



Written Testimony in Opposition to Senate Bill 123
Submitted by Emily Roberts, Vice President, Colorado BioScience Association
Senate Health & Human Services Committee
March 8, 2021

Chairwoman Fields 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 supporting the response to 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 our closed drug supply chain and increasing 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 Additionally, the Canadian government has said repeatedly that it will not guarantee the safety of medicines intended for export to the United States. These concerns about patient safety should not be ignored.

Secondly, importation will not save Colorado patients money, particularly when one takes into account the cost of new regulatory schemes to ensure the safety and quality of imported drugs. Former FDA Commissioner Scott Gottlieb made this point several years ago, underscoring that no government official would implement a drug importation scheme without a reasonable measure of regulatory oversight. He stressed that there are too many channels for counterfeit medicines to enter an importation program and as a result, regulators would require a robust FDA regulatory system.

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

However, if importation is done under an adequate regulatory system, the costs are too high, and it will not end up saving money.²

Finally, 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 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.

² Gottlieb, Scott. (2016, March 4.) What Trump Should Have Said on Drug Prices. *Forbes*. Retrieved from <http://www.forbes.com>.

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

Senate Health & Human Services Committee Hearing
SB21-123 Expand Canadian Rx Import Program
Monday, March 8, 2021

Chairwoman Fields and distinguished members of the Committee; my name is Ingrid Moore, from Longmont. I'm a concerned citizen writing on my own behalf **in support of** Senate Bill 21-123.

I strongly support this bill.

In 2019, the general assembly enacted, and the governor subsequently signed into law, Senate Bill 19-005, which created the Canadian prescription drug importation program, which requires the department, upon approval of the program by the United States secretary of health and human services, to access lower-priced prescription drugs in Canada; and many other countries have even lower prescription drug prices than Canada, as well as different supplies of specific drugs.

Since the program has already been created, it only makes sense to expand its scope.

Please vote YES on this important legislation.

Thank you for your time and attention.

Ingrid Moore
Longmont, Colorado
7 March, 2021

March 8, 2020

Chairwoman Fields
Senate Health and Human Services Committee
200 E Colfax Avenue
Denver, CO 80203

Re: Healthcare Distribution Alliance (HDA) Comment Letter on SB 123, expanding the Canadian Pharmaceutical Importation Program.

Chairwoman Fields, Vice Chair Ginal and Members of the Senate Health and Human Services Committee,

The Healthcare Distribution Alliance (HDA) offers this letter to indicate our opposition to Senate Bill 123, expanding the Canadian Pharmaceutical Importation Program. HDA is the national trade association representing primary pharmaceutical wholesale distributors — the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies and other healthcare settings nationwide. Specific to Colorado, our members provide daily deliveries to over 4,000 pharmacies, hospitals and other points of care across the state. On behalf of the industry, HDA would like to express our concerns with SB 123.

The U.S. pharmaceutical supply chain is the most sophisticated, efficient and highly secure drug supply chain system in the world. The security of the supply chain was further strengthened in 2013 by the passage of the federal Drug Supply Chain Security Act (DSCSA). This law outlines steps to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States. Once operationalized in 2023, the system will improve the detection and removal of counterfeit, stolen and potentially dangerous drugs from the drug supply chain.

Allowing for the introduction of pharmaceutical products from foreign entities would impede on the protections established by the DSCSA, and thereby increase the risk of illegitimate or counterfeit medications entering the US market. Notably, the danger is not necessarily due to the foreign country’s pharmaceutical supply, the concern is opening up the United States’ closed distribution system.

These concerns have been well noted. Four FDA Commissioners wrote an open letter to Congress in March 2017 expressing their continued concerns with a drug importation program stating 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.”¹

The National Association of Boards of Pharmacy also expressed concern with state and federal importation efforts, noting in an October 2020 statement that “allowing Americans to import medications from Canada and other foreign countries opens an additional point of vulnerability in the US prescription drug supply chain. Specifically, each separate proposal effectively creates a new and distinct prescription drug supply chain that will require state regulatory oversight and monitoring, only with fewer protections. This patchwork approach is a step away from

¹ Open letter to Congress authored by four FDA commissioners opposing drug importation, (March 2017) https://www.documentcloud.org/documents/3519007-FDA-Commissioners-Drug-Reimportation.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals

the tightly regulated supply chain and safeguards currently in place to ensure the efficacy and safety of prescription medications.”²

Colorado, or any state, has yet to develop a federally approved prescription drug importation program. Establishing a new law allowing for additional nations to participate in the state program, we believe is premature. Due to these concerns, we request that you oppose Senate Bill 123. Please feel free to contact me at Llindahl@hda.org or (303) 829-4121, if you have any questions or would like to discuss this issue and our concerns further.

Thank you,

A handwritten signature in black ink that reads "Leah D. Lindahl". The signature is written in a cursive, flowing style.

Leah Lindahl
Senior Director, State Government Affairs
Healthcare Distribution Alliance

² NABP Position Statement on New Federal Importation Rules, (October 2020)
<https://nabp.pharmacy/mailbag/october-1/#memo-1>

Testimony of Shabbir Imber Safdar
Executive Director of the [Partnership for Safe Medicines](#)
March 8, 2021 - SB21-123 (Opposed)

Madame Chair, members of the committee, 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.

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.

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. 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

1

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

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

Thank you, and I am available for questions.

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

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

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.



March 6, 2021

Senate Health & Human Services Committee
Colorado General Assembly
200 E. Colfax Avenue
Denver, CO 80203

Re: SB21-123 - Expand Canadian Rx Import Program

Dear Members of the Senate Health & Human Services Committee:

My name is Ann Sutton, living in Westminster CO. This testimony represents the position of the League of Women Voters of Colorado on the bill to expand the prescription drug importation program to apply to nations other than Canada.

The League position is to Oppose this bill because the necessary foundation is not in place and the proposal to advance the program is not timely and not an effective use of legislative resources.

The bill has major flaws.

- There is no enabling legislation passed by the U.S. Congress at this time to allow importation from any nation other than Canada, named or un-named. Any expenditure of funds by HCPF to implement expansion to an additional country, for example by engaging consultants to identify products and assure compliance with federal regulations, would be based on speculation.
- The description "a nation other than Canada" is open-ended with respect to which nations might be considered.

I have over 40 years of professional experience in the regulation of pharmaceutical products; first as a scientist and regulatory reviewer in the Food & Drug Administration (27 years) with responsibilities for regulatory review of applications for clinical studies and for marketing approval including on-site inspections of manufacturing facilities in the U.S., Canada, and the EU, and subsequently as a consultant to the biopharmaceutical industry (13 years) including all phases of product development from design to marketing approval. My experience as a consultant has included drug product regulation and on-site due diligence activities in the U.S., Canada, UK, EU, India, and Australia.

In researching the regulatory environment for this bill I have read the entire Final Rule with comments) for FDA's implementation of the Section 804 Importation Programs (SIP) in order to compare Colorado's SIP draft proposal and SB21-123 to the requirements of the Final Rule.

Because Colorado's final SIP has not been submitted to FDA, HCPF has not yet demonstrated that SB19-005 (CRS Title 25.5 Part 2 Canadian Prescription Drug Importation Program) can be implemented as originally described. In my opinion, the Draft SIP submitted to FDA in March 2020 not compliant with the Final Rule

The Section 804 Importation Program is limited to importation from Canada only and the Final Rule is very specific about requirements for licensing, registration and other oversight of eligible prescription drugs by Health Canada. Health Canada is the national authority that regulates, evaluates, and monitors the safety, efficacy, and quality of drugs available to Canadians. Section 804 defines Eligible prescription drugs for import as drugs that could be sold legally in either the Canadian or American market with appropriate labeling.

SB21-123 would amend current Colorado law (Canadian Prescription Drug Importation Program) to require HCPF to provide evidence comparing the other exporting nation's regulatory system to the regulatory system administered by FDA. The bill does not define criteria for determining this comparability. As noted above, Section 804 Final Rule specifies about requirements for licensing, registration and other oversight by Health Canada.

In my opinion current CRS Title 25.5 Part 2 that incorporates SB19-005 is not fully compliant with the Final Rule and should probably be amended to bring it into alignment. For example, SB19-005 does not match certain definitions, such as Manufacturer, Foreign Supplier, Eligible prescription drug. SB21-123, in proposing to add section 208, would have the same missing or non-aligned definitions.

It is my professional opinion that the Colorado SIP in draft can be revised to become compliant with the Final Rule and is likely to be approved by FDA at a future time. When this process is completed, Colorado will have an opportunity to achieve the objective of significant reduction in costs of a number of prescription drugs that can be obtained by pharmacists in the state and who are assured of the quality of the drugs they will provide.

The League looks forward to the future implementation of a Canadian Prescription Drug Importation Program that will help make prescription drugs more affordable and reduce overall costs of health care.

Sincerely,



Ann Sutton Volunteer Lobbyist
League of Women Voters of Colorado
1410 Grant Street, Suite B-204
Denver, CO 80203

Witness Signup List

Senate Health & Human Services

Witness List - SB21-123 Expand Canadian Rx Import Program

First Name	Last Name	Position	Representing	Testifying	Registered
Brian	Tapley	For	DOC	In Person	3/8/2021 13:27
Kim	Bimestefer	For	HCPF	In Person	3/8/2021 12:37
Kelly	Swartzendruber	For	HCPF	In Person	3/8/2021 12:42
Shabbir	Imber-Safdar	Against	Partnership for Safe Medicines	Remotely	3/4/2021 17:52
Gregory	Glischinski	For	AARP	Remotely	3/4/2021 18:24
Sarah	Staron	For	Young Invincibles	Remotely	3/5/2021 11:51
Emily	Zadvorny	For	Colorado Pharmacists Society	Remotely	3/7/2021 21:04
Jennifer	Roberts	For	Colorado Cross Disability Coalition	Remotely	3/7/2021 12:16
Michael	Neil	For	Colorado Cross-Disability Coalition	Remotely	3/8/2021 13:31
Tony	Gagliardi	For	NFIB Colorado	Remotely	3/8/2021 8:33
Sami	Diab	For	Self	Remotely	3/8/2021 10:56
Robert	Smith	For	Colorado Business Group on Health	Remotely	3/8/2021 11:09
Isabel	Cruz	For	Colorado Consumer Health Initiative	Remotely	3/8/2021 12:34
Michael	Neil	For	Colorado Cross-Disability Coalition	Submitted text	3/7/2021 22:26
Leah	Lindahl	Against	Healthcare Distribution Alliance	Uploaded file	3/6/2021 10:27
Ingrid	Moore	For	Self	Uploaded file	3/7/2021 18:15
Ann	Sutton	Against	League of Women Voters	Uploaded file	3/8/2021 9:06
Emily	Roberts	Against	Colorado BioScience Association	Uploaded file	3/8/2021 9:39
Robert	Smith	For	Colorado Business Group on Health	Uploaded file	3/8/2021 11:36
Shabbir	Safdar	Against	Partnership for Safe Medicines	Uploaded file	3/8/2021 11:51
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Senate Health & Human Services

Testimony - SB21-123 Expand Canadian Rx Import Program

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Witness Signup List

SB 123

Thank you, Chairwoman Fields and Vice-Chair Ginal. Thank you esteemed members of Senate Health and Human Services. My name is Michael Neil and I rise to strongly support SB 21-123 on behalf of CCDC and on behalf of myself and my family. Thank you, Senator Ginal and Senator Coram for bringing this bill. I support both the 2019 initial creation of the Canadian importation, as well as its expansion. I take a number of prescription medications, three of which would be affected significantly by both bills. My Myrbetriq costs \$430 and my Amitiza costs \$288.10, since they are not on my formulary. My Motegrity costs \$396.53, only because my physician requested prior authorization, which put it on the formulary. Without such authorization, it would cost \$476.26. As for my mother, she takes Xiidra, costing \$553.33, according to GoodRx. All of these costs are for a one month supply. Do the yearly math. While some of our medications are much cheaper, payment for these prescriptions is onerous and painful. While I do not know precisely how much cheaper these particular prescriptions are in Canada, according to DrugWatch, the average savings for all prescription drugs in Canada is 65%. However, savings rise to 67% in France, according to the same source. Moreover, competition from multiple countries, if federally allowed within the United States, might drive costs even lower thanks to market forces. Thank you very much and I hope you vote aye on SB 123. Thank you for your time.

Michael	Neil	For	Colorado Cross-Disability Coalition	Submitted text
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Ingrid	Moore	For	Self	Uploaded file
Ann	Sutton	Against	League of Women Voters	Uploaded file
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Witness Signup List

Robert Smith For Colorado Business Group on Health Uploaded file

Witness Signup List

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Senate Health & Human Services

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Witness Signup List

Robert Smith For Colorado Business Group on Health Uploaded file

Witness Signup List

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shabbir@safemedicines.org

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robert.smith@cbghealth.org

To: Senate Health & Human Services, Senator Rhonda Fields, Chair; Senator Joann Ginal, Vice Chair; Senator Sonya Jaquez-Lewis; Senator Janet Buckner; Senator Barbara Kirkmeyer; Senator Cleave Simpson; Senator Jim Smallwood

From: Gregory Glischinski

Subject: SB 21-123, Expand Canadian Rx Import Program Testimony

Madam Chair, Members of the Committee, my name is Greg Glischinski. I am a volunteer with AARP Colorado. AARP has 673,000+ Colorado members age 50+. **AARP supports SB21-123, Expand Canadian Rx Import Program** providing older adults and other consumers with an alternative to skyrocketing prescription drug prices, through importing drugs, using the Canadian Rx Import program model, from additional countries such as France and Australia. This program can increase competition in the market.

To put our drug prices in context here compared to Canada, an antibiotic I was prescribed a little more than a decade ago, my out of pocket cost was \$855/month, today's cost is \$4500/month, a 426% increase. **Today the generic brand of this drug in Canada costs \$137/month, or 3185% less than Colorado.** I can not find where you can buy the generic here.

Older adults are more likely to need prescription drugs related to heart disease, diabetes, respiratory disease and post cancer treatment. Some older adults can't budget for both food and prescription drugs with increasingly high out-of-pocket expense for many on a fixed income. High drug costs affect patient compliance leading to further medical problems.

SB19-005 passed by the Colorado legislature, is being successfully developed. With Federal legislation it is projected that it could be in place by mid-2022. SB21-123 provides for expansion using this successful frame in place for Canadian prescription drug importation.

Through two administrations Federal progress to authorize drug importation from Canada continues to move with bi-partisan support. The FDA has publicized a Final Rule that States may submit importation proposals to the FDA for review and authorization.

Colorado is working carefully on the Canadian program:

- Ensuring importation would not be engaged where Canadian shortages exist
- Going through each drug with Canadian officials for their approval
- Soliciting Canadian Wholesalers and U.S. Importers through Request for Information process getting interest form both
- Product would be re-tested, labeled and U.S. safety rigorously protected
- Fiscal note on this bill anticipates cost savings for multiple entities.

With industry consolidating and the lack of competition, we have to find ways to bring these costs under control.

Sincerely,



Gregory Glischinski



To: Senate Health and Human Services Committee
Date: March 8, 2021
Re: SB21-123 Expanding Canadian Prescription Drug Importation

Good Afternoon Committee Members:

As the Executive Director of The Colorado Business Group on Health (CBGH), I would like to express strong support for SB21-123 on expanding Canadian drug importation as introduced by Senator Ginal, Senator Coram, and Representative McCormick.

CBGH and our new affiliate, The Colorado Purchasing Alliance, represent 19 healthcare purchasers including public and private sector employers, a Taft-Hartley plan, and two employer trusts serving dozens of school districts.

All of these purchasers continue to experience annual healthcare cost increases well in excess of either inflation or of the direct costs of providing such services. In fact, as reported last month by The Commonwealth, Colorado employers experienced premium increases from 2018-2019 that were twice the national average and ***Colorado families saw their contribution increases go up at a rate five times the US average.***

Alongside hospital pricing, prescription drug prices are a principal cause of this major socio-economic challenge. *Drug prices continue to increase – rather typically for apparently no legitimate reason.* Last October, Kaiser Health News reported that of nine drugs with the greatest annual price increases, seven were increased without evidence of any improved clinical efficacy or costs to justify the increases. This forces patients and insurers in the U.S. to spend an added \$5.1 billion. Another report from Institute of Clinical and Economic Review, ICER, noted that the seven top-selling drugs by sales revenue had price increases that were more than two times inflation, as measured by the medical consumer price index.

In large part, this happens because of a market failure. Unlike any OECD country, US healthcare is set up as a free-market. But for markets to function, we need competition - competition that will be enhanced with the expansion allowed in this bill.

Finally, we support this bill because we cannot and should not rely on just a single country like Canada, particularly as additional states pursue this approach. The prescription drug market is now a global market and importation from other countries will be beneficial for all purchasing countries.

Thank you for allowing us this opportunity to support this bill.

Respectfully,
Robert Smith, Executive Director