inhaler I use is Spiriva which costs over \$30 a day.

I have tried everything I can to stop using these inhalers, have frequently gone without them due to cost, or have used them less to save money. Each time, it has seriously impacted my ability to breathe. The only way to obtain them less expensively is to get them from outside of the United States.

I have two health care goals. One is to get people on both sides of the aisle to agree on a plan and stick to it. The ACA drastically improved my life, but my access to health care is now constantly in danger. The disability community will be greatly impacted if it is repealed this summer. No matter the party in power, I will always need my medication to survive. If this bill passes, I will know that I can pay cash for my medicine no matter what happens.

I hope you will support SB 123 to save Coloradans money and give them the dignity of choice. Thank you.

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
 For more information or to provide feedback contact shabbir@safemedicines.org

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

Analysis of Colorado Draft Importation Plan - Partnership for Safe Medicines
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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	0.025mg/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.

Analysis of Colorado Draft Importation Plan - Partnership for Safe Medicines
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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.

Testimony of Shabbir Imber Safdar (EXTENDED)
Executive Director of the [Partnership for Safe Medicines](#)
April 7, 2021 - SB21-123 (Opposed)

Madame Chair, members of the committee, I am Shabbir Imber Safdar, the Executive Director of the Partnership for Safe Medicines. I am here today to testify in opposition to SB 123, which would expand the not-yet-functioning Canadian drug bulk importation program from Canada to the rest of the world.

Importation from Canada did not work, it will not work anywhere else.

The well-intentioned arguments in favor of this bill are familiar, because you've heard them before. The first time you heard this idea it was to import medicine from Canada. When that legislation was being considered Canadian pharmaceutical wholesalers, pharmacists, patients, law enforcement, and even the Canadian government itself said they wouldn't go along with it. They said the population difference between the countries was too great and they did not make the medicines they take, and had no ability to increase supply in their country to meet U.S. demand.

Over their objections the bill passed, two million dollars was appropriated to implement it and immediately wasted. The Canadian government put a ban on mass exports to make it clear they would not participate in the Colorado program. Colorado has not been able to secure a Canadian wholesaler, cooperation from anyone in the Canadian healthcare system, or explicit permission from the Canadian government.

All that Colorado state tax money is still being spent today to implement a program that can never begin. Today HCPF staff are designing the program and planning to hire a vendor for a program that can never begin. And now, you are being asked to expand this program to other countries who will have the same problem with this as Canada.

The impediments to this program are significant. There is a federal prohibition on states importing medicine from other countries besides Canada. It would take a major, bi-partisan change to federal law for this program to be implemented. I think we know how hard it is to pass any kind of bi-partisan legislation in Washington today.

Testimony of Shabbir Imber Safdar (EXTENDED)
Executive Director of the [Partnership for Safe Medicines](#)
April 7, 2021 - SB21-123 (Opposed)

All the while, Colorado's HCPF will continue spending state tax dollars on this program.

France and most other countries will have the same objections as Canada.

I understand this step is being taken because the Canadians have stated repeatedly that their country doesn't have enough medicine to make a dent in U.S. drug prices due to our population size differences. Recently, for example, HCPF stated that there were significant savings possible in France and Australia if Colorado were to just be allowed to buy from there.

However the population of the US is six times larger than France and thirteen times larger than Australia. Both of these countries are currently experiencing drug shortages and both import most of their medicine. Neither is likely to be any more thrilled than Canada was with having Americans bulk export their drug supply. And while advocates in Colorado might say the state has a much smaller population than those countries, Canada didn't see it that way. They saw any state importation as being something that would be replicated in dozens or all fifty states.

Better ways to reduce healthcare costs

Let's go back to what we agree on: reducing healthcare costs is a priority, and since medicine is about 20% of healthcare costs, an important area.

There are very practical proposals to reduce the cost of medication that you could implement that are entirely within the power of the state.

Regulating Pharmacy Benefit Managers

The first is regulating pharmacy benefit managers operating in your state. All over the country, states are starting to realize just how much money PBMs take out of the pockets of health insurers, states health programs, and patients, and it's a lot.

One of the best examples of this is West Virginia, where they replaced the PBM's managed care services on their Medicaid program to eliminate the price spread.

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An outside actuarial study¹ found that they saved \$54mm in a year. West Virginia's Medicaid population is only about half a million citizens.

There are certainly PBMs profiting from spread pricing in private insurance in Colorado and possibly state programs as well, and that's costing Colorado patients money. There's very attainable savings there.

Utilizing generics

The second opportunity lies in generic utilization. My research team and I scrutinized the draft Colorado drug importation program released last March and in particular were puzzled by something: the plan's authors wanted to import brand name medications from other countries when there are cheaper generics of these medicines right here on the market in Colorado.

We wondered why you would go through all the trouble to import something you could get for less without leaving the state? When we looked deeper, we started counting up all the products that you could save by buying generics and found it added up to \$43mm worth of medicine for one year. Basically, given the quantities HCPF said they wanted to import, you could save \$43mm on that if you just bought generics.

No special permission from the recalcitrant Canadian government required. No state outlays of money to create a program that may never become operational because it violates Track and Trace. Just buy the cheaper, medically equivalent product.

You can read our report on our website analyzing the costs and [I've appended it here in my testimony I've submitted for the record.](#)

There are real savings out there with these measures today, and controlling these costs is a priority for everyone.. Importation will never provide any savings,

1

<https://dhhr.wv.gov/bms/News/Documents/WV%20BMS%20Rx%20Savings%20Report%202019-04-02%20-%20FINAL.pdf>

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certainly any sustainable ones, and I hope that you take a serious look at these other two.

How are other states addressing drug costs?

The question at hand is “What strategies can elected officials use to lower the cost of medicine for Americans?” We offer these because the Canadian government has made it clear that importing from Canada is a dead end.

Generic medications drive down cost: Hands down, the largest single driver of savings in the U.S. are generics. 90% of all prescriptions dispensed today in the U.S. are generic, but they represent only [22% of the healthcare dollar spend](#). In 2018, generics represented \$292.6 billion in savings to Americans, and \$2 trillion over the previous ten-year period. Over the next ten years, generics for biologics (biosimilars) are [slated to save Americans \\$54 billion](#). States looking to import brand-name medication should look first at their own use of brand name medications when cheaper, generic alternatives already exist.

PBM regulation and transparency saves states and patients money: States all over the country are finding that their pharmacy benefit managers are overcharging them and pocketing the profits. Examples include [New York \(\\$300 million\)](#), [Ohio \(\\$224 million\)](#), [Kentucky \(\\$123 million\)](#), and [West Virginia \(\\$54 million\)](#). Regulating PBMs to align their financial incentives to states and patients saves money.

Reverse auctions for Pharmacy Benefit Managers: Asking pharmacy benefit managers to provide their lowest bids for providing benefits to the state is a new strategy that is being used by Maryland, New Hampshire, and New Jersey. New Jersey began this effort with legislation in 2016 and they estimate that the program, which is up and running, will [save a total of \\$2.5 billion by 2022](#).

“Netflix” model to eradicate diseases like Hepatitis C: Washington State and Louisiana are running programs where manufacturers of medicines that cure Hepatitis C bid to provide the state an unlimited supply of the medication for a flat annual fee. The fee includes patient outreach to maximize utilization, with the goal of eradicating the disease entirely. The program makes future budgets more predictable and provides a significant discount from market pricing. Louisiana estimated that they would be able to increase the number of citizens treated through this program from 1,170 to 10,000 by the end of 2020.

Up and coming techniques we’re watching

Nonprofit generic drug manufacturers: Civica RX is a Utah-based nonprofit working to address drug shortages and pricing issues by contract-manufacturing generic medications that are at risk of shortage to control price spikes. Its participants include over 50 U.S. hospital systems, representing 1,350 hospitals and 30% of all hospital beds in the U.S.

THE DEADLY COUNTERFEIT DRUG TRADE THRIVES IN COLORADO

Grand Junction, August 2018:
A pill press and hundreds of counterfeit fentanyl pills were seized from an apartment.

May 2013: FDA sent letters to 12 doctors in Colorado to stop purchasing medicine from an unlicensed drug seller that sold fake cancer medications.

54 COLORADO DOCTORS LINKED TO FAKE DRUG RINGS

Counterfeit cancer drugs have touched Colorado as well. 54 different medical practices in Colorado 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.

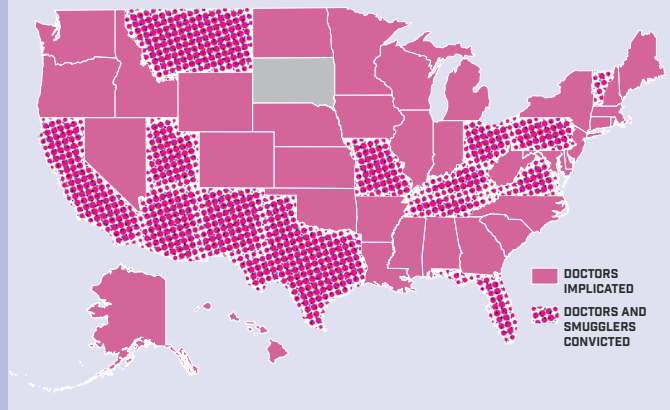
THE COUNTRY HAS SEEN AN UPSURGE IN COUNTERFEIT PRESCRIPTION PILLS MASQUERADING AS PAINKILLERS AND XANAX.

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.

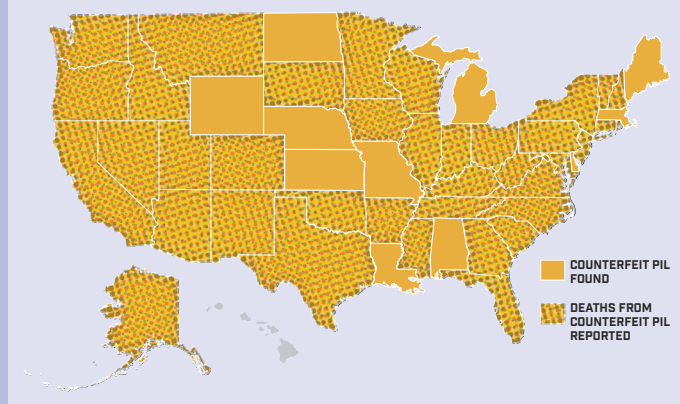
Fentanyl is a serious threat in Colorado. In July 2019, police in Longmont arrested twenty members of a drug trafficking ring and seized nearly 1,500 counterfeit oxycodone pills containing fentanyl. The pills have also been found in Colorado Springs, and deaths caused by fake fentanyl pills have been reported in Boulder, Carbondale, and Grand Junction.

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

Fake Cancer Drug Crisis



Fentanyl-Laced Counterfeits & Related Deaths



COUNTERFEIT AND BLACK MARKET DRUG INVESTIGATIONS IN COLORADO (2011–2019)



BASED ON REPORTED INVESTIGATIONS.

NOTE THAT EACH INVESTIGATION COULD HAVE AFFECTED HUNDREDS OF COLORADO RESIDENTS.

COUNTERFEIT PILLS MADE WITH FENTANYL

- September 2019:** The Northern Colorado Drug Task Force arrested ten individuals and seized a variety of drugs, including counterfeit fentanyl pills.¹
- July 2019:** Law enforcement arrested 14 people with ties to a Colorado Springs drug ring and seized 3,100 fentanyl pills among 19 pounds of other drugs.²
- July 2019:** Police in Longmont arrested twenty members of a drug trafficking ring and seized nearly 1,500 counterfeit oxycodone pills containing fentanyl.³ Boulder County District Attorney's office indicted an additional individual in October.⁴
- January 2019:** Authorities announced federal indictments against five individuals for their roles in the counterfeit pill death of Grand Junction resident Ashley Romero, who died on June 11, 2018.⁵
- January 2019:** Police in Grand Junction seized 251 grams of suspected counterfeit oxycodone pills made with fentanyl during a traffic stop.⁶
- August 2018:** A police raid on an apartment in Grand Junction led to the seizure of a pill press and hundreds of counterfeit pills, including some made to look like Xanax and others that contained fentanyl.⁷
- July 2018:** A 27-year-old Grand Junction man pleaded not guilty to distributing the counterfeit oxycodone pill containing fentanyl that killed 30-year-old Jonathan Ellington on December 28, 2017 in Carbondale.⁸ In August 2018, authorities indicted a second individual, who allegedly made monthly trips to Mexico to purchase fentanyl pills. In January 2019, they also charged the second individual for his alleged role in the death of Grand Junction resident Ashley Romero.⁹
- June 2018:** 22-year-old Benjamin Schwartz pleaded guilty to selling several Xanax pills, one of which was a counterfeit laced with fentanyl, to Boulder resident Madeline Globe. Globe ingested the fake pill and died on August 10, 2017.¹⁰
- October 2017:** U.S. Department of Justice announced indictments against two Chinese nationals for distributing fentanyl across the U.S., including to addresses in Colorado.¹¹
- August 2017:** Charges were announced against Lakewood resident Carlos Ramirez. DEA agents discovered him in possession of 40 pounds of fentanyl at a hotel in The Bronx, NY. Police said this much fentanyl could cause 7 million overdoses.¹²
- November 2016:** A Utah-based drug counterfeiting operation shipped two buyers in Colorado a total of 30 fentanyl-laced counterfeit oxycodone pills.¹³

BLACK MARKET AND COUNTERFEIT CANCER DRUGS

- April 2015:** The FDA warned three Colorado medical practices and more than 270 nationwide to stop buying drugs from Gallant Pharmaceuticals, which sold more than 39 non-FDA approved medications.¹⁴
- May 2013:** The FDA warned 780 medical practices, 12 in Colorado, to stop doing business with unlicensed drug seller Medical Device King, which had sold 31 non-FDA approved medications, including counterfeit Avastin.¹⁵
- 2012–2013:** A Colorado doctor was among more than 500 U.S. medical practices across the country warned to stop buying from CanadaDrugs.com subsidiaries that had sold American doctors counterfeit Avastin.¹⁶

MISBRANDED AND COUNTERFEIT BOTOX

- March 2016:** The FDA warned 34 Colorado doctors and more than 1,200 nationwide to stop buying from Canadian distributor TC Medical, which sold 22 different kinds of non-FDA approved medications, including counterfeit Botox.¹⁷
- November 2012:** Two Colorado doctors were among over 350 U.S. medical practices that received warning letters indicating that they may have purchased counterfeit versions of Botox from Quality Specialty Products (QSP), a CanadaDrugs subsidiary.¹⁸

OTHER DRUGS

- January 2011:** Chinese national Shengyang Zhou pleaded guilty in federal court in Denver to selling counterfeit versions of the weight loss drug Alli that were adulterated with sibutramine. One person who took the fake drugs suffered a stroke.¹⁹

FOOTNOTES

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