2021 SENATE HUMAN SERVICES

SB 2209

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

SB 2209
1/27/2021

A BILL for an Act to create and enact a new section to chapter 19-02.1 and a new chapter to title 19 of the North Dakota Century Code, relating to increased access to low-cost prescription drugs; to amend section 43-15.3-12 of the North Dakota Century Code, relating to drug wholesaler fees; to provide for a report; to provide a continuing appropriation; to provide for a transfer; and to provide a contingent effective date.

Madam Chair Lee opened the hearing on SB 2209 at 11:38 a.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Wholesaler licensing in ND
- Licensure fee increase
- Security of supply chain
- Drug importation general fund
- Pharmacy board legal authority in Canada

[11:38] Senator Howard Anderson, District 8. Introduced SB 2209 and provided testimony #3680 in favor.

[11:40] Janelle Moos, Associate State Director, Advocacy, AARP of North Dakota. Provided testimony #3655, #3656, #3657, #3658, and #3659 in favor.

[11:41] Michael Horner, Fargo, North Dakota. Provided testimony #3511 in favor.

[11:47] Mark Hardy, Executive Director, State Board of Pharmacy. Provided neutral testimony #3602.

[11:52] Leah Lindahl, Senior Director, State Government Affairs, Healthcare Distribution Alliance. Provided testimony #3705 and #3706 in opposition.

[11:53] Shabbir Imber Afdar, Executive Director, Partnership for Safe Medicines. Provided testimony #3565, #3566, #3567, #3568 in opposition.

Additional written testimony: (9)

Ellen Schafer, Volunteer, AARP. Provided written testimony #2999 in favor.

Roger Roehl, Mandan Citizen. Provided written testimony #3430 in favor.

John Hoke, Director, State Government Affairs, Biotechnology Innovation Organization (BIO). Provided written testimony #3193 in opposition.

Rayette Brown, WomenHeart, Jamestown. Provided written testimony #3425 in opposition.

Christina Adams, Chief Pharmacy Officer, Canadian Society of Hospital Pharmacists. Provided written testimony #3488 in opposition.

Don Bell, Partnership for Safe Medicines. Provided written testimony #3580 in opposition.

Daniel Chiasson, Canadian Association for Pharmacy Distribution Management. Provided written testimony #3615 in opposition.

Peter Fjelstad, PhRMA. Provided written testimony #3670 in opposition.

Daniel Weiss, Senior Executive Director, Sanford Health Plan. Provided neutral written testimony #3471.

Madam Chair Lee closed the hearing on SB 2209 at 11:54 a.m.

Justin Velez, Committee Clerk

Senate Bill 2209

Testimony of Senator Howard C. Anderson Jr. of District 8

Madam Chair and members of the Senate Human Services Committee. This bill is about getting access to lower prescription drug prices for the North Dakotans

You will notice that this bill and my testimony are very similar to SB 2212. That is intentional as we only need one of these two bills. This one puts the responsibility on the Board of Pharmacy where the ability exists, with your approval, to increase licensure fees on drug manufacturers to pay for the program to import their drugs..

Most of us inherently perceive the prices for the things we buy are too high and the prices for the things we sell are too low. Prescription drugs are no different. Some of these drugs are lifesaving and we need them very badly.

Others will speak to the prices they pay for medications and the experience they have had with the same, or very similar (a conciliation to the manufacturers) medications purchased in Canada.

Manufacturers of prescription drugs do not like these bills. They say, “we are a free market country and we should be able to charge what we want to charge”. OK, then let them explain to us and the American people why they should charge us more than those across our borders. We let them advertise on television, create a market for their product, and then tell our insurance companies and Medicaid what they will charge. The patient has very little ability to shop for the best price.

The pharmacy is stuck in the middle. They are trying to serve their patient while the Government or the insurance company, perhaps through their Pharmacy Benefit Manager is establishing the Maximum Allowable Cost for the drug and setting the fee the pharmacy can charge.

Way back in 2003 our then Senator Dorgan got the current law set in USC 504 allowing importation of drugs from Canada. No administration ever implemented it until in December 2020 rules were promulgated and these two bills, SB 2212 and SB 2209 were drafted to take advantage of those rules.

This idea was developed as a model bill by the Nation Academy of State Health Policy with input from the American Association of Retired Persons and others.

Some will say, “why Canada”? Well there are many countries with lower prescription prices than the United States. But we like Canada, particularly here in North Dakota. They are our neighbors. If we go to Canada or know Canadians, we are comfortable they get good drugs and have good health care. When a drug is approved by Health Canada, we are as comfortable with it as one approved by our own Food and Drug Administration.

Most of us have never heard a good explanation of why the same drug a few miles across the border sells for 40%, 30% or even sometimes 20% of the price for the same drug in North Dakota.

Other states have adopted this approach and I am not sure if any have a program ready to import drugs, as yet. This bill does have provisions which allow us to join other states who are working on the same process or who get a program up and running.

Now Canada may not be happy with us importing from them and using up their drug supply. The market usually flows to where the business is so I think they will solve that over time. There is a risk, if we are successful, prices might rise north of the border. They might also go down here.

Thank you,

Howard

Will States Save by Importing Drugs from Canada? Yes, Here's How

#3655

States can control profit margins and make sure savings are passed on to payers and consumers:

A state can limit imported drug mark-ups and profit margins of suppliers, wholesalers, and distributors.

The state can limit what wholesalers and distributors charge for their administrative services.

Pharmacies and other dispensers must charge payers the Canadian price without any mark-up.

Pharmacies must charge uninsured people or those in their deductible period the Canadian price without any mark-up.

Health plans and other payers pay only the Canadian price without mark-up.

The state audits the program regularly to ensure consumers and payers benefit financially.

Drug Product	Price in the US* **	Price in Canada*** (in USD)
Advair-Diskus (100 mg capsule) GSK	$9.52	$3.96
Eliquis (5 mg tablet) Bristol-Myers Squibb	$6.21	$1.60
Harvoni (90/400 mg tablet) Gilead Sciences	$1,090.35	$797.62
Lyrica (25 mg capsule) Pfizer	$6.04	$0.63
Strattera (100 mg tablet) Eli Lilly	$14.81	$3.96
Tecfidera (120 mg capsule) Biogen	$119.24	$11.92
Tracleer (125 mg tablet) Actelion Pharmaceuticals Ltd.	$173.09	$47.18
Triumeq (300 mg tablet) ViiV Healthcare	$83.36	$31.51
Xarelto (15 mg tablet) Janssen Inc.	$12.44	$2.11

NASHP
NATIONAL ACADEMY FOR STATE HEALTH POLICY

Center for State Rx Drug Pricing

*Centers for Medicare and Medicaid Services. Medicaid.gov. National Average Drug Acquisition Cost. Accessed online May 22, 2017 at https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html

**Drugs.com. Accessed online at https://www.drugs.com/

***Government of Saskatchewan. Saskatchewan Online Formulary Database. Accessed online May 22, 2017 at http://formulary.drugplan.ehealthsask.ca/

How North Dakota Residents Are Impacted By High Rx Costs

#3656

60,228
North Dakota Residents
have been diagnosed with cancer.[1]

58,718
North Dakota Residents
have pre-diabetes or diabetes.[1]

22,311
North Dakota Residents
have heart disease.[1]

Between 2012 and 2017, the price of these name brand drugs increased:

Revlimid
treats forms of cancer

from $147,413/yr

to $247,496/yr[2]

Lantus
treats diabetes

from $2,907/yr

to $4,702/yr[2]

Aggrenox
treats heart disease

from $3,030/yr

to $5,930/yr[2]

Rx 31%

In 2017, 31% of North Dakota Residents stopped taking medication as prescribed due to cost.[3]

Sources:

[1] Total does not include skin cancer. Source: AARP Public Policy Institute analysis using 2017 data from the Behavioral Risk Factor Surveillance System.
[2] Stephen W. Schondelmeyer and Leigh Purvis. Rx Price Watch Reports. Washington, DC: AARP Public Policy Institute, June 2019, https://doi.org/10.26419/ppi.00073.000.
[3] Among 19-64 year old population. State Health Access Data Assistance Center (SHADAC) analysis of National Health Interview Survey data, State Health Compare, SHADAC, University of Minnesota, statehealthcompare.shadac.org, Accessed September 5, 2019

STOP GREED CUT DRUG PRICES NOW™ AARP Real Possibilities

#3657

Rx PRICE GOUGING vs. 50+ INCOME

Americans pay among the highest drug prices in the world and many are having to choose between buying the medications they need and other essentials. Meanwhile, brand name drug prices continue to increase at rates that far exceed general inflation. These relentless price increases could force many Americans to pay drug prices that exceed their entire income for a year.

AVG. ANNUAL COST

The average annual cost for one brand name drug, used on a chronic basis, was around $6,800 in 2017, almost $1,000 more than in 2015.[1]

PhRMA SPENDS BILLIONS

Big Pharma spent nearly $169 million for lobbying and more than $6 billion for advertising in 2018. [5]

IN OUR STATE

The average annual cost of prescription drug treatment increased 57.8% between 2012 and 2017, while the annual income for North Dakotans only increased 6.7%.[6]

NUMBER OF PRESCRIPTIONS

The average older American takes 4.5 prescription drugs, typically on a chronic basis.[2]

AMERICANS PAY MORE

Americans can pay double what similar countries pay for the same name brand drugs.[4]

RESEARCH & DEVELOPMENT?

Nearly 80% of every Big Pharma dollar goes to something other than research and development.[3]

STOP Rx GREED
CUT DRUG PRICES NOW℠

AARP® Real Possibilities

[1,2] Stephen W. Schondelmeyer and Leigh Purvis, "Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2017 Year-End Update," AARP Public Policy Institute, Washington, DC, September 2018.
[3] https://www.csrxp.org/wp-content/uploads/2019/05/CSRxP_One_pager_III_FINAL-SITERELEASE.pdf
[4] https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf
[5] https://www.opensecrets.org/lobby/induscode.php?id=H4300&year=2018 and https://jamanetwork.com/journals/jama/fullarticle/2720029
[6] Based on the price associated with taking 4 widely used brand name prescription drugs. Income is based on median person-level income.

Is It Safe for States to Import Drugs from Canada? Yes, Here's Why

Drug manufacturing is already global.

- 80% of active ingredients used in the manufacture of drugs in the US are imported.
- 40% of prescription drugs sold in the US are produced abroad.*

Safety standards are comparable: Federal regulations already ensure the safety of foreign-produced drugs entering the US market.

- More than 30 Canadian drug manufacturers are FDA-registered to produce drugs for US markets.**
- EU regulatory inspections of drug manufacturing facilities in Europe meet US safety standards.***

Wholesale drug importation from Canada allows states to access a less expensive global drug market.

A licensed wholesaler can help a state implement a wholesale importation program to ensure product safety

- Manufacturers
- Wholesalers
- Pharmacies and Hospitals

NASHP National Academy for State Health Policy

Center for State Rx Drug Pricing

*FDA Commissioner Margaret Hamburg, "The Safety of Prescription Drugs Made Outside the U.S.", The Diane Rehm Show (Feb. 20, 2014). Transcript accessed Sept. 7, 2017. https://dianerehm.org/shows/2014-02-20/safety-prescription-drugs-made-outside-us.

**US Food and Drug Administration Database, "Drug Establishments Current Registration Site", Accessed Sept. 7, 2017. https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

***FDA press release, "Mutual Recognition promises new framework for pharmaceutical inspections for United States and European Union", (Mar. 2, 2017). Accessed Sept. 7, 2017. https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm544357.htm

#3659

Senate Human Services Committee
SB 2209
Prescription Drug Cost Importation
January 27, 2021
Janelle Moos, AARP North Dakota
jmoos@aarp.org – (701) 355-3641

Chair Lee and members of the Senate Human Services Committee,

My name is Janelle Moos, Associate State Director of Advocacy for AARP North Dakota. I appreciate your time today and look forward to working with you on an issue that is crucial to our members and one we are already seeing that they are passionate about.

Before I get into the reasons we are working so hard to fight the high cost of prescription drug prices I'd like to spend just a moment reminding you who we are and why we are here. AARP is a nonpartisan, nonprofit, nationwide organization with nearly 38 million members. 84,000 of those members live in North Dakota – a staggering number when you consider the overall population of our state.

Our story dates back 60 years, to when our founder, Dr. Ethel Percy Andrus found a former colleague of hers living in a chicken coop. I know we talk about that often, but we think it says a lot about why we fight for what we do. A lot of issues touch older Americans and their ability to live safe, independent and healthy lives. Most of our work fits into three areas; helping people choose where they live, remain financially secure and access affordable health care.

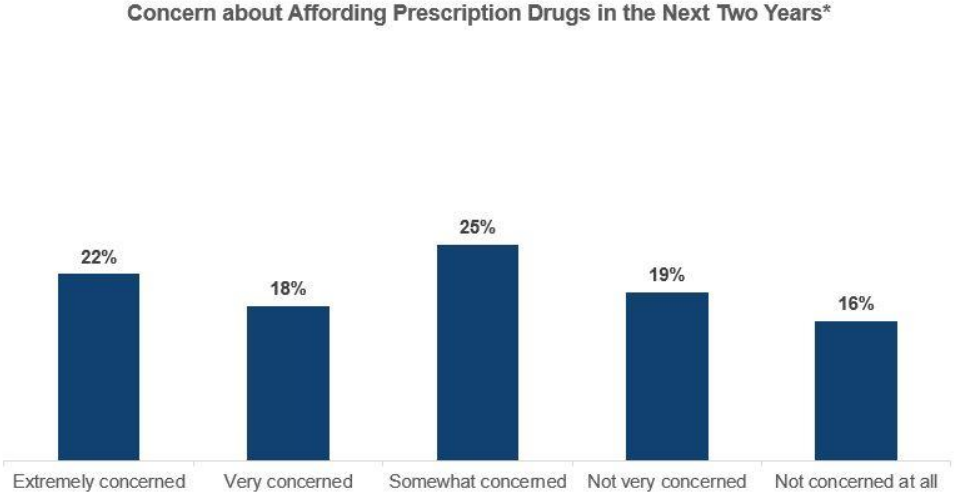
The rising cost of prescription drugs hits our members, and frankly all North Dakotans, in all three areas. It's a high priority for us, not only at the state level, but at the federal level as well. Let me outline just a couple of the reasons why.

The average older American takes 4.5 prescription drugs on a chronic basis. The average annual cost of prescription drug treatment increased 57.8% between 2012 and 2017, while the annual income for North Dakotans only increased 6.7%.

The high cost of prescription drugs doesn't just impact Medicare beneficiaries it impacts all North Dakotans, especially those age 50 and older. In AARP's 2020 survey of North Dakota adults, almost 1 in 4 individuals did not fill a prescription they were prescribed in the last two years. Of those who didn't fill a prescription, 44% of respondents said they had decided not to fill a prescription that their doctor had given them because of the **cost** of the drug. Further, 65% of them are at least somewhat concerned about being able to afford prescription drugs.

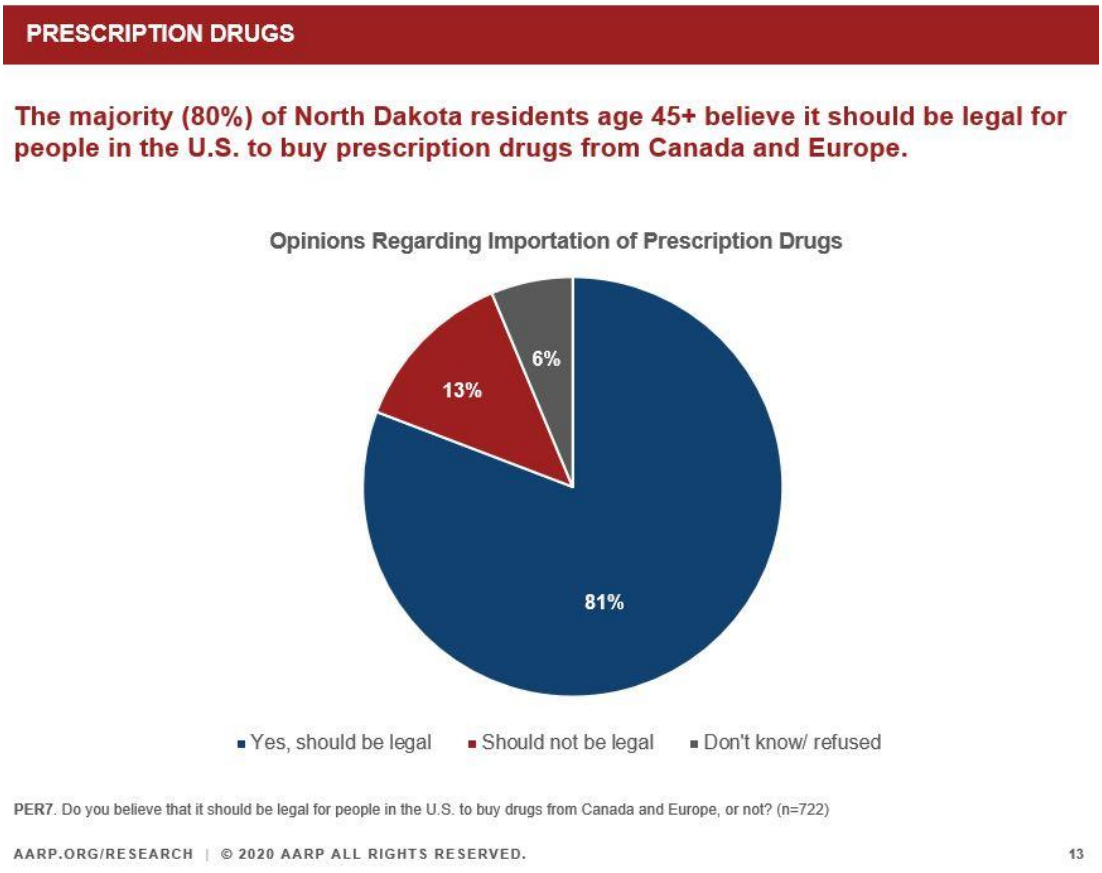
PRESCRIPTION DRUGS

Nearly two-thirds (65%) of North Dakota residents age 45+ are at least somewhat concerned about being able to afford prescription drugs over the next two years.



PER5. How concerned are you about being able to afford the cost of needed prescription drugs over the next two years? (n=722)
*Not equal to one-hundred percent due to removal of small cells; see annotation for all categories

Finally, 81% believe it should be legal for people in the U.S. to buy drugs from Canada.



Attached are two handouts along with my testimony, so you can get a good feel for why North Dakotans often have to make that crushing choice between buying medicine or buying food for themselves or their family. Near the top of the page are three common illnesses in North Dakota – cancer, diabetes and heart disease – with the number of residents of our state who have been diagnosed. More than 60,000 with cancer and nearly as many with diabetes. Below those numbers are common drugs used to treat them and their costs from 2017. Please, take note that we've included what those same drugs cost just five years earlier. **One nearly doubled, another jumped $100,000!**

Now, please take a look at the second fact sheet I included (the yellow one with the circle in the middle). It shows the average annual cost of prescription drug treatment soared more than 57 percent between 2012 and 2017. But, now, look at income. The average income in North Dakota increased just 6.7 percent. It's no wonder people are concerned.

And finally, on our Facebook page you can see some videos of North Dakotans facing these costs. There is one from Pat who told us a drug she took 10 years ago was $60. Now she pays $600! And Roger, who you will hear from today, who has found a way to import the leukemia drug he needs from Canada, saw the price of his medicine jump from 10 bucks to 24-hundred bucks in a month! Why? Because he moved from his great PERS plan to Medicare.

Prescription drug wholesale importation programs, like the one outlined in SB 2209- which would be administered by the State Board of Pharmacy- is one approach that states are considering trying to relieve consumer's financial burdens as it relates to prescription drugs.

I'd like to walk you through some of the common questions you may have heard related to wholesale prescription drug importation programs. I've included a copy of this handout along with the citations for the data and studies I will be referring to.

So, what is wholesale importation? And how is it different that personal or individual importation?

The majority of proposals moving through state legislatures intend to establish importation programs for the state to administer. This is different from personal importation, whereby an individual buys drugs directly from a pharmacy in another country. Personal importation is already allowed by the FDA under certain circumstances. A state-administered wholesale Canadian drug importation program can assure product safety, potency, and purity, as well as consumer cost savings.

Why are we focused on Canada?

The primary reason is that the safety, development and approval standards for prescription drugs in Canada are similar to standards to the U.S. Both the U.S. and Canada have strong clinical trial structure, data and reporting requirements, and post approval measures. And U.S. standards for manufacturing and handling of prescription drugs are similar to those of Canada and the two countries have a long-standing reciprocity agreement for sharing information about manufacturing and compliance.

Has the federal government outlined a process for wholesale importation?

Under the Federal Food, Drug, and Cosmetic Act, the U.S. Secretary of Health and Human Services has the authority to allow for the importation of certain drugs if safety and consumer savings can be assured. The Federal government drew on this authority when it published a final rule on importation in September 2020. The Final rule provided some broad parameters for a state importation program. A state may only import drugs that are currently marketed in the U.S. and approved by Health Canada, and, other than the labeling, meet the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA).

Under this rule, a state-administered wholesale drug importation program could be structured in a variety of ways and could:

• Be available to all state residents or just people covered under state payer programs (such as Medicaid, state employees, or prisons);
• Include all state-licensed payers, distributors, and dispensers, or just a subgroup; and
• Include many drugs or just a small number of products.

Again, the program outlined in SB 2209, would not be a program of personal importation, but instead the state itself would contract with a fully licensed,

regulated supplier from Canada or another country that is required to provide only drugs that are fully regulated and compliant with that country's laws.

Several other states have considered similar legislation including Vermont, in 2018, three other states (Florida, Colorado and Maine) in 2019, and last year New Mexico and New Hampshire passed laws. Similar bills have been introduced in another 21 states across the country.

It is no secret that the US pays the highest prices for prescription drugs in the world. By importing equally safe, less expensive drugs, North Dakota can anticipate reducing our overall expenditures on drugs and, depending on how the state program is structured, can pass on those savings on to North Dakotans who are impacted by the program. Establishing an importation program may take time but fiscal analyses estimate significant savings for the state and consumer. AARP believes that such efforts should be implemented in conjunction with other policy changes that will help reduce prescription drug prices.

Doesn't importation put research and development at risk?

Big Pharma currently spends nearly 80% on something other than research and development and there is tremendous crossover among the manufactures selling drugs in Canada and the US. Currently, there is more than 30 Canadian drug manufacturers are FDA-registered to produce drugs for US markets.

Thank you again for your thoughtful work on this issue. We wholeheartedly appreciate any effort to make medicine more affordable. North Dakota should not sit on the sideline. We should be taking action to help consumers afford their medicines. This bill is a step to do so and we look forward to working with you to make it the best possible bill for North Dakotans.

Michael and Marilyn Worner's testimony for the Senate Human Services Committee- - January 27, 2021

Chairwoman Lee and Members of the Senate Human Services Committee- - We are Michael and Marilyn Worner and have resided in Fargo for the past four years after living in Mayville for thirty years. We are both retired educators.

We are testifying this morning in support of Senate Bill 2209 and are very grateful that Senator Anderson and this committee are tackling this challenging and critical issue.

The rising costs of prescription drugs affects everyone in our great state- - and especially impacts older North Dakotans like ourselves. Most of us live on very modest and fixed incomes and cannot absorb the continuous escalating costs of health care including prescription drugs.

This year my wife and I will declare $22.000.00 in medical costs when we file our income tax. This represent over 30% of our total income. Our prescription drug costs are a major part of this expense and cause us constant concern. We worry that we will be prescribed a drug that we simply cannot afford. You are likely aware according to ARRP that between 2012 and 2017 the average amount of prescription drugs has increased by 57%.

I would like to share my personal story related to prescription drugs and the strategies that I must use to lower my drug costs. I have an eye problem called "dry eyes" that is an issue that cannot be resolved by using over the counter medications. My eye doctor prescribed a medicine that seems to relieve my problem, but costs about $1,700 for a three month supply- -my insurance pays approximately $1,600 of that cost and I pay $120.00. I must use the medication twice each day in order to relieve the symptom of itching which results in painful rubbing of my eyes. About two years ago, when I talked to my doctor and informed him that I was having difficulty paying for the expensive medication, he suggested that I use only half of the prescribed medication daily. He stated that there was not an alternative medication. I have been able to follow his recommendation with fairly good results. This is one method I use to save money - - by rationing my drugs.

A second strategy that I have used to avoid high prescription costs is that I am able to purchase this same medication out of the country at a significantly lower cost. I am able to get a three month supply for about $60.00- - compared to $1.700.00 that it costs me here with my insurance plan. A point of interest is that the medication that I purchase from another country is manufactured in Waco, TX! In my opinion, this is not right. Why can someone purchase a prescription drug for $60.00 when I am paying $1,700.00 for that same drug?

My wife and I are very concerned about the skyrocketing costs of medical and prescription drugs. Will we be able to continue to purchase prescription drugs out of the country? How long will we be able to pay for our prescription drugs?

We are thankful that you are dealing with these important issues and hopeful that you will pass Senate Bill 2209.

Thank you for the opportunity to testify today. We are available to answer any questions that you might have.

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Mark J. Hardy, PharmD, R.Ph.
Executive Director

Senate Bill No 2209 – Prescription Drug Importation

Senate Human Services Committee – Sakakawea Room
10:00 AM - Wednesday – January 27th, 2021

Madam Chair Lee, members of the Senate Human Services Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today about Senate Bill 2209 and offer our perspective on this bill, as well as discuss the fiscal note on the bill and answer any questions you may have about this legislation.

I understand that this is part of a larger discussion and that the two other bills, SB2170 and SB2212 may also factor in on the committee's wishes on this legislation.

Certainly, the Board of Pharmacy stands ready and willing to act on any legislation that you determine to be appropriate to be implemented for the State of North Dakota, and will assist in whatever capacity needed.

The concept of a *Drug Importation Plan* is certainly not new to the Board of Pharmacy, as previous Executive Director, now Senator Howard Anderson was instrumental in working with Senator Dorgan on some of the efforts back in the early 2000s, to put the legislation in place which is now being acted upon Federally. The model was termed the "*Prairie Prescription Project*."

There is a deep layer of complexity with how this plan may work for the State of North Dakota. We certainly understand and appreciate the need for legislative solutions relative to the pricing of prescription medications. Our Office hears about the issues in pricing models from the public entities, patients and even our pharmacists. The current broken model of drug pricing with the many players involved continues to be a bone of contentious. We also must deal with the flip side, the illicit transportation of medications, purported to be Canadian Drugs that flow to consumers of our State. Often, in fact, these medications are actually adulterated and are shipped from third-world countries that are only marketing themselves as Canadian Drugs, often on the internet.

The proposal in SB2209 sets forth a legitimate process for importation of prescription medications to flow from approved Canadian Wholesalers to the State of North Dakota and sets a fairly complex process for how those medications would actually get to the consumers in our State.

Of note, this legislation is going to place a significant burden on the Board of Pharmacy, we are thankful that the Bill Sponsor recognizes and provided a revenue stream the Board can look to enact to assist in funding if the legislature determines to move forward with a *Drug Importation Program.* The Board is a self-sustaining agency, which operates strictly on the license fees collected.

In the prepared fiscal note you will see the revenue, which is a fairly accurate representation of increasing licensing fees on the specific business license type from $400 to $1,000. On the expense side, it is a very difficult proposition to understand the true implementation and running of a program such as this importation model. Our best estimate would be that we would run as a percentage of what the RFP that was run in the State of Florida, which was $30 million dollars. By population, that roughly equates to about one million to the State of North Dakota. It is important to note that there were no bids that were received on the RFP in Florida to begin and operate a *Drug Importation Program*. There are also provisions in the Legislation that has some capacity for streamlining work on a model, including linking up with other State's programs and coordinating with other agencies, as the Board of Pharmacy sees fit.

To be completely transparent, we have deep concerns about our ability to implement and enforce such a program, both in process perspective and in the ability to garnish a working model of importation with a Canadian Wholesaler. Our contacts with our counterparts in Canada indicate a deep resistance within the legitimate wholesale channels of Health Canada to assist states develop a *Drug Importation Program*. The Canadian Government has already taken preemptive steps to make exportation from Canada illegal for any medication that could be in a shortage. Furthermore, states that have been more actively soliciting, to our knowledge, have not found suitable partners for a working program.

I do believe there will be the large challenges to a workable *Drug Importation Program and* have been closely monitoring other states for any developments. Certainly, choosing a wholesaler that may not be a legitimate source is definitely *NOT* an option for North Dakota as the health and welfare of our citizens is paramount. The proven integrity of those products must be assured.

Lastly, we are happy to work with committee members, as well as other agencies involved in previous legislative bills to see if there is a workable model, where the Board of Pharmacy could lend its expertise. Again, we stand ready to assist the State in whatever capacity it determines to move forward.

If you have any questions, I would be happy to answer them at this time.

#3705

THE RISKS AND REALITIES OF COMMERCIAL DRUG IMPORTATION

An End-to-End Analysis of Drug Importation Policy on Patient Safety and the Pharmaceutical Supply Chain

HDA RESEARCH FOUNDATION

SUMMARY

The impact of commercial drug importation on the pharmaceutical supply chain is not well understood. This report explores proposed drug importation policy, in general and with emphasis on proposed legislation since 2013, for commercial feasibility, operational costs to the supply chain, and impact to patients.

Multiple methods were used for qualitative and quantitative analysis as described in the appendices, including expert-panel interviews, literature reviews, and quantitative data modeling.

KEY POINTS:

- *Responsible importation relies on enacted policy achieving the current standard of drug quality and safety.*
- *Significant barriers to importation exist independent of United States (U.S.) policy proposals. These include: limited supply by the small number of countries with compatible approval and safety regulations, limits on products feasible to import, and legal and exclusivity provisions covering many high-cost medicines.*
- *Products viable for importation do not align with the greatest concerns for U.S. patients (e.g., cost and access) due to limitations imposed by handling requirements, available supply, and legality.*
- *Interviews with experts suggest that enacting moderate drug importation policy will likely lead to a 5% increase in drug-related adverse events (AEs). Further, modeling and analysis of AE data predicts a significant increase in costs to patients, conservatively estimated at $200M and potentially reaching $1.4B.*
- *Collectively, patient, regulatory, and supply chain impacts suggest a minimum threshold of $1.1B to $2.9B in costs that must be funded or accounted for in revising or implementing commercial drug importation approaches.*

This analysis concludes that the current proposed drug importation policies, as written, may not provide comprehensive guidance and funding requirements to meet current safety and quality standards for drugs in the U.S. The present realities of global drug supply and permissible product scope indicate that barriers will overshadow benefit to patients in the next three to five years. Lastly, proposed importation policies likely place the integrity of the commercial supply chain at risk.

Definitions:

Commercial Drug Importation is an activity in which a manufacturer, wholesaler, pharmacy, or third party brings drugs to the U.S. that (1) were produced outside the U.S. (2) lack Food and Drug Administration (FDA) approval, and (3) lack oversight of elements contributing to product safety and quality (i.e. ingredients, labeling, manufacturing/production, and/or handling methods) in accordance with and pursuant to a FDA approval.

Drug reimportation is a subset of approved product importation: a case where drugs manufactured and approved in the U.S., but intended for sale outside the U.S., are redirected or reimported into the U.S. commercial supply chain.

This study focuses on federal, rather than state, policies covering commercial importation.[1] Personal importation by patients physically visiting overseas pharmacies is out of scope of this analysis.[2,3]

UNCLEAR PATHS FOR PROPOSED IMPORTATION POLICY

The U.S. governance of drug standards dates to 1937 and has since been evolving (Appendix II Figure 1). This is a closed pharmaceutical system where only drugs that the FDA has reviewed and approved are permitted into the U.S. The comprehensive review and approval process includes: labeling, packaging, manufacturing, clinical data, and other information. Therefore, the system can conclude that there is substantial evidence that the benefits of the drug to U.S. patients will outweigh its risks under the FDA-approved labeled conditions of use. Maintaining these standards should be a requirement of commercial drug importation approaches.

The challenge with foreign drug imports, even if they have been approved by competent, comparable foreign authorities, is that there is no guarantee that the standards for a particular drug are the same as the FDA-approved product. This poses inherent risk to the product standards of the U.S. system and ultimately, to the patient.

In July 2018, the U.S. Department of Health and Human Services (HHS) directed the FDA to develop focused drug importation options to address access challenges. The directive was specific to single-source generics with limited patient availability while respecting patents and exclusivities.[4] This action is one example of the intent to address the increasing gap in affordability of medicines and the desire to improve patient access.

This is not the first time that changes to drug importation regulations have been considered. Lawmakers have made repeat proposals for new importation policies largely since the Medicare Modernization Act was enacted in 2003.[5] Examples of these

[1] Vermont S.175 (Act 133), enacted in 2018, permits wholesale importation of drugs from Canada pending HHS certification that this would reduce costs to consumers and pose no risk to public health. Maine's LD 171, enacted in 2013, did not require HHS certification but was overturned by the Maine District Court, which contended that federal importation provisions preempt any conflicting state laws [*(Ouellette v. Mills, 2015 WL 751760 (D. Me. Feb. 23, 2015)]*

[2] Personal importation is officially permitted only under certain circumstances, including situations in which medicines are not available within the U.S.; however, the American Bar Association notes "in practice the FDA is allowing such importation even though an equivalent drug is commercially available." *(Importing Prescription Drugs Remains Risky Business Due to FDA and DEA Regulation, American Bar Association, Mar 23, 2018)*

[3] The FDA definition of personal importation *does* include importation via courier or mail, which *is* inscope, as a party outside the U.S. is shipping product to a patient. (*"Is it legal for me to personally import drugs?" FDA*)

[4] FDA Press Announcement July 2018 webpage: https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-formation-new-work-group-develop-focused-drug

[5] In particular, the Safe and Affordable Drugs from Canada Act (S.61, 116th ; previously S.2549, 113th; S.122, 114th; S.64 and S.92, 115th); the Affordable and Safe Prescription Drug Act (S.97, 116th; previously S.469, 115th); the Affordable Medications Act (S.3411, 115th); the Improving Access to Affordable Prescription Drugs Act (S.771, 115th); the Personal Drug Importation Fairness Act (H.R. 934, 115th; previously H.R.2623, 114th, and H.R.3715, 113th); the Pharmaceutical Supply and Value Enhancement Act (S.3455, 114th). Proposals introduced in both chambers are referenced by Senate identifier only.

proposals can be reviewed in Appendix II Figure 2. Proposals can be classified by their level of restrictions on the scope of drug importation as: wide open, moderate, or restricted. Experts agree the moderate or restricted importation proposals are most likely to be enacted (Appendix III Figure 2). Supporters of drug importation approaches contend that they will reduce prices and other barriers to treatment for U.S. patients, citing lower prices for similarly branded and generic products in Canada and Europe.[6,7] While this intent is noted, these proposals have considerable variability and lack specificity for execution.

As recently as 2013, the Drug Supply Chain Security Act (DSCSA) established stringent requirements for electronic traceability for all supply chain stakeholders, creating a stricter standard for products entering the U.S. supply chain. As an example, these newer DSCSA requirements have not been accounted for in current proposed drug importation policy.

If not comprehensive enough to meet current standards and legislation, proposed drug importation policy may adversely affect the quality and safety of drugs and patient health. It will also impact the operations of the pharmaceutical supply chain, which acts to maintain the current high standards. Therefore, both patient health standards and execution pathways are at risk.

Appendix II Figure 1 shows importation-related proposals since 2003. Many proposals borrow language both from each other[8] and from related terms in the Medicare Modernization Act. However, these proposals vary in detail regarding execution, and have not been reviewed in depth by the Congressional Budget Office (CBO).[9] Proposals also vary in clarity of traceability, identification, labeling, and packaging requirements.

DEFINING RESPONSIBLE IMPORTATION

To avoid emphasis on the terms of specific proposals and to promote an objective analysis, this report used detailed interviews with experts to determine a framework and definition for responsible importation (Appendix I and Appendix II Figure 2). Most experts agree (~80%) that as written, current drug importation proposals are not detailed enough for execution. This poses inherent risk to existing U.S. processes and standards that enable the flow of drugs to the patient (Appendix III Figure 2). Therefore, a framework for minimum requirements for "responsible" commercial drug importation (1-3) and supply chain execution (4) would include:

[6] Sentiment on this topic is visible from a variety of avenues, including the Trump administration (e.g., "Remarks by President Trump on Prescription Drug Prices," October 25, 2018), the media (e.g., " High U.S. Drug Prices Fuel Outrage, Innovation Debate: QuickTake," *Washington Post*, May 11, 2018), actions from Congress (e.g., Congress holds first hearings on insulin, high drug prices," *Reuters*, Jan 29, 2019), and indicators of public sentiment (e.g., "KFF Health Tracking Poll – February 2019: Prescription Drugs," *Kaiser Family Foundation*, Mar 1, 2019).

[7] Specific reports and studies regarding pricing levels include *Kesselheim AS, Avorn J, Sarpatwari A. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. JAMA. 2016;316(8):858–871.*, and data from the Canadian Patented Medicine Prices Review Board (e.g., "Annual Report 2017," Patented Medicine Prices Review Board)

[8] For example, the Safe and Affordable Drugs from Canada Act has been reintroduced several times since 2014 (S.61, 116th; previously S.2549, 113th; S.122, 114th; S.64 and S.92, 115th). The text of the Affordable and Safe Prescription Drug Act (S.97, 116th; previously S.469, 115th) can also be found within the Affordable Medications Act (S.3411, 115th) and Improving Access to Affordable Prescription Drugs Act (S.771, 115th)

[9] "Preliminary Estimate – S.469, the Affordable and Safe Prescription Drug Importation Act (as introduced)." Congressional Budget Office, July 2017

1) Country of Origin: Comparable regulatory standards and supply conditions;

2) Product Categories: Products capable to be imported based on chemical make-up, stability, non-FDA oversight, and handling requirements;

3) Legal and Competitive Status: Transactions that abide by exclusivity, active patents, and other legal considerations; and,

4) Supply Chain Interaction: Achievement of review, tracing, and monitoring and management per the stipulations for supply chain stakeholders.

As outlined above, experts in this study recommend these minimum requirements to define "responsible importation," or importation proposals that would preserve current quality and safety standards.

COUNTRIES MATCHING U.S. REGULATORY STANDARDS HAVE LIMITED SUPPLY OF VIABLE AND NEEDED MEDICINES

Secondary research and modeling quantified the requirements for responsible imports.

Findings suggest that the supply of importable products is limited and that these products may not align to areas where U.S. patients experience the greatest difficulties with cost and access. Successful importation also depends on foreign governments' willingness to facilitate exports. Most in-scope products are expressly intended for consumption in their own market, and some sources suggest that not all countries will support exportation to the U.S.[10]

> ***"Foreign countries [will not] allow their local supply to be skimmed off, only to create local shortages of important medicines."***
>
> *- Dr. Scott Gottlieb, former FDA Commissioner* [17]

Country of Origin: Canada and the five leading economies of the European Union (EU5: Germany, the United Kingdom, France, Italy, and Spain) are the most viable sources of drug imports, as their regulations are most comparable to U.S. standards and their geographic distance might enable efficient transport. These criteria are based on expert recommendation of each country's comparable regulatory approaches, limits of transport, and analysis of their potential available supply (Appendix II Figure 4).

Product Categories: Viable products would likely be limited to oral, small-molecule drugs (Appendix II Figure 5). Biologics would be difficult and costly to import outside the current supply chain due to product complexity and handling requirements. Some proposals also exclude biologics and complex agents outright.[11] Controlled substances would also be excluded, as they are regulated separately by the Controlled Substances

[10] Lack of overseas willingness was identified as a challenge by Dr. Scott Gottlieb, FDA Commissioner 2017-2019, in a 2016 contribution to *Forbes*: "foreign countries [will not] allow their local supply to be skimmed off, only to create local shortages of important medicines." The Canadian Minister of Health for 2008-2013 previously proposed such restrictions, and voiced opposition to drug export in a 2017 contribution to the Washington Post. *Gottlieb, "What Trump should Have Said on Drug Prices," Forbes, Mar 4, 2016; Aglukkaq, "Dear Bernie Sanders: Canada is not the United States' drugstore," Washington Post, May 12, 2017*

[11] For example, The Safe and Affordable Drugs from Canada Act (S.61, 116th), the representative policy for the moderated scenario

Act of 1970.[12] The result is limited importable product supply, with little alignment to categories of need, like products of highest price and limited access.

Legal and Competitive Status: Importable drugs will most likely need to be chemically equivalent to those approved for U.S. patients to see significant demand. Drugs will also be viable to import only if they do not infringe upon any active U.S. patents or other exclusivity provisions[13], as the cost of potential lawsuits would deter importers from bringing in protected products. [14,15] Branded medicines that have already passed U.S. exclusivity remain in scope (Appendix II Figure 6)

Based on these three criteria, drugs representing $40.3B in Canadian and EU5 sales fall in scope for this analysis (22% of the $184.7B in total annual sales across the six included markets at local prices).

Applying these criteria to 2018 sales in the U.S. suggests that responsible imports would compete with 14% to 18% of U.S. sales in that year. It should be noted that these figures represent the full *potential* scope. Most of the $40.3B in international sales would be distributed in their own markets. Therefore, the volume of non-FDA approved drug imported into the U.S. would be constrained (Appendix II Figure 3).

Pharmaceutical Sales $Bn U.S. Dollar Sales revenue
Canada, UK, Germany, France, Spain, and Italy

Scope of Importation
Estimated 2018 Pharmaceutical Sales

Importation Requirements for Study	Ex-U.S.	U.S.
1 **Countries of Origin** Estimated 2018 pharmaceutical sales in proposed countries of origin	184.7 *(+/- 8.6)*	527.6 *(+/- 24.6)*
2 **Viable Product Category** Est. 2018 pharmaceutical sales of products within scope of import: chemical or biological makeup, controlled substance status, and feasibility of management and transport	84.8 *(+/- 3.9)*	217.8 *(+/- 10.0)*
3 **Legal & Competitive Status** Est. 2018 pharmaceutical sales of inscope products that are both equivalent to a product in the U.S. (left) or outside of the U.S. (right), and not blocked by an active patent	40.3 *(+/- 1.9)*	107.8 *(+/- 5.1)*

[12] The CSA was originally introduced as H.R.18583 (91st) and enacted into effective May 1, 1971; current rules are recorded in U.S. Code Title 21 Chapter 13. Proposals explicitly barring importation of controlled substances include the Affordable and Safe Prescription Drug Act (S. 97, 116th) and the Safe and Affordable Drugs from Canada Act.
[13] The FDA guarantees exclusivity of at least five years for brand-name drugs containing new chemical entities, seven years for "orphan" drugs that treat rare diseases and are unlikely to recover development costs, and three years for in some other circumstances. Pediatric drugs gain six months additional exclusivity. The first generic drug to successfully launch against a brand-name drug also receives six months of exclusivity under current policy. "*Patents and Exclusivity," FDA, May 19, 2015*
[14] U.S. law allows patent holders to exclude others from making, using, selling, or importing a product. However, these rights are only enforced if the patent holder acts on them. Many U.S. pharma patents also cover aspects besides physical composition. This suggests that *some* protected drugs may be able to physically enter the U.S., but would likely struggle to move through the supply chain, as awareness and ability to enforce likely increase as a drug gets closer to patients
[15] Reimportation has become more complicated following the Supreme Court's 2017 decision in "Impression Products vs. Lexmark," which established that authorized sales outside the U.S. still exhaust patent rights within the U.S. However, strategies have been proposed to circumvent this ruling, and the risk of litigation still presents a potential cost barrier.

PATIENT BENEFIT AND SAFETY IS PARAMOUNT

Although importation proposals aim to reduce prices and improve access to medicines for patients, patient benefit is not guaranteed due to the limited viable product scope. Given the product scope and supply requirements, lower-priced branded and generic products are the likeliest to be imported (Appendix II Figure 7). The pricing advantage for imports in these segments is likely too small to drive significant benefit to patients.[16]

There is inherent risk to patient safety when introducing overseas imports into the supply chain and thus permitting entry for counterfeit and other unsafe drugs. Likely challenges include inspecting and validating potential imports. Even with requirements for responsible importation, counterfeit or unsafe product can enter the U.S.

Precedent suggests that authorities are not confident enough in existing regulations to certify importation. For example, the Medicare Modernization Act permits importation from Canada if the HHS Secretary certifies that this would pose no risk to public health and safety and would create significant cost savings for patients. However, all secretaries since 2003 have declined to provide these certifications.[17,18] Four former FDA Commissioners voiced similar concerns regarding safety in a 2017 letter to Congress.[19]

With these concerns in mind, costs associated with patient safety were quantified by investigating rates of drug-related adverse events (AEs). Costs required for patients to seek AE-related treatment were also included. Expert analysis predicted an estimated 5% increase in drug-related AEs under moderate or restricted terms, due to increases in counterfeiting and other sources of unsafe product. While there is little research regarding the predicted costs of drug-related AEs due to possible enacted importation policy, available estimates and incidence data combined with expert estimates result in increases ranging from $200M (based on incidence data and estimates of cost *per AE*) to $1.4B (based on estimates for *total cost* from drug-related AEs, Appendix II Figure 11).

Any increase in AEs is challenging. This study finds a lack of tangible benefits (either for pricing or access) from commercial drug importation proposals, as written, with exception of certain restricted cases. In addition, there is little evidence that benefits from these imports outweigh the safety risks to patients. This analysis provides a glimpse into the patient impacts, and the opportunity exists to further assess the patient risk/benefit through future proposals.

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[16] This is expected generally, but not universally. For example, insulin has attracted attention due to price differences between the U.S. and Canada; while insulin's status as a biologic excludes it from most importation proposals, permissive regulations could see some importation as the price difference drives importers to look past the higher logistics costs.

[17] The Medicare Modernization Act directs HHS Secretaries to permit "pharmacists and wholesalers to import prescription drugs from Canada into the United States[…]only if the Secretary certifies to the Congress that the implementation of this section will (A) pose no additional risk to the public's health and safety; and B) result in a significant reduction in the cost of covered products[…]" (H.R.1, 108th, Sec. 1121). All Secretaries since 2003 have declined to make this certification.

[18] Reliable estimates of potential savings are hard to come by. The Pew Charitable Trusts notes, "The Congressional Budget Office (CBO) estimated that potential savings from a similar policy - the Pharmaceutical Market Access Act of 2003, which would have allowed pharmacists, wholesalers, and individuals to import drugs from 25 countries, among them Australia, Canada, Japan, and a number in Europe - could have produced total savings of $40 billion over ten years in the U.S., including savings of $2.9 billion for the federal government […] *CBO also estimated that savings from the policy would be minimal if imports were permitted only from Canada*" (emphasis ours).

[19] Letter to Congress from Robert Califf (2016 - 2017), Margaret Hamburg (2009-2015), Andrew Von Eschenbach (2006 – 2009), and Mark McClellan (2002 - 2004), March 17, 2017. Accessed at https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final_signed.pdf

THE FDA WILL BE RESPONSIBLE FOR THE QUALITY AND SAFETY OF IMPORTED MEDICINES

The challenge of regulating safety in a globalized and technological economy is already formidable.[20] Expert interviewees agreed that the burden of defining processes and ensuring the quality and safety of imported drugs would fall on the FDA. This means that the FDA will lead the planning and funding for responsible importation. Former FDA commissioners have echoed this sentiment.[21] Given the FDA's relationships with government and regulatory bodies in Canada and the European Union, the agency is well positioned for this task.

Despite having the technical expertise, added responsibility would increase the FDA's operational costs and overhead. Interviewees estimated that a moderate importation policy would lead to an eight to ten times increase in costs, including domestic and foreign inspection, headcount, staff training, quality assurance, and traceability technology. These increases would collectively triple the FDA's existing cost to operate foreign offices, inspect foreign facilities, and screen imports.

Quantitative analysis based on these estimates and published FDA budgets suggest that at least $270-350M annually would be required for the agency to handle these new responsibilities. This range aligns with estimates from interviewees with intimate knowledge of FDA processes[22](Appendix II Figure 8).

These additional costs and responsibilities to regulate importation would fall on an agency that is already experiencing capacity constraints. The Government Accountability Office (GAO) has reported on the FDA's activity overseas since 1998 and consistently identifies concerns with the program.[23] One recent report notes that almost 50% of overseas positions were vacant as of July 2016 and that inspections had yet to be conducted at over 1,000 facilities already involved in the U.S. supply chain.[22,23] The GAO's findings suggest that current funding is insufficient for the targeted volume of inspections. The FDA will likely need to address these deficits before expanding efforts to manage commercial drug importation.

Responsible importation should specify the processes, funding, authority, and timeline for expanded FDA oversight and ensure that adequate contingencies are in place.

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[20] The National Academy of Sciences, for example, notes that safety concerns and recalls even of U.S.-approved drugs present a challenge for the FDA (Pray and Robinson, "Challenges for the FDA: The Future of Drug Safety, Workshop Summary," National Academy of Sciences). Fraud and counterfeiting also remain global concerns, with data published by the Pharmaceutical Security Institute suggesting that worldwide incidents of pharmaceutical crime rose nearly 63% from 2013 to 2017 (Pharmaceutical Security Institute Incident Trends. Accessed April 3, 2019)

[21] Letter to Congress from Robert Califf (2016-2017), Margaret Hamburg (2009-2015), Andrew Von Eschenbach (2006-2009), and Mark McClellan (2002-2004), March 17, 2017.

[22] Additionally, a 2016 GAO report estimated $92m for foreign drug inspections in 2015; inspections of conventional and biologic drugs have collectively increased from 1139 in 2015 to 1407 in 2018, suggesting that the figure has increased since then. "FDA Has Improved Its Foreign Drug Inspection Program but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices." Government Accountability Office, Dec 16, 2016; FDA 2017 and 2019 Budget Summaries

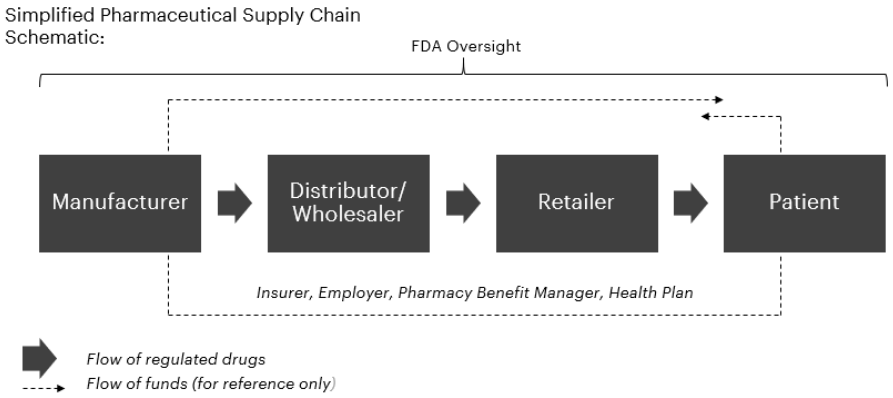
[23] The GAO has issued several reports on overseas FDA activity starting in 1998 ("Improvements Needed in the Foreign Drug Inspection Program," GAO, Mar 17, 1998) and continuing in 2008 ("Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program," GAO, Sep 22, 2008), 2009 ("High Risk Series: An Update," GAO, Jan 22, 2009), 2010 ("FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed," GAO, Oct 25, 2010), and 2016 (see previous)

This study recognizes the FDA's continued efforts to innovate, create international drug transparency, and raise quality standards. In the longer term, these global partnerships could pave the way for co-evaluation and co-approval measures for importable product.[24] This is likely a sustainable alternative to the current proposals on this topic.

THE COST TO STAKEHOLDERS EXCEEDS $1B

The standards set by regulators are implemented by supply chain stakeholders. This stakeholder analysis focuses on manufacturers, who develop and produce finished products; distributors and wholesalers,[25] who facilitate the storage and efficient transportation of product; and retail pharmacies, who dispense product and educate patients in obtaining product.

Manufacturers are important partners to the FDA to ensure product quality and patient safety. It is in their interest to preserve these standards for medicines in their market space for competitiveness and innovation. Nevertheless, some branded and generic manufacturers would see greater near-term risk, due to high overlap between their products and product scope suggested by a responsible importation policy.



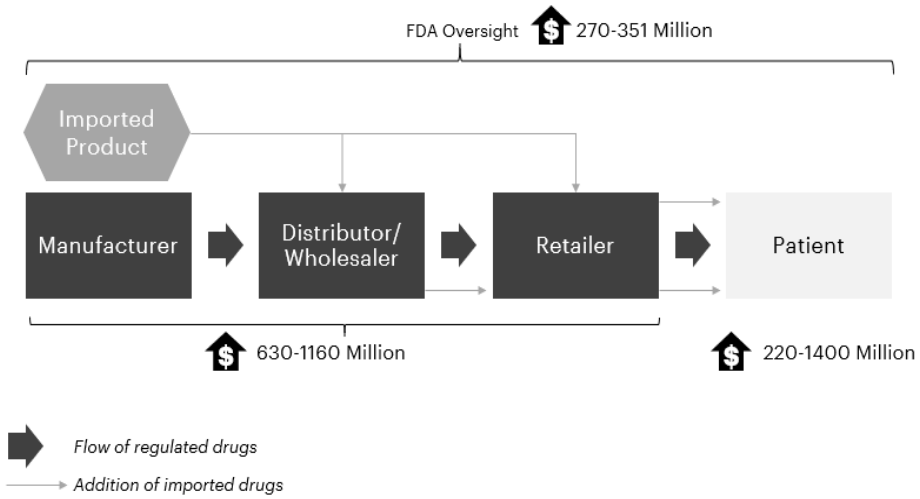
Manufacturers may also decide to protect their products and increase investments to defend patents and channels. If importers choose to challenge exclusivity provisions, litigation costs across the entire manufacturing segment could reach as high as $390-$430M per year (Appendix I Methods and Appendix II Figure 9a).

Distributors have greater flexibility and, if permitted, could choose to import product directly by collaborating with overseas suppliers. The additional costs revolve around the logistics of moving and storing imported product (e.g., warehousing and shipping). However, distributors would also need to absorb losses from product returned by retail pharmacies (e.g., recalls or overstocks); these returns likely would not be eligible for the manufacturer credits currently covering 90% of U.S. returns.[26] This analysis estimates that these would drive $240-$730M in added costs per year, depending on volume of product imported (Appendix II Figure 9b).

[24] Regarding safety, the FDA would ideally have access to foreign clinical trial reports discussing the actual effects of a drug on its biological pathway. Intellectual property confidentiality, however, may still present a significant barrier.
[25] For the remainder of the paper, "Distributor" will refer to companies in both the distribution and wholesaling sectors.
[26] 89th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (2018-2019), Table 47

Pharmacies have closer relationships with patients and may be more cautious with imports in the near term. However, costs could be incurred in protecting brand credibility and filling any gaps in compliance or pharmacovigilance. Estimated costs for regulatory oversight and supply chain stakeholders are a significant hurdle – a minimum of $900M per year – to execute a moderate importation proposal (Appendix II Figure 10). Combined with the cost to patients related to AEs, there is an estimated minimum threshold of more than $1.1B annually to overcome.

Simplified Pharmaceutical Supply Chain with Commercial Drug Importation Schematic:
TOTAL COST THRESHOLD MINIMUM: $1120 Million



SHIFTS ARE IMMINENT

If implemented, expanded importation will shift pricing models, stakeholder revenues, therapeutic dynamics, drug pricing models, and supply chain pathways.

Pricing Models: The combination of revenue disruption and impacted therapeutic categories may reshape pricing. Under manufacturers' current pricing structures, the higher prices charged in wealthier countries are used to subsidize sales in other economies and to help fund research on new therapeutics. If overseas prices spread to the U.S., manufacturers may respond by raising prices elsewhere or restricting international supply.[27] Importation could therefore interfere with the global benefits afforded by the current approach and prompt negative reactions from foreign governments concerned about their own drug prices and availability.

Stakeholder Revenues: Manufacturers (both brand and generic) may see the greatest revenue losses for a given level of adoption. For example, if 33% of in scope importable drugs replace U.S. sales, there would be an annual revenue impact of roughly $7.9B. Distributors and pharmacies may buffer lost sales of U.S. product by buying and selling the new imports. Distributors may therefore experience a smaller decrease of around $5.3B and pharmacies a decrease of around $6.1B, per year (Appendix II Figure 12).

[27] U.S. manufacturers are likely to mitigate the impact of importation on their pricing models by limiting the amount of product they sell to foreign countries and, thus, the amount of their product that could be reimported back into the U.S., at cheaper international prices.

Therapeutic Dynamics: Analysis suggests that imports will compete most heavily in the cardiovascular (62% of sales exposed), gastrointestinal (40%), and genitourinary (33%) segments (Appendix II Figure 13). These therapeutic areas differ from those identified by experts as the highest-need areas for U.S. patients, like oncology, orphan and rare disease categories. This further suggests that areas of highest viability for importation may differ from U.S. populations with the highest need and potential adoption.[28] Importantly, the issue of patient trust in medicines should be considered. Experts say that despite any decline in revenues, quality of medicines and patient safety is the mission of supply chain stakeholders.

Supply Chain Pathways: Introducing competing products may squeeze already-low margins in the generics space. This potentially reduces the number of viable players, further driving the endemic shortages and drastic price increases in the segment. On the other hand, innovative biopharmaceutical companies, may stop competing for these types of products and shift their focus to more complex and personalized drugs. Some industry leaders contend that lower prices in impacted product categories will lead to reduced investment in R&D to preserve existing margins, though other parties question the extent of this effect.[29]

Distributors may choose to maintain their traditional logistics roles or expand their capabilities and start buying directly from companies beyond U.S. governance and FDA oversight. Similarly, U.S. pharmacies could choose to partner with global pharmacies and evolve to become direct providers to patients. Non-traditional players are also likely to enter the mix. These factors change interactions across the supply chain in the longer term.

Overall, mismatches between importable supply and patient needs, potential revenue loss, and new investment requirements make commercial drug importation a challenging proposition for supply chain stakeholders. The interlock of stakeholders - which today enables appropriate delivery of medicines to patients - will face disruption.

EXPLORING ALTERNATIVES

The drug approval system in the U.S. sets a standard of quality and safety unlikely to be preserved by current proposals on commercial drug importation. For this reason, alternatives should be explored for addressing patient access and high drug costs. It should be noted that the price of a new medicine aims to reflect its value. Pricing systems try to consider therapeutic, economic, demographic, epidemiologic, and other factors that differ across countries and change over time. This flexibility aims to balance access to medicines and ongoing investment in research and development.[30]

Therefore, measures that maintain standards while reducing patient challenges and preserve flexibility for investment in innovation are preferred. For example, modifications to the "Safe Harbor" for manufacturer rebates and progress on drug

[28] It bears reiterating that some therapeutics of note, including insulin, are outside the scope of this analysis due to handling requirements and exclusion from many proposals.
[29] For example, Bach et. al. argue against the position that U.S. pricing is necessary to subsidize global R&D investment ("R&D Costs for Pharmaceutical Companies Do Not Explain Elevated U.S. Drug Prices," *Health Affairs Blog*, March 7, 2017.DOI: 10.1377/hblog20170307.059036). PhRMA and the U.S. Chamber of Commerce have expressed dissenting views (https://catalyst.phrma.org/government-imposed-price-controls-threaten-innovation-and-access)
[30] Global Pricing Flexibility for New Medicines. Global Policy and International Public Affairs, *Pfizer Inc*. October 2017

pricing transparency may be viable paths to channeling savings to patients by 2020.[31,32] The administration and Congress have proposed other initiatives targeted at price reductions,[33] approaches to increase supply and access to generic drugs,[34] and additional price transparency measures.[35,36]

The longer term challenge for the U.S. supply chain will be to strategically evolve global partnerships and regulatory mechanisms to maximize shared benefits and improve global drug approval and review standards. It is important for architects of drug importation approaches to improve their understanding of global economics of product supply, costs of aging populations, shortages, and chronic disease burden that are likely to be issues beyond U.S. borders. These must be considered for sustainable relationships with other governments.

Responsible and transparent standards, traceability, and supply are necessary for global drug standards, approval, and trade. Importantly, systems must be in place to guarantee globalized product quality and safety. Medicines are unique: patients have no easy way to ascertain the authenticity of a given drug, and supply chain disruption can have unintended consequences. Future progress should consider the terms of responsible importation as proposed and aim to address the requirements demonstrated by this study to ensure patient safety.

[31] https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html
[32] Actual patient impact of rolling back Safe Harbor protections is out of scope for this analysis. However, the measure is *intended* to reduce patient cost burden.
[33] Trump Administration proposals, and part of the Prescription Drug Price Relief Act, S.102 (116th) (PDPRA)
[34] Core component of the CREATES Act (S.340, 116th) and associated proposals
[35] PDPRA HR1035 the Prescription Drug Price Transparency Act, and HR1034 the Fair Pricing Act
[36] ANPRM International Pricing Index Model for Medicare Part B Drugs; CREATES Act; Medicare Prescription Drug Price Negotiation Act (H.R. 275, 116th). Implied under public option and Medicare expansion proposals such as the Medicare-X Choice Act (S.981, 116th).

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PLATINUM:

GOLD:

SILVER:

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APPENDICES:

APPENDIX I: METHODS SUMMARY

This analysis was conducted through a combination of literature review, expert interviews, and quantitative modeling.

The policy baseline was defined through review of existing commentary on importation published by the Congressional Research Service ("Prescription Drug Importation: A Legal Overview," 2008) and FDA summaries ("Milestones in U.S. Food and Drug Law History").

Legislative proposals were identified using the records at Congress.gov, filtering for legislative proposals in the 113th-116th Congresses with the health subject-policy area. Approximately 4,400 bill titles were reviewed to identify those related to pharmaceuticals, and those bills were then reviewed individually to identify twenty-three entries with terms covering importation, representing ten unique proposals. The terms of these policies were also leveraged to shape prompts and questions to be further validated by experts. These were direct inputs into the importation scenarios framework.

Further literature analysis was conducted via review of reports from the last five years produced or sourced via FDA.gov, HHS.gov, the Government Accountability Office, the Congressional Research Service, PubMed, the European Medical Association, and supported by other key sources of perspectives on the topics investigated throughout the analysis. The references of materials leveraged for this research are within the end-notes section.

In parallel, a group of experts were identified as respondents to structured interviews, scenario prompts for consensus development, and validation of assumptions on data (n=22 completed the interview process). These experts satisfied screening questions requirements on experience, depth of knowledge on drug importation and direct experience on elements of execution relating to drug importation. Interviewees were selected such that there was balanced representation from regulators, policy makers, manufacturers, distributors, retail pharmacies and medical advisors.

Interviews were structured, presenting the same prompts and questions to each interviewee. These interviews were conducted by phone and averaged 60 to 90 minutes each. Interviewee answers were logged and if the answer was ambiguous, the input on that question was removed from the final analysis. Interviews were conducted across five areas: regulatory baseline and proposed policy/bills, requirements for responsible importation, regulatory impacts/costs, supply chain stakeholder impacts/costs, patient impact, and general questions about the topic of drug importation.

Literature, data, and interview results were used to develop inputs into the quantitative analysis to model the impacts as outlined in this paper and the appendices.

Quantitative analysis was conducted in four phases.

First, markets of interest and countries of origin were identified by interviewees and validated based on investigation into their history of drug exports and similarity to the U.S. in both approval processes and traceability requirements. Pharmaceutical spending in these countries and in the U.S. were then estimated using data published by IQVIA.

Second, spending was segmented between branded and generic products using data from IHS Markit. These expenditures were then allocated between "in-scope" and "out-of-scope" based on product-level data from EvaluatePharma and the U.S. Drug Enforcement Agency (DEA). Out-of-scope drugs were identified based on route of administration, classification as small molecule or biologic, and presence on the DEA list of controlled substances as of December 2018. In-scope drugs were then filtered to exclude products still under U.S. patents or lacking ex-U.S. competition based on their active ingredients. In-scope dollars were further allocated between market segments based on their target markets and between therapeutic areas. An average conversion factor between international and U.S. pricing was also generated for generic and branded drugs, based on data published by the Canadian Patented Medicine Prices Review Board.

Third, revenue impact analysis was conducted using a simplified model of the U.S. supply chain, under which U.S. manufacturers sell to distributors a discount against their official wholesale acquisition cost (WAC) and distributors sell to pharmacies at a lower discount based on the same official WAC. Pharmacy pricing was simplified to a percentage upcharge against official WAC, as explicit modeling of pharmacy benefit managers was out of scope for this analysis. Total U.S. sales based on IQVIA reports were assumed to represent pharmacy revenues. Manufacturer and distributor sales were then calculated based on a 5%-off-WAC manufacturer discount to distributors and a 4%-off-WAC distributor discount to pharmacies. Potential impacts were estimated based on assumptions that overseas markets could export at most 20% of their in scope sales volume to the U.S., that all *adopted* imports would directly replace sales of existing U.S. products, and average pricing of remaining U.S. products in affected segments would decline at a level proportional to level of adoption. Distributors and pharmacies were assumed to benefit from sales of imported products. Estimates of potential adoption of imports by U.S. patients were not available, so calculations were conducted for a range of adoption levels from 0% (no patients accepting commercial imports) to 100% (patients accept all available commercial imports).

Fourth, operational cost analyses were conducted by first consulting experts as to potential areas of increased cost and then identifying cost metrics that could be used to estimate potential changes. Regulator costs were estimated using FDA budget data and GAO estimates. Manufacturer costs were estimated using product-level data from EvaluatePharma, and cost of patent litigation cases published by the American Intellectual Property Law Association. Distributor costs were estimated based on benchmarks published by the Healthcare Distribution Alliance. Patient costs were estimated using a combination of expert estimates regarding increased AE rates, data from the FDA AE Reporting System (FAERS) and estimates of per-AE and total AE-related costs identified during literature review.

APPENDIX II: REPORT FIGURES

Figures include literature and policy analysis, and quantitative modeling also informed by expert interviews outlined in Appendix III.

Figure 1: Policy Baseline[37,38]

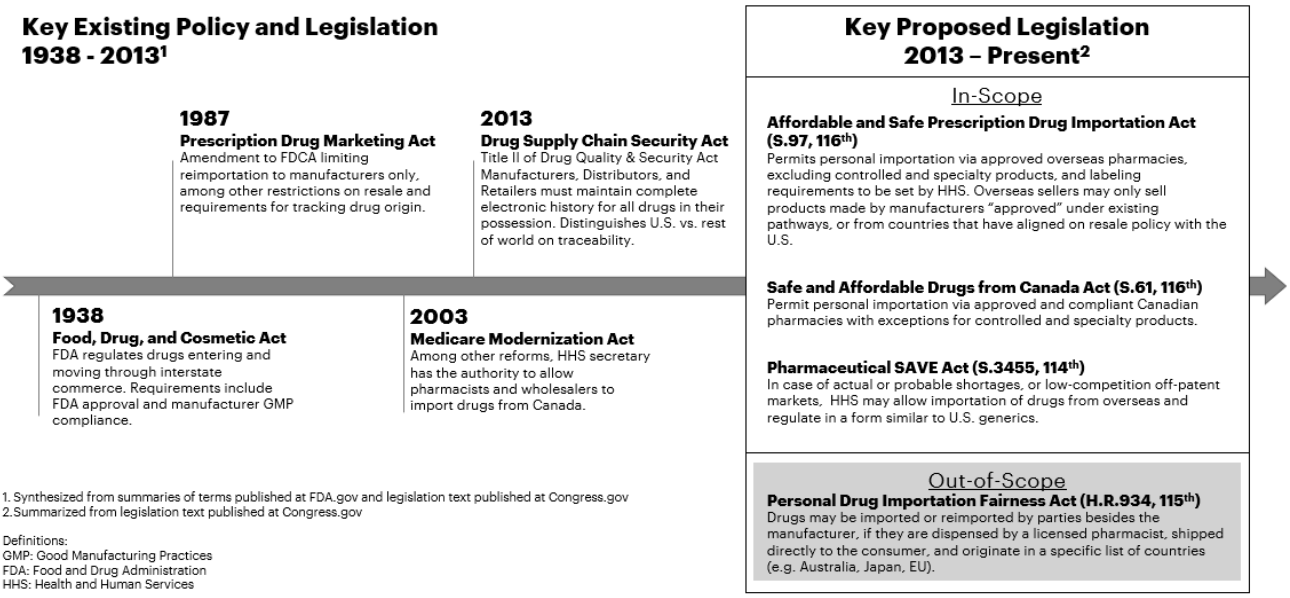


Figure 2: Importation Scenario Framework

"Wide Open"	"Moderated"	"Restricted"
Some restrictions on origin and product type, subject to specific approvals	Subject to specific and well-defined restrictions by product type and country of origin	Only in specific circumstances, subject to restrictions beyond product type and origin
Representative Policy: Affordable and Safe Prescription Drug Importation Act (S.97, 116th) • Permitted from a range of countries at HHS discretion, with options for further expansion • Few restrictions on types of products • No special requirements e.g., patent status, etc. • Importation into all parts of the supply chain, with specific licensure requirements for distributors and pharmacies	**Representative Policy: Safe and Affordable Drugs from Canada Act (S.61, 116th)** • Permitted from a set list of countries at HHS discretion, with no options for expansion • Products largely restricted to non-biologic drugs with no handling requirements • No special requirements regarding patent status, etc. • Drugs may be imported only by end consumers and in limited quantities	**Representative Policy: Pharmaceutical Supply and Value Enhancement Act (S.3455, 114th)** • Minimal country-level guidance; left to HHS discretion regarding country of origin • Products largely restricted to non-biologic drugs with no handling requirements • Specifically excludes drugs that would compete with any existing patented product

[37] Synthesized from summaries of terms published at FDA.gov and legislation text published at Congress.gov
[38] Summarized from legislation text published at Congress.gov

Figure 3: Potential Product Supply Estimation

Figure 4: Key Characteristics of Permitted Countries for Feasibility

	Canada	Germany	U.K.	France	Italy	Spain	EU (All)
History of Exporting to U.S.?	Yes (Personal)	No	No	No	No	No	No
Regulatory comparability (expert panel)?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Significant Shortages (as indicator of supply challenges)?	Yes[39]	Yes[6,40]	Yes[7]	Yes[7,41]	Yes[7,8]	Yes[7,8]	Yes[7,8]
Ability to Export (Est. % volume)	*20%*	*5-15%*	*5-15%*	*5-15%*	*5-15%*	*5-15%*	*NA*

[39] Canadian sources reported as many as 400 drug shortages per month in 2017 following the rollout of the new shortage tracking system. The average duration of known shortages in 2016 was 80 days with a maximum of 414. *Donelle et al, "Assessing Canada's Drug Shortage Problem," C.D. Howe Institute, 2018*

[40] 26% of German outpatient pharmacists surveyed by ABDA in Oct. 2016 reported that shortages had caused a disruption in treatment, and that most shortages impact generics. French shortages increased 30% in 2017 compared to 2016, with similar changes seen in other European (e.g., Netherlands). *"Drug Supply Shortages in Germany," IHS Markit,* 2018

[41] Among pharmacists surveyed by the EAHP in 2018, >75% of Italian, >90% of Spanish, and>95% of U.K., French, and German hospital pharmacists responded that shortages significantly disrupted their ability to provide care or run the hospital pharmacy. >50% of Italian, >70% of Spanish, >85% of English and French, and >95% of German pharmacists also stated that these shortages happened on a weekly or daily basis. 77% of respondents across the EU found generics frequently in short supply, and 65% likewise for branded. Average shortage duration was approximately or at least 2 months for all five countries. *European Association of Hospital Pharmacists 2018 Medicines Shortage Survey*

Figure 5: Out-of-Scope vs. In-Scope Sales[42,43]

Market	Classification	Branded* (2018 est., $b)	Generics (2018 est., $b)	Total (2018 est., $b)
Canada + EU5	***Total***	***138.5 (+/- 6.6)***	***46.2 (+/- 2.0)***	***184.7 (+/- 8.6)***
	Out of Scope *Biologics, Non-Orals, Controlled Substances*	77.8 (+/- 3.7)	22.1 (+/- 1.0)	99.9 (+/- 4.7)
	In Scope *Conventional, Oral*	60.7 (+/- 2.9)	24.1 (+/- 1.1)	84.8 (+/- 3.9)
U.S.	***Total***	***381.8 (+/- 15.1)***	***145.8 (+/- 5.8)***	***527.6 (+/- 20.9)***
	Out of Scope[9,10] *Biologics, Non-Orals, Controlled Substances*	240.9 (+/- 9.6)	68.9 (+/- 2.7)	309.8 (+/- 12.3)
	In Scope *Conventional, Oral*	140.9 (+/- 5.6)	76.9 (+/- 3.1)	217.8 (+/- 8.6)

*Brand covers all products approved in the U.S. as NMEs and covers both patent-protected and off-patent branded drugs

Figure 6: Intellectual Property Considerations

	Segment	Total Inscope Sales	No Off-Patent* U.S. Competitors	Competes with Off-Patent US Product
Canada + EU5	Branded	60.7 (+/- 2.9)	35.4 (+/- 1.7)	25.3 (+/- 1.2)
	Generic	24.1 (+/- 1.1)	9.1 (+/- 0.4)	15.0 (+/- 0.7)
	Total	**84.8 (+/- 3.9)**	**44.5 (+/- 2.1)**	**40.3 (+/- 1.9)**

	Segment	Total Inscope Sales	On-Patent* or no Ex-U.S. Equivalent	Off-Patent with Ex-U.S. Equivalent
U.S.	Branded	140.9 (+/- 5.6)	114.6 (+/- 4.5)	26.3 (+/- 1.0)
	Generic	76.9 (+/- 3.1)	18.1 (+/- 0.7)	58.8 (+/- 2.3)
	Total	**217.8 (+/- 8.6)**	**132.7 (+/- 5.3)**	**85.1 (+/- 3.4)**

U.S. Patent Status and product-level sales estimates from EvaluatePharma

Figure 7: Commercial Segmentation[9,10]

	Segment	Branded	Generics	Total
Canada + EU5	**Hospital Focus** *Conventional, Oral*	4.3 (+/- 0.2)	1.3 (+/- 0.1)	5.6 (+/- 0.3)
	Mixed Focus *Conventional, Oral*	5.1 (+/- 0.3)	2.3 (+/- 0.1)	7.3 (+/- 0.4)
	Primary Care and DTC *Conventional, Oral*	15.9 (+/- 0.8)	11.5 (+/- 0.5)	27.4 (+/- 1.3)
	Total	25.3 (+/- 1.3)	15.0 (+/- 0.7)	40.3 (+/- 1.9)
U.S.	**Hospital Focus** *Conventional, Oral*	5.5 (+/- 0.2)	4.9 (+/- 0.2)	10.4 (+/- 0.4)
	Mixed Focus *Conventional, Oral*	8.5 (+/- 0.3)	10.7 (+/- 0.4)	19.1 (+/- 0.8)
	Primary Care and DTC *Conventional, Oral*	12.3 (+/- 0.5)	43.2 (+/- 1.7)	55.5 (+/- 2.2)
	Total	26.3 (+/- 1.0)	58.8 (+/- 2.3)	85.1 (+/- 3.4)

[42] IQVIA Global Outlook for Medicines Through 2021
[43] Generic and Brand shares from IHS Markit; formulation/makeup and target markets from EvaluatePharma; controlled substances from DEA

Figure 8: Estimated Regulatory Costs[44]

All cost figures in $m	Approach 1	Approach 2
Total FDA Human Drugs Budget and Fees	197.8	
Est. Domestic Inspection Allocation	107.7	80.8
Est. Foreign Inspection Allocation	45.1	72.0
Est. Import Inspection Allocation	45.1	45.1
Total Foreign + Import	90.2	117.1
Est. Cost Increase Factor	3	3
Est. Final Cost	**270.5**	**351.3**

Figure 9: Summary Costs for Manufacturers and Distributors

9a: Manufacturers	Approach 1	Approach 2
Customer Education	Insufficient Data	
Damage Control	Insufficient Data	
IP Litigation[45,46]	$390	$430
Total	$390	$430

9b: Distributors	Approach 1	Approach 2
Inventory[13,47] *Includes Product Recalls*	$210	$630
Warehousing and Shipping[13,14]	$31	$93
Customer Education	Insufficient Data	
Total	$240	$730

9c: Pharmacies
Insufficient Data
NB: No pharmacy cost increases currently identified ***Experts agreed that in the one to three year time frame, pharmacies would not see significant changes in operational cost***

Figure 10: Total Stakeholder Cost Summary

All cost figures in $m	Approach 1	Approach 2
Regulators	270	350
Manufacturers	390	430
Distributors	240	730
Pharmacies	N/A	
Total	900	1,510

[44] 2019 FDA Budget Estimates (retrospective to 2018)
[45] Bloomberg Law, American Intellectual Property Law Association
[46] IQVIA, IHS Markit, DEA, EvaluatePharma
[47] 89th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (2018-2019)

Figure 11: Patient Impact Estimates – Two Methods

	Approach 1 *FAERs; Watanabe et al*	Approach 2 *NEHI*
Adverse Events (AE) (2018) *Excludes Foreign-Reported AEs*	1.4M[48]	N/A
Average Cost per Event (2018) *Adjusted from 2014*[49]	$3.1K[50]	N/A
Cost of Adverse Events	$3.6B	$27.3B[51,52]
Estimated Increase in AEs (expert panel)	~5%	
Estimated Patient Impact	$200M	$1.4B

Figure 12: Estimated Revenue Impact by Stakeholder

Modeling assumes that all importation goes through U.S. distributors and includes the impact of both declining U.S.-origin sales and replacement sales from imported drugs. Sample cases assume that only 33% of in scope ex-U.S. product will be imported.

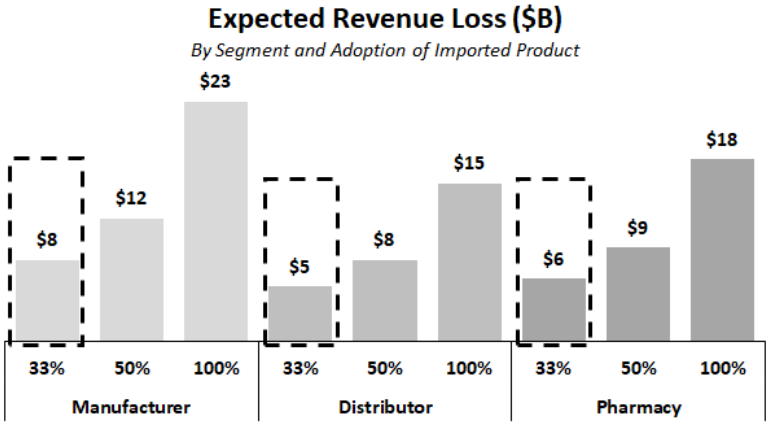


Figure 13: Therapeutic Area Impacts[53]

Therapeutic Area (TA)	"Safe" Sales	Sales "At Risk"	% of TA "At Risk"	Example "At-Risk" Products
Neurology	70.6	18.3	21%	Lamictal (Epilepsy), Abilify (Antipsychotic)
Cardiovascular	11.6	18.6	62%	Ranexa (Chest Pain); Multaq (Arrhythmia)
Genitourinary	19.6	9.7	33%	Cialis, Viagra (ED)
Gastrointestinal	11.9	7.9	40%	Nexium (GERD), Pentasa (IBD)
Endocrine	39.4	8.1	17%	Medrol (inflammatory issues)
Other TAs	289.5	22.6	7%	

Other therapeutic areas: Hematology, Dermatology, Immunodilators, Musculoskeletal, Oncology, Respiratory, Sensory Drugs (e.g., Ophthalmology), Anti-Infectives, and miscellaneous uncategorized products

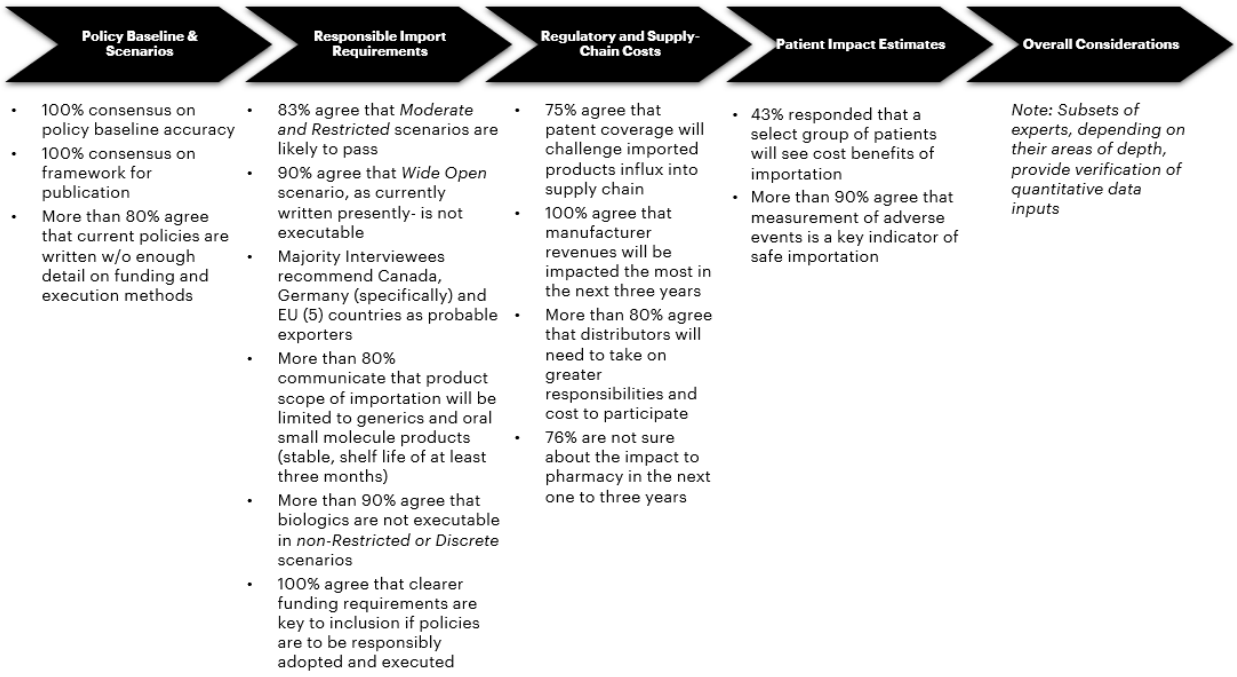
[48] FDA Adverse Event Reporting System
[49] Adjusted from 2014 to 2018 based on health expenditure values from CMS Office of the Actuary
[50] Watanabe, J. H., McInnis, T., & Hirsch, J. D. (2018). Cost of Prescription Drug–Related Morbidity and Mortality. Annals of Pharmacotherapy, 52(9), 829–837. https://doi.org/10.1177/1060028018765159
[51] New England Health Institute. Preventing medication errors: a $21 billion opportunity
[52] Adjusted from 2012 to 2018 dollars based on health expenditure values from CMS Office of the Actuary
[53] Therapeutic area data provided by EvaluatePharma

APPENDIX III: INTERVIEWEE EXPERT PANEL SUMMARY

Figure 1: Expert Credential Summary

• 22 Expert Interviews • Requirements – Minimum 20 years in relevant roles with direct authority and influence over decisions or execution in drug importation-related topics • Structured expert interviews were conducted to enable qualitative and quantitative assessment of consensus • Semi structured interviews were conducted to validate data assumptions	3	Former Lead Advisor, CDER, FDA
	3	Former Global Head, Pharmaceuticals
	2	Former Head of Pharmacovigilance, Pharmaceuticals
	1	Former CMC Review, FDA
	1	Former C-Level Advisor, Regulatory Affairs (cross-stakeholder)
	1	Former Senior Regulatory Lead, Pharmaceuticals
	2	Former Head and General Counsel, Generics Pharmaceuticals
	3	Security/Distribution/Global Ops Lead, Distributor/Wholesaler
	2	Director of Health Policy, Major Pharma Association(s)
	1	Former Director of Policy and Regulatory
	2	Chief Medical Officer, Life Science Industry
	1	Senior Health Policy Advisory to Life Science and Health Industries

Figure 2: Interview Key Points- Top 15



HDA RESEARCH FOUNDATION

HDA Research Foundation
901 North Glebe Road, Suite 1000
Arlington, VA 22203

(703) 787-0000
(703) 812-5282 (Fax)

www.hda.org/foundation

Healthcare Distribution Alliance

PATIENTS MOVE US.

#3706

January 26, 2021

North Dakota Legislative Assembly
Senate Human Services Committee
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: Healthcare Distribution Alliance (HDA) Opposition to SB 2209 and SB 2212

Chairwoman Lee, Vice Chair Roers and Members of the Senate Human Services Committee,

The Healthcare Distribution Alliance (HDA) offers this letter to indicate our opposition to Senate Bill 2209 and Senate Bill 2212, relating to the importation of prescription drugs from Canada. HDA is the national trade association representing healthcare wholesale distributors — the vital link between the nation's pharmaceutical and healthcare manufacturers and more than 180,000 pharmacies, hospitals, and other healthcare settings nationwide. On behalf of the industry, HDA would like to express our concerns with SB 2209 and SB 2212 due to the potential impact on pharmaceutical supply chain and risk to patient safety.

The U.S. pharmaceutical supply chain is the most sophisticated, efficient and highly secure drug supply chain systems 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, commonly referred to as 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. This will enhance the Food and Drug Administration's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve the detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Under the confines of DSCSA, any drug distributed in the U.S. must be distributed to and from an authorized trading partner and must be a serialized product incorporating the National Drug Code, Serial Number, Lot Number and expiration date. Drugs that are sold or designated for sale in Canada as well as other countries do not conform with U.S. traceability regulations, simply affixing a new label on an imported product will not ensure the product adheres to the full FDA standards set forth by DSCSA prior to its importation. Furthermore, allowing for the importation of drugs from Canada, or other countries, would hinder the intent of the DSCSA statute, and therefore increase the risk of illegitimate or counterfeit medications entering the U.S. market.

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 the tightly regulated supply chain and safeguards currently in place to ensure the efficacy and safety of prescription medications. The National Association of Pharmacy Regulatory Authorities, NABP's counterpart in Canada, has expressed concern that exportation of medicines out of Canada will threaten the supply available to its citizens. This, in turn, will increase the opportunity for counterfeit medications to enter its supply chain, endangering both US and Canadian patients."[2]

Regarding Senate Bill 2209, the legislation requires the North Dakota Board of Pharmacy to increase license fees on wholesale distributors and other supply chain entities in order to fund the state's importation program. Licensure by the Board of Pharmacy is intended to protect, preserve and promote public health and welfare of the citizens of North Dakota; however, under the legislation the Board will be required to earmark additional licensure funding to support a program that is opposed by many of those same entities due to safety concerns.

Ultimately allowing for importation of prescription drug products increases the likelihood of counterfeit or adulterated drugs entering the country. Due to these concerns, we ask that you oppose both SB 2209 and SB 2212. In addition to my testimony, I have also included a study conducted by the Healthcare Distribution Alliance Foundation in partnership with Accenture entitled "The Risks and Realities of Commercial Drug Importation," the study concludes that "proposed importation policies likely place the integrity of the commercial supply chain at risk." Please contact me at Llindahl@hda.org or (303) 829-4121 if you have any questions or would like to discuss this issue further.

Thank you,

Leah D. Lindahl

Leah Lindahl
Senior Director, State Government Affairs
Healthcare Distribution Alliance

[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

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

#3565

Canadian Drug Importation

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

Shabbir Imber Safdar
Executive Director
The Partnership for Safe Medicines

Academy of Managed Care Pharmacy
ADAP Advocacy Association
Alabama Pharmacy Association
Alaska Pharmacists Association
American Pharmacists Association
Arizona Pharmacy Alliance (AzPA)
Association for Accessible Medicines
Biotechnology Innovation Organization
Colorado BioScience Association
Community Access National Network
Connecticut Pharmacists Association
Delaware Pharmacists Society
Healthcare Distribution Association
HealthCare Institute of New Jersey
HealthHIV
Illinois Pharmacists Association
Institute for Safe Medication Practices
International AntiCounterfeiting Coalition
International Health Facility Diversion Association
Kansas Pharmacists Association
Maine Pharmacy Association
Maryland Pharmacists Association
Men's Health Network
Minnesota Pharmacists Association
Mississippi Pharmacists Association
Missouri Pharmacy Association
National Alliance of State Pharmacy Associations
National Alliance On Mental Illness
National Association of Boards of Pharmacy
National Association of Chain Drug Stores
National Association of Drug Diversion Investigators
National Association of Manufacturers
National Coalition for LGBT Health
National Consumers League
National Grange of the Order of Patrons of Husbandry
Nebraska Pharmacists Association
NeedyMeds
New Hampshire Pharmacists Association
New Mexico Pharmacists Association
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oncology Managers of Florida, Inc.
Pennsylvania Pharmacists Association
Pharmaceutical Industry Labor-Management Association (PILMA)
Pharmaceutical Researchers and Manufacturers of America
Pharmaceutical Security Institute
RetireSafe
Rx Outreach
Rx Partnership
Texas Pharmacy Association
University of New England College of Pharmacy
Virginia Pharmacists Association

Illinois' Experience With ISaveRX, 2003–2006

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

Select IG findings:

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

REPORT DIGEST

MANAGEMENT AUDIT OF THE

FLU VACCINE PROCUREMENT AND THE I-SAVERX PROGRAM

Released: September 2006

State of Illinois
Office of the Auditor General

WILLIAM G. HOLLAND
AUDITOR GENERAL

Minnesota RXConnect, 2004-2010

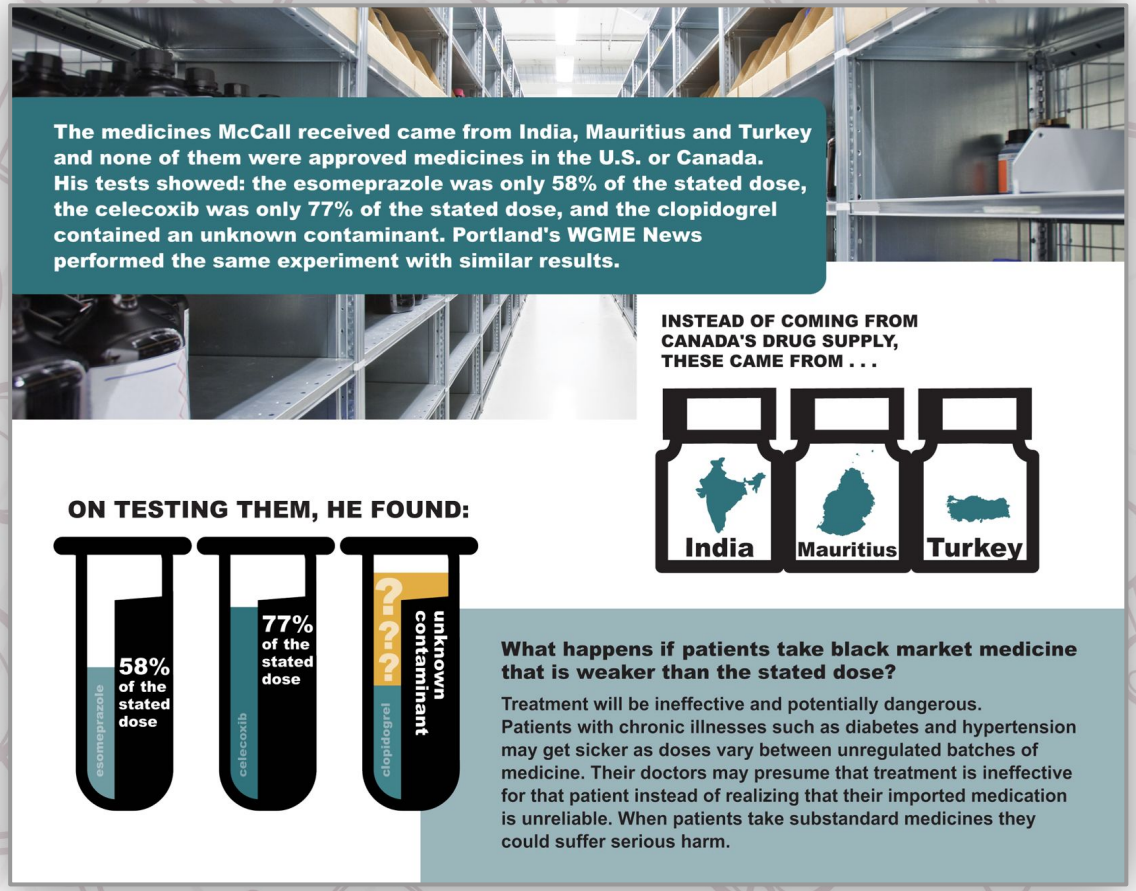
An online pharmacy regulation program started by Gov. Tim Pawlenty. After launch, the FDA cited a number of patient safety issues, including several found during a pre-announced visit by Minnesota's own inspectors:

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

Maine's program: 2013-2015

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

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



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

Colorado

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

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

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

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

Maine

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

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

Drug Name	Generic or Chemical Name	Condition	A Current: Net unit cost (after rebates and all other discounts). Please be sure to match price / units	B Drug Utilization (2Q FY 2019 utilization)	C Plan Total Net Spend Multiply Column A , plan net price by Column B	D Canadian Price* (in USD)	E Canadian Price with mark up in USD NASHP-estimated 45% mark up for supply chain profit + costs	F Plan Net Spend: Canadian Imports Multiply Canadian price with mark up (E) by utilization from 2Q FY 2019 (B)	G Plan Savings from Canadian Importation Subtract F – Plan Net Spend with Canadian price (with mark up) – from actual Plan Net Spend (C)
ABILIFY MAINTENA *300 mg injection pool* Otsuka Canada	Aripiprazole	Antipsycychotic		6		$342.14* (1 pod)	$ 496.10	$ 2,976.62	
ABILIFY MAINTENA *400 mg injection pool* Otsuka Canada	Aripiprazole	Antipsycychotic		49		$342.14* (1 pod)	$ 496.10	$ 24,308.69	
ADVAIR DISKUS *100 mcg/50 mcg* GlaxoSmithKline	Fluticasone-Salmeterol	Asthma/COPD		442		$56.84* (60 doses)	$ 82.42	$ 36,430.36	
ADVAIR DISKUS *250 mcg/50 mcg* GlaxoSmithKline	Fluticasone-Salmeterol	Asthma/COPD		1506		$68.02* (60 doses)	$ 98.63	$ 148,529.81	
ADVAIR DISKUS *500 mcg/50 mcg* GlaxoSmithKline	Fluticasone-Salmeterol	Asthma/COPD		585		$96.56* (60 doses)	$ 140.00	$ 81,902.78	
ATOMOXETINE *10 mg capsule* Generic	Atomoxetine HCl	ADHD	$ 1.91	7321	$ 13,968.88	$0.38	$ 0.56	$ 4,064.97	$ 9,903.91
ATOMOXETINE *18 mg capsule* Generic	Atomoxetine HCl	ADHD	$ 1.44	7705	$ 11,083.64	$0.43	$ 0.63	$ 4,816.27	$ 6,267.37
ATOMOXETINE *25 mg capsule* Generic	Atomoxetine HCl	ADHD	$ 1.78	13635	$ 24,268.33	$0.48	$ 0.70	$ 9,519.57	$ 14,748.76
ATOMOXETINE *40 mg capsule* Generic	Atomoxetine HCl	ADHD	$ 1.34	19373	$ 25,993.02	$0.55	$ 0.80	$ 15,524.76	$ 10,468.27
ATOMOXETINE *60 mg capsule* Generic	Atomoxetine HCl	ADHD	$ 1.56	9842	$ 15,318.34	$0.61	$ 0.88	$ 8,660.69	$ 6,657.64
BIKTARVY *50 mg/200 mg/25 mg* Gilead	Bictegravir-Emtricitabine-Tenofovir AF	HIV		14790		$29.42	$ 42.65	$ 630,819.38	
BUPROPION HYDROCHLORIDE *100 mg extended release (12 hr) tablet* Generic	Bupropion HCl	Smoking Cessation/Antidepressant	$ 0.06	41309	$ 2,284.51	$0.12	$ 0.17	$ 6,949.72	$ (4,665.20)
BUPROPION HYDROCHLORIDE *150 mg extended release (12 hr) tablet* Generic	Bupropion HCl	Smoking Cessation/Antidepressant	$ 0.08	109473	$ 8,465.84	$0.17	$ 0.25	$ 27,346.30	$ (18,880.46)
BUPROPION HYDROCHLORIDE *150 mg extended release (24 hr) tablet* Generic	Bupropion HCl	Smoking Cessation/Antidepressant	$ 0.15	213102	$ 32,995.08	$0.11	$ 0.16	$ 33,904.85	$ (909.77)
BUPROPION HYDROCHLORIDE *300 mg extended release (24 hr) tablet* Generic	Bupropion HCl	Smoking Cessation/Antidepressant	$ 0.10	160728	$ 16,325.30	$0.22	$ 0.32	$ 51,161.65	$ (34,836.35)
EPCLUSA *400 mg/100 mg* Gilead	Sofosbuvir-Velpatasvir	Hepatitis C		1834		$535.71	$ 776.79	$ 1,424,624.97	
GABAPENTIN *100 mg capsule* Generic	Gabapentin	Nerve Pain	$ 0.02	475609	$ 9,383.84	$0.03	$ 0.05	$ 21,518.55	$ (12,132.71)
GABAPENTIN *300 mg capsule* Generic	Gabapentin	Nerve Pain	$ 0.04	1930973	$ 76,174.59	$0.08	$ 0.11	$ 212,513.26	$ (136,338.68)

Projected loss if imported:

$927,983.28

Florida

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

Nobody bid.

Miami Herald

Florida fails to attract bidders for Canada prescription drug importation program

PHIL GALEWITZ
OCTOBER 23, 2020 01:38 PM

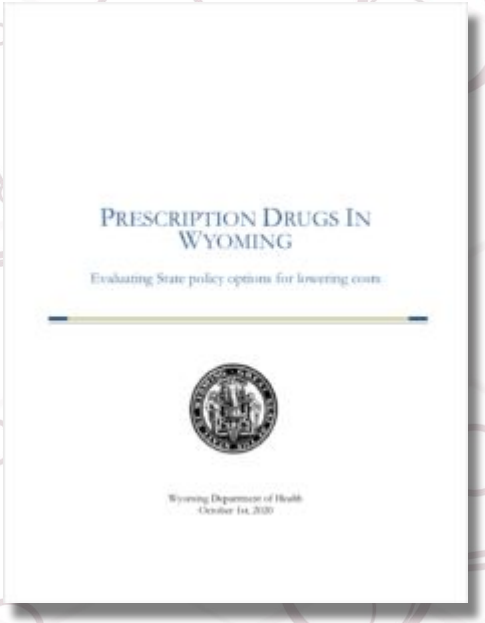
New Mexico

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

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

Wyoming

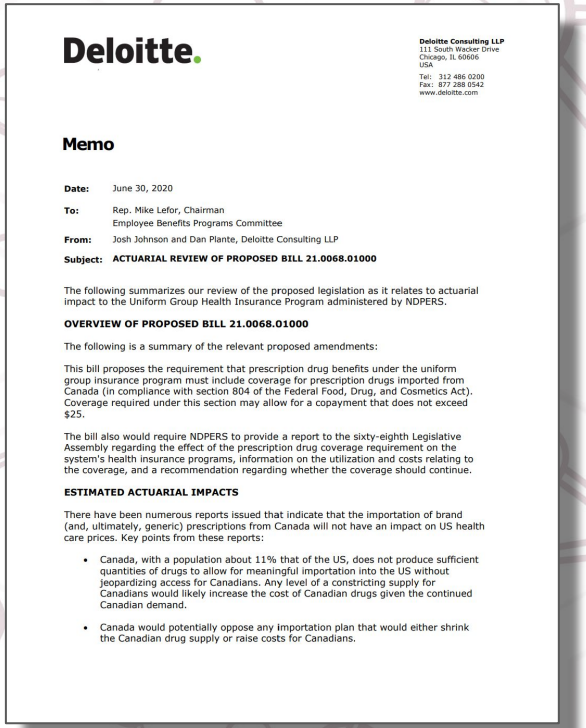
"This [limited state control] makes it virtually impossible to guarantee that consumers will actually see savings, particularly in the case of Canadian drug importation. Basic economics also suggests fundamental problems with this plan that make it unsustainable in the long-run."



October 10, 2020
WY Dept. of Health

North Dakota

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



Deloitte.

Deloitte Consulting LLP
111 South Wacker Drive
Chicago, IL 60606
USA

Tel: 312 486 0200
Fax: 877 288 0542
www.deloitte.com

Memo

Date: June 30, 2020

To: Rep. Mike Lefor, Chairman
Employee Benefits Programs Committee

From: Josh Johnson and Dan Plante, Deloitte Consulting LLP

Subject: **ACTUARIAL REVIEW OF PROPOSED BILL 21.0068.01000**

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

OVERVIEW OF PROPOSED BILL 21.0068.01000

The following is a summary of the relevant proposed amendments:

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

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

ESTIMATED ACTUARIAL IMPACTS

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

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

June 30, 2020

Has anyone analyzed cost of these programs? Yes.

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

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

JPHSR Journal of Pharmaceutical Health Services Research

ROYAL PHARMACEUTICAL SOCIETY

State Pharmaceutical Importation Programs: An Analysis of the Cost Effectiveness

Colorado College Working Paper 2019-02 June 2019

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

Kristina M.L. Acri née Lybecker
Colorado College - Department of Economics & Business

Date Written: June 12, 2019

Abstract

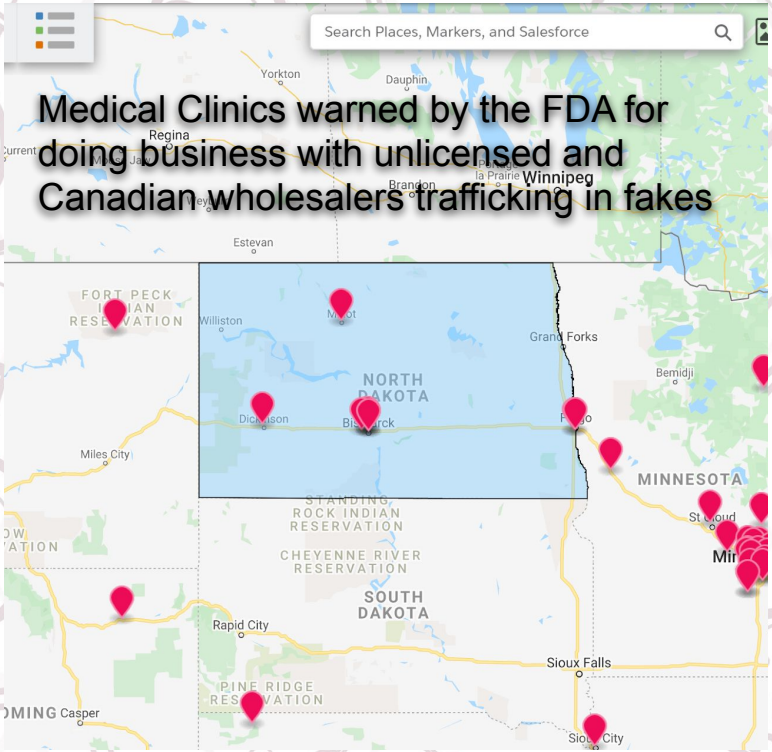
Recently proposed legislation in Colorado, Connecticut, Florida, Maine, Missouri, Oklahoma, Oregon, Utah, Vermont and West Virginia aims to reduce spending on pharmaceuticals by importing them from Canada. To examine the cost effectiveness of importation, this study analyzes 24 drugs from an online Canadian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

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

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

Suggested Citation:

History of counterfeits in North Dakota



Real (top) and fake (bottom) Avastin

We struggle to extradite Canadian criminals.

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

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

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

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

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

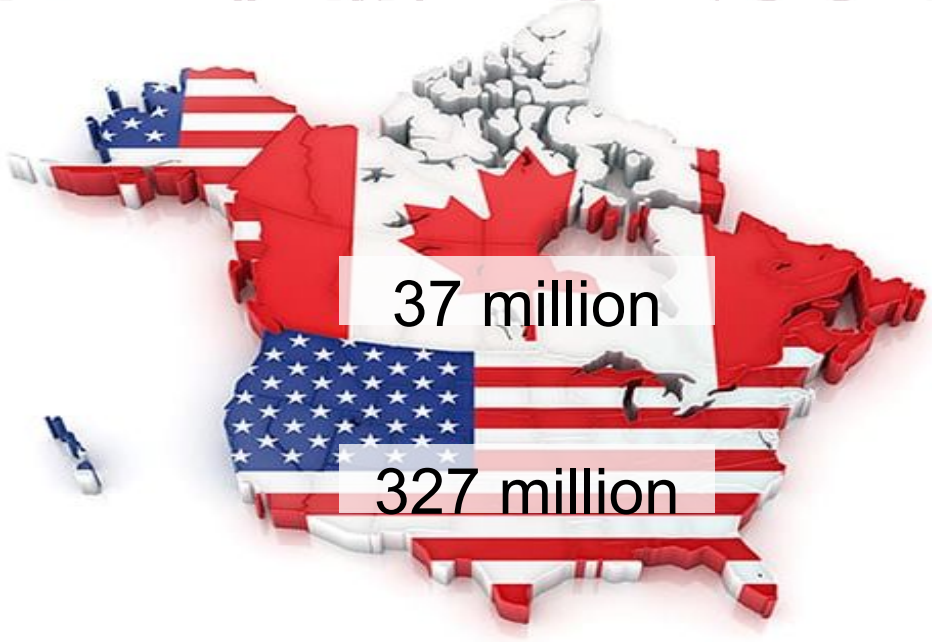
We cannot outsource regulation of our medicine supply chain to Canadian entities.

Canada has no track-and-trace system

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

Shortage issues

Respective population - 2018



CBC

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

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

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

Canadian action

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

November 29, 2020

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

END OF PRESENTATION

Testimony of Shabbir Imber Safdar
Executive Director, Partnership for Safe Medicines
January 27, 2021 - SB 2209 and 2212 (Senate Human Services Committee)

I am writing to explain my concerns with and opposition to SB 2209 and SB 2212 that would establish Canadian drug importation. I am Shabbir Imber Safdar, the Executive Director of the Partnership for Safe Medicines, a seventeen-year-old not-for-profit that accepts no corporate members or donations. Our members are other nonprofits and trade associations that represent manufacturers, wholesalers, pharmacists, and patients—everyone that touches medicine from the factory floor to the patient.

We take positions almost exclusively on pharmaceutical supply chain safety issues, tightly focusing on policies that reduce the threat of counterfeits in the American drug supply. That includes regulations around pill presses, training and resources for law enforcement to recognize counterfeit drugs and counterfeit drug traffickers, and policies that weaken or strengthen the supply chain.

SB 2209 and 2212 propose to require the North Dakota Board of Pharmacy and the state's department of health to design a program for prescription medicines imported from Canada under Sec. 804 of the U.S. Food, Drug, and Cosmetics Act. Below we outline the many reasons this proposal is unsafe and unworkable for the North Dakota Board of Pharmacy and the health department.

Lack of Funding or Statutes for Required Screening and Enforcement

The proposed legislation requires that the program created involve carefully screening Canadian suppliers and preventing any imported medicine from leaving the state of North Dakota. However, no funding is identified for enforcement of either of these functions for the Board of Pharmacy (BOP) or state law enforcement. Nor are there any new criminal penalties created for taking these prohibited products out of the state.

A Board of Pharmacy Has Limited Powers

The powers given to North Dakota's BOP expire at the state's borders. Even if the state's drug importation program gives the BOP the right to inspect foreign facilities, the BOP would be at the mercy of that facility to allow that inspection. Inspecting foreign facilities is a time and labor intensive process, something that the U.S. Food and Drug Administration (FDA) struggles with. Dr. Janet Woodcock's testimony for the FDA at a House subcommittee in December 2019 showed this:[1] records showed that in 2016 there were 965 foreign manufacturing facilities licensed by the agency that had never been inspected. Though progress was made, by 2019, there were still 470 that needed inspections.

[1] Testimony: Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program," Janet Woodcock, M.D. for U.S. Food and Drug Administration, December 10, 2019.

Testimony of Shabbir Imber Safdar
Executive Director, Partnership for Safe Medicines
January 27, 2021 - SB 2209 and 2212 (Senate Human Services Committee)

Regulating a Foreign Entity Will Be an Impossible Task

Despite no secretary of HHS previously allowing a state to try a drug importation plan, states have tried and they have failed. North Dakota and the state's Board of Pharmacy will find it impossible to regulate a foreign entity as previous drug importation programs have. Minnesota tried to make Canadian drug importation work for seven years. The program, RxConnect, started in 2003 and quickly ran into trouble.[2]

While Maine is currently attempting to run a state-sponsored drug importation program, the state did allow a personal drug importation program beginning in 2013. Long before a federal judge ruled that the law was in violation of federal law, counterfeit and substandard medicine was being illegally shipped into the state.[3] The former head of the Maine Pharmacy Association filed a lawsuit after testing of drugs he purchased showed that all of the drugs did not have enough active pharmaceutical ingredients and one of them had an unknown, potentially hazardous contaminate.[4] While Maine's law required the medications to be sourced from a limited set of countries, the medications received came from unapproved countries anyway (India, Mauritius, and Turkey.[5])

If a serious violation does occur, holding a Canadian vendor responsible will not be easy. Even if the case warrants the involvement of the U.S. Department of Justice, that does not mean that justice will be easy to achieve. For example, CanadaDrugs.com was indicted in November 2014 for selling $78 million worth of unapproved, mislabeled, and counterfeit cancer drugs to doctors across the U.S.[6] including North Dakota. The Canadian defendants spent years objecting to the case until a deal was brokered. In April 2018, the CEO of CanadaDrugs.com finally stood in a U.S. courtroom and admitted to the widespread illegal sale of misbranded and counterfeit drugs. [7] No one involved received even a one-day jail sentence. The fines and forfeiture came to just over $34 million.

Any Canadian Vendor Would Be Operating in a Legal Grey Area

Health Canada regulates Canadian wholesalers and pharmacies that distribute medications to Canadian citizens, and going back as far as 2004 it has said Health Canada "does not assure

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[2] "Minnesota's Experiment With Drug Importation: RxConnect 2003-2010," The Partnership for Safe Medicines, March 11, 2019.
[3] Jackie Farwell, "Judge Overturns Maine Law Allowing Prescription Drug Imports," *Bangor Daily News*, February 24, 2015.
[4] "MYTH: 'We Are Getting the Same Drugs Canadians Take,'" The Partnership for Safe Medicines.
[5] Idib.
[6] Superseding Indictment, U.S. District Court, District of Montana, Butte Division, Case No. 2:14-cr-00027-DLC.
[7] "Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States," U.S. Department of Justice, April 13, 2018.

that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future."[8] However, the U.S. Food and Drug Administration has limited to zero say over Canadian pharmacies and wholesalers. Any state doing business with a Canadian vendor would be making a leap of faith, and that leap has not worked out very well for other states that tried to do drug importation.

Drug Importation Breaks Track-and-Trace

Given that Canada has not implemented a track-and-trace system for any medical products, any drug importation plan would automatically be breaking track-and-trace. Simply slapping an identifier onto a bottle when it enters the country only gives you information as far back as that. The state would just need to trust everyone else earlier in the supply chain that the medication is what they say it is, it has been handled properly. Additionally, Canadian entities cannot be categorized as Trusted Trading Partners under the DSCSA because they do not possess state-issued wholesaler or pharmacy licenses.

Negotiated Drug Prices by Canada Are Not Transferable

While Canada does have universal healthcare coverage that includes medications when administered in the hospital setting, the same is not true for any prescription drugs taken outside of a hospital.[9] Much like in the U.S., most Canadians have prescription drug coverage through a patchwork of public and/or private insurance plans. Canada's Patented Medicines Prices Review Board sets prices to ensure that brand-name medication is not priced excessively, but those prices are for Canadian citizens.[10] There is nothing that can compel any Canadian wholesaler to give those same discounted prices to a U.S. state looking to import prescription drugs from Canada. This fact was one of the items listed in Deloitte's June 30, 2020 memo to the state's Employee Benefits Programs Committee as the committee was debating a drug importation bill.[11]

Canadian Drug Importation Is Not a Sustainable Solution

In the same memo, Deloitte stated that North Dakota would see "little if any potential savings" because of Canada's limited drug supply and the price equalization that would follow even a small percentage of prescription drugs being exported to the U.S.[12] Wyoming's Department of Health (WY-DOH) came to the same conclusion. In a report released last year, the WY-DOH stated that the concept of sustained savings via the importation of Canadian drugs has a fundamental economic flaw: it relies on a form of arbitrage.[13] Savings found in the exploitation of

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[8] Report on Prescription Drug Importation, Department of Health and Human Services, December 2004.
[9] Prescription Drug Insurance Coverage, Government of Canada, last modified December 3, 2020.
[10] Patented Medicines Prices Review Board, Government of Canada.
[11] Acturial Review of Proposed Bill 21.0068.01000, Deloitte, June 30, 2020.
[12] Idib.
[13] "Precription Drug Costs in Wyoming," Wyoing Department of Health, October 1, 2020.

price differences are fleeting and generally cause the prices to converge, eliminating any savings.

Drug Importation Will Not Help Most North Dakotans

Ninety percent of prescriptions in the U.S. are filled with generic drugs, the vast majority of which costs less than $20.[14] Seventy-seven percent of the money that U.S. patients spend is on the ten percent of prescriptions that are filled with brand-name drugs. So North Dakota's potential pool for citizens that would benefit from drug importation would be limited to people for whom there is not an FDA-approved generic option.

Importation programs can only work on paper if they operate at scale and North Dakota does not have the opportunity to do that. However operating a Canadian drug importation program at scale is exactly what has caused Canada to act to refuse cooperation with these programs.

Canada Promises to Protect Its Limited Drug Supply

Any state looking to import prescription drugs from within the Canadian drug supply chain would need Canada to be a willing participant, which it has never been. A bill proposed in 2005 would have allowed the Health Minister to ban the bulk exportation of prescription drugs from Canada to the U.S.[15] In a March 2020 comment submitted to Health and Human Services during the proposed rulemaking comment period, the Government of Canada warned that drug importation "would not provide an effective solution to high drug prices in the U.S."[16] As the federal government continued pressing forward with the issue, Canada imposed an interim order in November 2020 banning the export of prescription drugs that would cause or exacerbate drug shortages in that country.[17] If North Dakota attempts to do its own drug importation program or if the state works in tandem with another or other states, Canada will still protect the drug supply it has secured for its citizens.

Additional Issues to Canadian Drug Importation

Canada Has and Continues to Experience Crippling Drug Shortages

As of January 25, 2021, Canada has over 1,600 drugs listed as currently being in shortage.[18] A report found that between 2017 and 2018, nearly 25 percent of medications in Canada were in

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[14] "2018 Generic Drug Access and Savings Report," Association for Accessible Medicines.
[15] Beth Duff-Brown, "Health Minister Says Canada Intends to Ban the Export of Bulk Prescription Drugs," *Consumer Watchdog*, June 28, 2005.
[16] "Government of Canada Comments on the Proposed Rulemaking 'Importation of Prescription Drugs' (Docket No. FDA-2019-N-5711", Government of Canada.
[17] Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply), Government of Canada, November 27, 2020.
[18] Summary Report, Drug Shortages Canada, January 25, 2021.

shortage.[19] A national survey released in 2018 by the Canadian Pharmacists Association found that one in four Canadians had either personally experienced or knew someone who had experienced a drug shortage in the past three years.[20] The COVID-19 pandemic has worsened the prescription drug situation in Canada.[21]

Drug Importation Will Not Help Medicaid Beneficiaries

While wanting to help constituents lower their prescription drug costs is a laudable goal, drug importation will be of no benefit to the 11 percent of North Dakotans who are on Medicaid due to the discounted prices that the state is already able to get for those citizens.[22] So if drug importation cannot help the neediest in the state, who can it help? Despite the negative experiences in its attempt to do personal drug importation, Maine is currently pursuing a Canadian drug importation plan. When MaineCare, Maine's version of Medicaid, examined to see if drug importation would be a benefit for those beneficiaries, the state's analysis showed the state would lose close to $1 million because of all of the rebates the program already receives.[23]

The Costs of Federally-mandated Testing Will Eliminate All Savings

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that any drugs imported be statistically tested to ensure the safety of all imported medicines.[24] Dr. Kristina M.L. Acri née Lybecker examined if it was possible to test cheap drugs into safety, and she found that doing the required amount of testing quickly ate up all monies saved.[25] Dr. Acri also found that if a patient were to receive substandard or counterfeit medicine, a single adverse medical event could eliminate a drug importation program's savings anywhere from days to decades.[26]

Fiscal Impact Analysis

The theory that importing drugs from Canada will allow patients to see significant savings is just that: a theory. Many states looking into drug importation have applied a blanket 45% increase to the Canadian, but no state actually knows if this number is accurate. While no state has yet to operate an HHS-approved drug importation program, some have tried and there are lessons to be learned from them. Illinois operated a program called i-SaveRx in the mid-2000s. The Office

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[19] "Nearly a Quarter of Drugs Marketed in Canada Reported Shortages: Study," *CTV News*, September 1, 2020.
[20] "One in Four Canadians Touched by Drug Shortage in Last 3 Years," Canadian Pharmacists Association.
[21] Brooklyn Neustaeter, "Drug Shortages Could 'Imperil the Lives' of Canadians, Doctors Warn Ottawa," *CTV News*, August 13, 2020.
[22] "Medicaid in North Dakota," Henry J. Kaiser Family Foundation, October 2019.
[23] "Maine's Medicaid Program Analysis Shows the Truth: Importing Medicine from Canada Would Cost More, Not Less," The Partnership for Safe Medicines, December 1, 2020.
[24] Text: H.R.1 — 108th Congress (2003-2004), U.S. Congress, December 8, 2003.
[25] Dr. Kristina M.L. Acri nèe Lybecker, "State Pharmaceutical Importation Programmes: an Analysis of the Cost-effectiveness," Journal of Pharmaceutial Health Services Research, March 18, 2020.
[26] Idib.

of the Auditor General released a report in 2006 that showed the program was expensive for the state to run[27]:

- Twenty-eight agencies reported that 521 employees provided almost 5,600 hours of assistance at an estimated payroll cost of $488,000
- Illinois had significant expenditures on the program, including travel, contractual services, marketing, and legal services.

Additionally, no state discussion importation to date has actually addressed the cost of testing outlined above. Testing alone is sufficient to make most every importation program financially unworkable.

Colorado is one of the states currently pursuing a Canadian drug importation program. In March 2020, the state released a draft of its plan that included a list of potential drugs to import. PSM did an analysis and found that nearly one-third of the drugs on the list already had a generic version on the U.S. market and that the state could save over $43 million just by switching to the generic versions of those drugs.[28] Over a two-year period, Colorado budgeted $3 million of taxpayers' money to get its drug importation program up and running. The state has still not submitted its plan to HHS and no patient has saved even a single penny. Even Florida, with its $30 million contract, is struggling to find both a Canadian and a U.S. vendor.[29]

Drug Importation Will Weaken the Security of the Drug Supply Chain
The U.S. has one of the most secure drug supply chains in the world. Drug importation will only make it less secure, not more. In a 2017 report, former FBI director Louis Freeh warned that drug importation "would deplete and overburden already limited resources. In particular, importation proposals would force law enforcement agencies to make tough prioritization decisions that leave the safety of the U.S. prescription drug supply vulnerable to criminals seeking to harm patients."[30] North Dakota is not immune to this issue. Ten doctors received warning letters between 2012 and 2016 to stop purchasing medications from known black-market suppliers.[31]

There Are Other Safer Ways to Bring Down Prices.

There isn't an elected official today who doesn't hear from their constituents that health care costs are an issue, and pharmaceutical spending, which is less than 20% of overall healthcare

[27] "Report Digest Management Audit of the Flu Vaccine Procurement and the I-saverx Program," State of Illinois Office of the Auditor General, September 2006.
[28] "Analysis of Draft Colorado Importation Plan," The Partnership for Safe Medicines.
[29] Phil Galewitz, "Florida Fails to Attract Bidders for Canada Drug Importation Program," *Kaiser Health News*, October 26, 2020.
[30] "Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement," Freeh Group International Solutions, LLC.
[31] "The Deadly Counterfeit Drug Trade Thrives in North Dakota," The Partnership for Safe Medicines, April 2020.

spending, is certainly a piece of the problem. But states are finding other, safer ways to address these costs. California is aggregating its spending across different healthcare programs to achieve volume discounts. Louisiana has negotiated a “Netflix” subscription model, which will allow the state to treat hepatitis C at a fixed cost. West Virginia kicked their PBM out of their Medicaid program to use a pass-through entity and saved $52 million in their first year.

Canadian drug importation sounds like a good idea. However, history shows that previous drug importation programs, such as in Illinois and Minnesota, revealed patient safety issues and programs with operational costs that exceeded customer savings. Implementing this program in North Dakota is likely to consume state money without producing an operation program due to Canada’s statement of non-cooperation.

If North Dakota’s program were to somehow become fully operational, the program would rely on an existing black market of poorly regulated and counterfeit drugs. This bill incentives gray market wholesalers to ship counterfeit or substandard medicine into American that is expensive to detect and even more expensive for patients if we fail to detect it. North Dakota could help more people access healthcare by funding programs with less risk.

THE DEADLY COUNTERFEIT DRUG TRADE THRIVES IN NORTH DAKOTA

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

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

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

These pills are disguised as real medications but made with deadly fentanyl or its even deadlier variants, and even a fraction of a single pill can mean death in less than 30 minutes of ingesting it.

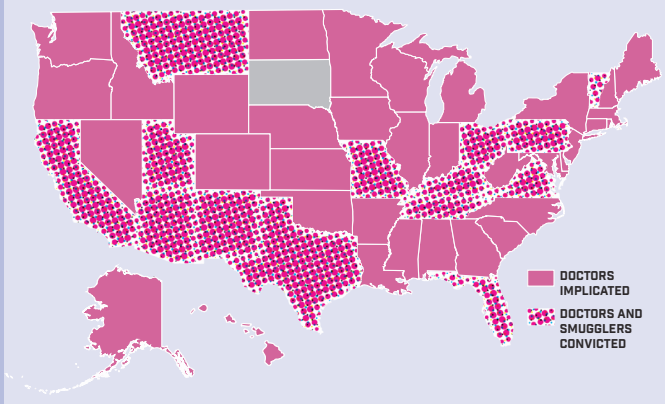
Fentanyl is a serious threat in North Dakota. Two North Dakotans suffered serious bodily harm after they ingested counterfeit pills made with fentanyl sold by a drug ring operating out of Texas. Between October 2017 and January 2018, five members of a drug ring that sold fake fentanyl pills in North Dakota and Minnesota each received prison sentences ranging from 24 to 65 months. One person in Grand Forks suffered a non-fatal overdose from a pill sold by this drug ring. In March 2020, another Grand Forks resident died after taking a fentanyl-laced counterfeit Xanax pill.

10 NORTH DAKOTA DOCTORS LINKED TO FAKE DRUG RINGS

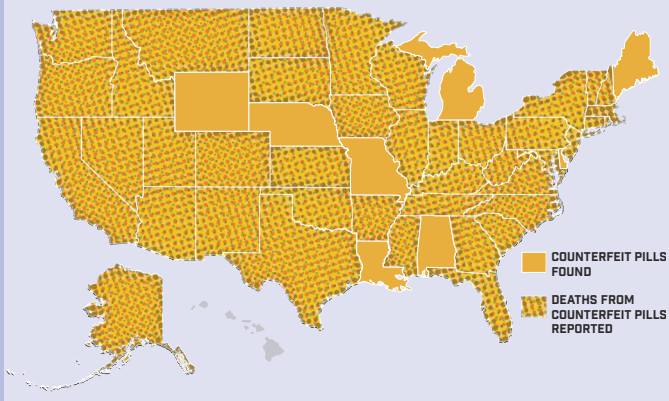
Counterfeit cancer drugs have touched North Dakota as well. 10 different medical practices in North Dakota have been implicated in various black market supply chains associated with counterfeit cancer treatments and other therapies. Families who have lost relatives to cancer will never know if their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

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

Fake Cancer Drug Crisis



Fentanyl-Laced Counterfeits & Related Deaths



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COUNTERFEIT AND BLACK MARKET DRUG INVESTIGATIONS IN NORTH DAKOTA (2012–2020)

BASED ON REPORTED INVESTIGATIONS.
NOTE THAT EACH INVESTIGATION COULD HAVE AFFECTED HUNDREDS OF NORTH DAKOTA RESIDENTS.

FENTANYL AND COUNTERFEIT PILLS MADE WITH FENTANYL

March 2020: A 24-year-old Grand Forks man died after he took a counterfeit Xanax made with fentanyl.[1]

October 2019: The leader of a Texas-based fake fentanyl pill drug ring received a 30-year sentence. Pills sold by this ring caused serious bodily injury to two residents of North Dakota.[2]

July 2019: Daniel Vivas Ceron pleaded guilty to operating an international drug trafficking ring while incarcerated in Canada from 2013 to 2017. The ring shipped several hundred pounds of fentanyl and fentanyl analogues across the U.S., causing 15 overdoses in North Dakota, Oregon, New Jersey, North Carolina, and Rhode Island, including four fatal overdoses, one of which was Grand Forks resident 18-year-old Bailey Henke.[3]

February 2019: The Jamestown Police Department reported seizing counterfeit oxycodone pills that contained fentanyl.[4]

June 2018: The U.S. Attorney's Office in Fargo indicted a Rhode Island man for his alleged role in a drug trafficking ring that distributed tens of thousands of counterfeit fentanyl pills throughout the U.S.[5]

October 2017: Chinese national Jian Zhang and eight other individuals were indicted in Fargo. Zhang faced multiple charges including Conspiracy to Possess with Intent to Distribute and Distribute Controlled Substances and Controlled Substance Analogues Resulting in Serious Bodily Injury and Death.[6] The U.S. Department of Justice issued a superseding indictment in April 2018, bringing the total number of defendants in this case to 28.[7]

August 2017: Police in Grand Forks issued a warning to members of the public after four people overdosed on fentanyl in just a few days.[8]

May 2017: The indictment of Aaron Shamo from Utah shows his fentanyl drug ring shipped 500 counterfeit pills into North Dakota.[9]

March 2017: The Narcotics Task Force seized hundreds of counterfeit oxycodone pills laced with fentanyl in Grand Forks and East Grand Forks.[10]

March 2017: Authorities arrested six residents of Grand Forks and East Grand Forks, Minnesota for fentanyl pill trafficking after fentanyl-laced oxycodone pills they sold caused a Grand Forks man to overdose.[11] Over the course of 2017 and 2018, six conspirators pleaded guilty in state or federal court and received sentences ranging from 24 to 65 months.[12]

BLACK MARKET AND COUNTERFEIT CANCER DRUGS

May 2013: The FDA warned 780 medical practices, two in North Dakota, to stop doing business with unlicensed drug seller Medical Device King, which had sold 31 non-FDA approved medications, including counterfeit Avastin.[13]

February–June 2012: Two North Dakota doctors were among the 136 nationwide that received warning letters indicating that they may have purchased counterfeit Avastin or Altzuan from Quality Specialty Products (QSP), a CanadaDrugs subsidiary.[14]

MISBRANDED AND COUNTERFEIT BOTOX

March 2016: The FDA warned 4 doctors and clinics in North Dakota 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.[15]

July 2013: The FDA warned four medical practices in North Dakota to stop purchasing fraudulent versions of Botox sold by Online Botox Pharmacy, Onlinebotox.com, and Onlinebotox.[16]

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FOOTNOTES

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14. "Historical Information: FDA Issues Letters to Doctors...," http://bit.ly/2rkvR5s.
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Memo

Date: June 30, 2020

To: Rep. Mike Lefor, Chairman
Employee Benefits Programs Committee

From: Josh Johnson and Dan Plante, Deloitte Consulting LLP

Subject: **ACTUARIAL REVIEW OF PROPOSED BILL 21.0068.01000**

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

OVERVIEW OF PROPOSED BILL 21.0068.01000

The following is a summary of the relevant proposed amendments:

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

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

ESTIMATED ACTUARIAL IMPACTS

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

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

- Canada would potentially oppose any importation plan that would either shrink the Canadian drug supply or raise costs for Canadians.

- Canadian drug distributors have argued against importation for similar reasons.

- Jim Greenwood, currently head of the biotech industry trade group BIO and a former Republican congressman, has indicated such importation would not result in lower prices for US consumers – citing both nonpartisan budget experts and past US Food and Drug Administration commissioners.

- Many drugs are cheaper in Canada due to Canadian government price controls. Such controls would likely not extend to drugs imported into the US, equating to drug costs higher than those experienced by Canadians.

- There is concern that some drugs imported from Canada did not actually originate in Canada, introducing concerns about safety.

The issues of potentially a very limited supply of imported drugs from Canada, and subsequent price equalization both indicate that little if any potential savings could be realized by the State's health program. We therefore cannot quantify an expected actuarial impact to the uniform group insurance program at this time.

January 27, 2021

Chair Lee and Members of the Senate Human Services Committee,

My name is Ellen Schafer. I live in Bismarck and I am an advocacy volunteer and member of AARP North Dakota's Executive Council. I am testifying this morning in support of all of the Senate Bills to support safe legal wholesale importation of prescription drugs (SB 2170, 2209 and 2212).

The rising cost of prescription drugs impacts all North Dakotans, but hits older North Dakotans particularly hard. Most Medicare beneficiaries live on relatively modest incomes. Their ability to absorb increasingly expensive prescription drugs is nearly impossible. Many of my friends, neighbors and family talk about the difficult decisions about how to live because of the price of those drugs.

My sister was diagnosed with chronic lymphocytic leukemia. The medication used to treat her leukemia is called Sprycel. Currently the drug costs $15,000 per month. She is retired and cannot afford this medication. The doctor placed her on a catastrophic list and which has helped her obtain a grant to pay for this medication. The cost of her medication will now be covered until December of 2021. After that she is not sure what will happen. If she is required to pay for the medication herself, she will have to quit this life saving medication.

Another drug the doctor has ordered for her is a respiratory inhaler called Trilogy to help her breathing. This medication currently costs $450.00 a month. She had to quit taking it because she cannot afford to pay for it.

My sister is not alone, AARP research shows that between 2012 and 2017, the average annual cost of prescription drug treatment increased 57.8%, while the annual income of North Dakotans only increased 6.7%. In AARP's 2020 survey of North Dakota adults, 44% of respondents decided not to fill a prescription that their doctor had given them because of the drug's cost. We cannot afford higher drug prices and bills like these would provide more affordable options to bring down the price.

Thank you again for listening to mine and other AARP members concerns as you work on this issue. I wholeheartedly appreciate any effort to make medicine more affordable. These bills are a step in the right direction and I hope you give at least one of these bills a favorable recommendation.

Thank you.

Why North Dakota Need to Tackle Prescription Drugs

January 27, 2021

Chair Lee and Members of the Senate Human Services Committee,

Five years ago, I nearly lost my life to leukemia, but it wasn't because of the disease, which was under control. It was because my wife and I couldn't afford my medication. Even though my doctors warned me the cancer would return if I didn't take the medicine, I did not fill my prescription through my Part D plan because of the cost. Luckily, I found a Canadian pharmacy, and I am healthy enough to advocate for others who aren't as fortunate as I am.

My story might seem dramatic, but it is shockingly common. Surveys have found that 79% of Americans think the price of medications is "unreasonable," and one in three adults did not take a medication as prescribed because of the price. There have been several high profile stories of people dying because they could not afford insulin. No one should be forced to make these horrible choices. That is why I share my story and have been volunteering with AARP to urge both our state and federal legislators to take action to lower prescription drug prices.

I know I'm not alone in wanting North Dakota to act to lower prescription drug prices. Voters have consistently made it clear that they – we – want policymakers to take action: according to polling from the Kaiser Family Foundation, 87% of adults think it is very or extremely important for Congress to lower prescription drug prices. While Congress certainly has a role, the State should act as well.

We need commonsense measures that address the root cause of the problem –it must address pharma's ever-growing high list prices, not just shift costs around in the system. That is why I support measures like the bills before you to allow for safe legal wholesale importation from Canada. The Trump administration authorized the rules and North Dakota should not sit idly by. Until the State acts, North Dakotans like me will continue to make hard choices about whether to stop taking a needed medication, skip other bills, or buy lower-cost drugs elsewhere. **Before I turned to Canada – a choice not everyone could or should make – I was staring down a bill of $2,400 a month, or almost $30,000 a year.** A researcher who discovered my medication has actually denounced the manufacturer's price, asking "When do you cross the line from essential profits to profiteering?" It's a shame Americans have to turn to foreign countries for affordable prices on life-saving drugs but if that will help consumers like me, I support it.

I know from telling my own story and hearing from others that there's a nationwide army of us that has come together for change. Some of us have joined because we are patients, some because we are caregivers, and some because we are taxpayers who know the current system is unsustainable and worry about the consequences for Medicare and other important programs.

Enough is enough. I live in the greatest country in the world, but I believe my government is failing me. It's time to take action and pass one of the bills before you to allow North Dakotans to access safe legal importation. North Dakotans and all Americans can't afford to wait any longer.

#3193

Biotechnology Innovation Organization

THE REAL COSTS OF DRUG IMPORTATION

MYTH

If we allow widespread importation of cheaper drugs from other developed countries such as Canada, patients will be able to keep more of their hard-earned money in their pockets without compromising the safety of our drug supply.

FACT

Unfortunately, that's not the reality. Such a move would likely expose patients to counterfeit, adulterated, or unapproved drugs, and any savings would mostly wind up as profits for middlemen, not lower prices for patients. Here are the untold costs of drug importation…

- A bipartisan group of four former FDA Commissioners recently wrote in a warning to Congress: "…importation represents a complex and risky approach — one that the evidence shows will not achieve the aim [of lowering costs], 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."
- Any improved access or cost savings resulting from importation are likely to be minimal — with most savings winding up as profits for middlemen.

Source: https://www.surgeongeneral.gov/news/testimony/t01262005.html

ESTIMATED SAVINGS FROM DRUG IMPORTATION

LESS THAN ONE PERCENT WOULD GO DIRECTLY TO PATIENTS

- The global counterfeit medicine market could be as high as $75 billion a year.

Source: http://www.who.int/bulletin/volumes/88/4/10-020410/en/

$75 Billion ESTIMATED SIZE OF GLOBAL COUNTERFEIT DRUG MARKET

- Online drug pharmacies are increasing the risk of counterfeit drugs making their way to U.S. patients.

Source: https://nabp.pharmacy/denying-consumers-access-patient-care-common-among-rogue-internet-drug-outlets-notes-nabp/

PROPORTION OF ONLINE DRUG RETAILERS OPERATING OUT OF COMPLIANCE WITH U.S. HEALTH & SAFETY STANDARDS

Biotechnology Innovation Organization

THE REAL COSTS OF DRUG IMPORTATION

U.S. Is Standard-Bearer for Ensuring Drug Safety and Efficacy

> **"[Importation] could lead to a host of unintended consequences and undesirable effects, including serious harm stemming from the use of adulterated, substandard, or counterfeit drugs. It could also undermine American confidence in what has proven to be a highly successful system for assuring drug safety."**
>
> — Robert Califf, Margaret Hamburg, Mark McClellan, and Andrew Von Eschenbach
>
> Four former FDA Commissioners (serving in both Democratic and Republican Administrations)
>
> **March 17, 2017 letter**

Leading Law Enforcement Officials Oppose Drug Importation

> **"[T]he National Sheriffs' Association opposes the passage of legislative drug importation proposals which would jeopardize law enforcement's ability to protect the public health; threaten the safety of our drug supply; and endanger law enforcement officers, their canines, and other first responders across America."**
>
> — The National Sheriff's Association
>
> **July 2017**

In June 2017, Former FBI Director Louis Freeh released a report entitled, "Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement," which found that:

- Drug importation would increase the threat of illegitimate products entering the U.S., fueling criminal organizations' activities and profits.
- Drug importation proposals would worsen the opioid crisis — a crisis that has already grown substantially worse due to the powerful opioid fentanyl and fentanyl analogue-laced counterfeit pills being produced by illegal drug trafficking organizations, including in China, and reaching the U.S. through Canada and Mexico.
- Already overburdened law enforcement and regulatory capacity would be unable to ensure a safe prescription drug supply under importation.

It's Canada… how dangerous can it really be?

Many people assume that if drugs are imported from other highly-developed countries like Canada, such supplies would pose little to no safety risks. After all, we don't read regular news reports about Canadian patients being harmed by drugs purchased at Canadian pharmacies. So what's the big deal?

While Canadian regulators ensure the safety and authenticity of medicines entering their market that are intended for use by patients in Canada, they do not apply those standards for medicines intended for export only.

In fact, according to a former Canadian government official, "The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada to the United States…"*

And former FDA Commissioner Robert Califf has testified that, "FDA evaluation revealed that, while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85% of such drugs were actually from different countries."

Given that drugs imported from abroad will effectively lack oversight by any health authority, there is a high likelihood that such drugs — if not counterfeit — could nonetheless be mishandled (e.g., proper temperature control not maintained, causing spoilage) or could display deceptive or incorrect packaging and labeling.

*Diane C. Gorman, Former Assistant Deputy Minister of Health Canada, May 2003, Letter to the Washington Post

January 27, 2021

Members of the Senate Human Services Committee:

On behalf of the organizations below and the thousands of North Dakota patients we represent, we urge you to proceed with caution when considering SB 2209, SB 2212 and other similar Canadian drug importation proposals.

Ensuring patients have access to affordable medicines is critical. However, permitting wholesalers and pharmacists to import medications from Canada — or elsewhere in the world — poses a serious risk to the public's health and safety that should not be ignored. Such proposals undermine important regulatory protections provided by manufacturer oversight and could lead to a host of unintended consequences, including opening our borders to a dangerous supply of counterfeit drugs. Additionally, there is no guarantee that any potential cost savings from these proposals will be passed on to patients.

The patients we work with on a daily basis rely on their medications to keep them healthy. The possible dangers of importing drugs without manufacturer authorization, even from seemingly safe places such as Canada, simply carry too great a risk. Nor is importation the solution to lowering patient costs. We urge you to focus on real solutions that protect the safety of the drug supply and directly address out-of-pocket costs for North Dakota patients.

Sincerely,

Community Liver Alliance

Family Voices of North Dakota

North Dakota Nurses Association

WomenHeart Jamestown

Canadian Society of Hospital Pharmacists | Société canadienne des pharmaciens d'hôpitaux

Statement of Christina Adams, Chief Pharmacy Officer
Canadian Society of Hospital Pharmacists

North Dakota SB 2209 / SB 2212 in Senate Human Services Committee
By invitation of the chair on Wednesday January 27, 2021

I am Christina Adams, the Chief Pharmacy Officer for the Canadian Society of Hospital Pharmacists. We are a non-profit that represents Canadian pharmacy professionals working in hospitals to improve patient care by safe and effective medication use. I am also a practicing pharmacist.

I understand and sympathize with the challenges of financial barriers to healthcare, but I am concerned because our nation of 38 million people does not have the pharmaceutical supply for America's 329 million citizens. In fact, even the roughly 700,000 residents of North Dakota would have an impact on our patient safety if they shifted their purchasing to Canada.

Even before the pandemic, Canada already suffered drug shortages that endangered Canadian patients. Canadian pharmacists already manage as many as 2,000 drug shortages at any given time, and in a recent survey, one in four residents reported being affected by drug shortages. In hospital settings, these shortages directly and negatively affect patient outcomes. Instead of doing clinical work with patients, pharmacists spend too much time sourcing scarce drugs, finding appropriate substitutes, repackaging for correct dosages, and communicating with other healthcare professionals about these shortages.

As an organization of pharmacists, CSHP is sympathetic to the challenges that North Dakota patients face in accessing affordable medicines, but importation is such a poor solution that we have joined the Alliance for Safe Online Pharmacies Canada to advocate for a ban on medicine exports for U.S. programs like these. In response, our federal government has delivered their message of opposition directly at the White House and in public comments on federal regulations. Additionally, they have recently enacted restrictions on Canadian wholesalers who wish to export medicine to the U.S. to make clear their intent to stop this practice.

Wholesale drug importation will hurt Canadians and it will not help North Dakota residents with drug prices. We hope you are able to pursue other avenues to make medicines more affordable.

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Written Testimony by

Don Bell
Chief Superintendent Ontario Provincial Police (ret.)
Director of Enforcement and Intelligence Canada Border Service Agency (CSBA) (ret.)
Orillia, Ontario, Canada

Submitted on behalf of the Partnership for Safe Medicines
To the North Dakota Senate Human Services Committee

On Senate Bills SB 2209 & SB 2212

Madame Chair and members of the committee, I submit this testimony to express my concerns and opposition to passage of SB 2209 & SB 2212, which aim to legalize the importation of prescription drugs from Canada. My opposition is based on my experience as a former Canadian law enforcement officer, combating organized crime groups operating in Canada and along the border with the United States for over three decades. I was a Chief Superintendent in the Ontario Provincial Police and a Director of Intelligence and Enforcement for the Canada Border Services Agency.

While prescription drug importation proposals are well-intentioned to help lower drug prices for average Americans, they are likely to trigger significant, long-lasting and dangerous unintended consequences by greatly expanding the illicit trade in adulterated, substandard and counterfeit drugs.

The Government of Canada has repeatedly stated opposition to any importation proposals, since the United States is nine-times larger than Canada. Our government most recently enacted an interim order on export restrictions for prescription medicines to counter importation proposals and avoid worsening drug shortages.[i]

This lack of genuine supply for any importation program will open the door to foreign and domestic criminals willing to fill the unmet demand with adulterated, substandard or counterfeit drugs. This will include the transshipment of illicit prescription medicines through Canada to make them appear legitimate.

While Canada's pharmaceutical supply chain is very safe, it was built to ensure the safety of drugs entering and being consumed in Canada. Canadian law enforcement and Canadian border agents are resourced to secure the Canadian drug supply, not to protect the safety of prescription drugs for export or transshipment to the United States. The priority of Canadian law enforcement and border protection is to maintain the safety on inbound packages destined for domestic use.

Canadian Law Enforcement and Border Protection do not routinely inspect outgoing or transshipped packages and cargo, unless presented with actionable intelligence from other law enforcement units or third parties. Transshipments into the United States, including those through Canada already present an avenue for illegal, dangerous, and counterfeit drugs. Legalizing importation schemes from Canada is going to exacerbate this issue.

Criminals are already in the business of supplying fake medicines and have repeatedly shown a disregard for human life and public safety by operating fake Canadian pharmacies, transshipping counterfeit medicines and trafficking in illicit medical supplies. Operation Pangea, an annual global law enforcement operation designed to enforce against the online sale of counterfeit and illicit medicines highlights the extent of the issue. During Operation Pangea XIII (conducted March 2020), law enforcement seized over 4.4 million units of counterfeit, adulterated or substandard medicines, medical supplies and devices worth over USD$14 million and took over 2,500 illegal websites offline.[ii] Seized fake medical products related to the COVID 19 pandemic, including unauthorized anti-viral medicines and fake PPE, provided a stark reminder that criminals will exploit every opportunity and every loophole, especially if driven by a lack of genuine supply.

In summary, since legitimate medicines will be unavailable from Canada in sufficient quantities for North Dakota's importation program, criminals will fill that void. Criminals driven by greed will offer medicines that they will claim are Canadian but are anything but. This is not some hypothetical future scenario but has already happened multiple times before.

CanadaDrugs.com, for example, was a Canadian online pharmacy operated by two Canadian licensed pharmacists. From 2009 – 2012, they sold $78 million worth of unapproved, misbranded, and counterfeit drugs to the U.S. clinics and patients. These drug products included Avastin, a counterfeit cancer medication, which had zero active pharmaceutical ingredients.

And while U.S. prosecutors, the DOJ and the FDA pursued the criminals with the full range of federal tools available, none of the CanadaDrugs.com ring leaders went to jail. The DOJ had to settle on a penalty of $34 million in fines and six-months of house arrest, in line with Canadian sentencing guidelines.[iii]

It may seem appealing to try and address drug pricing with drug importation, but we need to worry about the unintended consequences of such policies for the United States, as well as Canada. I urge you to dismiss these bills in the interest of the public safety of both or our nations. Thank you for allowing me to raise my concerns.

Sincerely,

Don Bell

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[i] "Health Canada issues new Interim Order to prevent bulk exportation of prescription drugs from Canada", accessed at https://www.pharmainbrief.com/2020/11/health-canada-issues-new-interim-order-to-prevent-bulk-exportation-of-prescription-drugs-from-canada/

[ii] https://www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations

[iii] Volz, M. (2018, April 13). *Canadian pharmacy fined $34 million for illegal imports*. https://www.usnews.com/news/news/articles/2018-04-13/canadian-pharmacy-to-be-fined-millions-for-illegal-imports.

CAPDM Driving | Healthcare

#3615

Statement of Daniel Chiasson, President & CEO
Canadian Association for Pharmacy Distribution Management
SB 2209/2212, North Dakota Human Services Committee
By invitation of the chair on January 27, 2021

Mr. Chairman, members of the committee, I submit the following testimony on behalf of the Canadian Association for Pharmacy Distribution Management (CAPDM). I am Daniel Chiasson, the President and CEO of CAPDM.

The Canadian Association for Pharmacy Distribution Management (CAPDM) represents the country's leading national and regional pharmaceutical distributors. CAPDM and its members share the priority of ensuring a safe, high quality and stable supply of medications for Canadians. We sympathize with the struggle American patients face accessing affordable medication.

We have reviewed the legislation you are considering, SB 2209 and 2212, that would enact a program to purchase medicine from the distributors and wholesalers of Canada. CAPDM represents the sellers you intend to purchase from. We are not supportive of any policy initiative or policy proposal that has the capacity to threaten the stability of medications available to Canadians, or worsen instances of already serious drug shortages.

The Canadian drug supply is insufficient for the Canadian market, let alone trying to divert it to a much larger market like the U.S.[1]

We oppose these proposals because Canada is in the midst of drug shortages that started before the pandemic and has only gotten worse since then. Any program to fulfill demand from the US side of the border would endanger Canadian patients and put us squarely at odds with our federal regulators who oppose programs like this and recently issued new regulations to discourage any interest in selling our drug supply to the U.S.

We are sympathetic to Americans struggling to afford healthcare costs, but this is not a workable solution.

Thank you for your time and consideration.

[1] https://www.capdm.ca/Issues/Drug-Shortages.aspx

Canadian Association for Pharmacy Distribution Management

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STATEMENT #3670

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to North Dakota
SB 2209
January 27, 2021

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes North Dakota Senate Bill (SB) 2209, which directs the state board of pharmacy, in consultation with other entities, to design a wholesale prescription drug importation program for the importation of drugs from Canada. This legislation mischaracterizes importation as a tool to lower drug costs and disregards the inherent threats to patient safety associated with drug importation.

In September 2020, the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) issued its final rule (the Final Rule) implementing a provision of federal law allowing the commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs sponsored by states or Indian tribes. The Secretary concurrently offered "certification" that the program would pose no additional risk to the public's health and safety and would result in a significant reduction in the cost to the American consumer as required by law. The Rule provided no proof that importation programs will not provide additional risk to public health and safety or result in significant cost savings. Instead, the federal government placed the responsibility of ensuring public safety and proving significant cost savings on the states.

A state importation program is unlikely to produce significant cost savings and fails to recognize the additional resources needed to implement and maintain an importation program.

The Federal Rule places the onus on states to prove "significant cost savings" from a state importation program (SIP) and acknowledges that "SIP Sponsors will face costs to prepare proposals, implement authorized programs, and produce records and program reports."[i] Extensive state resources are required for the implementation and administration of an importation program including but not limited to:

- ***Start-up and Ongoing Costs:*** A state importation program would ultimately assign numerous new responsibilities to the State of North Dakota, including: the design of the importation program; compliance with existing federal laws, including track and trace; development of a wholesale prescription drug importation list; and ongoing administrative costs.

- ***Compliance with Federal Law:*** Both the Foreign Seller and the Importer, under supervision of the state, will be subject to the supply chain security requirements set forth in the Final Rule and under the federal Food, Drug & Cosmetic Act (FD&C Act).

- ***Law Enforcement Costs:*** In July 2017, the National Sheriffs Association approved a resolution opposing state importation legislation because such programs would "jeopardize law enforcement's ability to protect the public health, threaten the safety of our (U.S.) drug supply, and endanger law enforcement officers, their canines, and other first responders."[ii] As former FBI director Louis J. Freeh recently wrote, "the sheer strain that legalized drug importation would have on law enforcement agencies cannot go unappreciated…[W]e've also been faced with resource and budget challenges that force us to do more with less. Rolling the dice on a drug importation law would undoubtedly take resources away from other important law enforcement efforts."[iii]

- ***Public and Stakeholder Education:*** Any statewide prescription drug program requiring voluntary participation from supply chain entities and consumers will require training and education.

In public comments to the FDA during the rulemaking process, several states that passed importation laws expressed concern with the ability to recoup state costs, prove significant savings, achieve appropriate levels of access, and operate efficiently under the parameters outlined in the proposed rule. The Final Rule failed to address these concerns. The Colorado Joint Budget Committee approved their state's Department of Health Care Policy and Financing's FY 2020-21 recommendation to delay of the implementation of Colorado's Canadian importation program in light of budget concerns. After conducting a study on the feasibility of importation, the state of Wyoming determined in September 2020 that a state drug importation program would likely not create significant savings and would be unsustainable in the long-term.

This legislation could increase the risk to consumer health and safety by weakening the closed supply chain and opening North Dakota to increased criminal activity.

Opening our closed distribution system to importation would gravely compromise the integrity and safety of the U.S. prescription drug supply. Importation presents a huge opportunity for unscrupulous suppliers and/or criminal organizations to increase the flow of substandard, adulterated or counterfeit drugs – including pills laced with deadly fentanyl – into the U.S. FDA is the gold standard in ensuring the safety and effectiveness of medicines for the U.S. market and importation would have the same effect as repealing current FDA and consumer protections.

The legislation fails to acknowledge the complexities of setting up a state importation program that adequately protects public health and safety. Specifically, it fails to acknowledge the challenges associated with adherence to the federal "track and trace" system established under the Drug Supply Chain Security Act (DSCSA) and the inherent risk to public safety if it is compromised. Both the draft legislation and the federal Rule place significant responsibility on states to adhere to federal track and trace requirements and demonstrate that any importation program would pose no additional risk to public health.

In 2013, Congress unanimously enacted bipartisan legislation to address concerns of unsafe and counterfeit drugs entering the U.S. pharmaceutical supply chain. The Drug Supply Chain Security Act (DSCSA) established an electronic system to uniquely identify each package of drugs and trace those packages as they are distributed. Through the DSCSA and prior actions, the U.S. has established one of the most secure supply chains in the world and ensures proper protection of patients. Drug importation programs severely undercut the protections of the DSCSA, compromising patient safety. If North Dakota pursues an importation program, it will assume significant risk and potential cost in an effort to ensure public safety.

Canadian law does not prohibit the transshipment of drugs from any country—including those in the third world—into Canada and then into the United States, heightening concerns about the safety and reliability of these medicines. The FDA determined that 85 percent of the drugs sold by supposedly Canadian pharmacies come from 27 countries other than Canada.[iv]

The Importation Final Rule raises significant legal concerns and is the subject of ongoing litigation.

On November 23, 2020, PhRMA, the Partnership for Safe Medicines (PSM), and the Council for Affordable Health Coverage (CAHC) filed a complaint in the U.S. District Court for the District of Columbia against the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA). The litigation challenges the final rule on Importation of Prescription Drugs (Final Rule) and an associated "certification" made by Secretary Azar on the grounds that they suffer from fatal flaws, including failing to demonstrate that importation will pose no additional risk to public health and safety or will result in significant cost savings.

The complaint alleges that the Final Rule disregards key patient safety protections of the Federal Food, Drug, and Cosmetic Act (FDCA). Section 804 of the FDCA authorizes HHS in certain circumstances to permit both the importation of drugs by pharmacists and wholesalers for commercial distribution and the importation of drugs by individual patients. **Section 804 is effective, however, only if the HHS Secretary certifies to Congress** "that the implementation of this section will—(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer." Although this law was enacted nearly twenty years ago, no previous HHS Secretary has been willing to make this certification due to inability to ensure both public safety and cost reduction. The Final Rule and Secretary Azar's "certification" letter, which apply only to commercial distribution, contain conclusory statements as to safety and cost savings without supporting evidence and punt the responsibility for safety and cost savings to state governments.

In addition, there is no indication that the Final Rule will reduce costs to actual American patients. In the preamble to both the proposed and Final Rule, HHS has acknowledged that it cannot quantify the savings, if any, that would result from its rule, even classifying it as "not economically significant" for purposes of review by the Office of Management and Budget. Indeed, in the budget document released with the rule, the cost savings chart was left completely blank, suggesting cost savings could not be calculated.

Furthermore, aspects of the Final Rule are contrary to the FDCA, violate manufacturers' First Amendment rights and raise serious questions under the Fifth Amendment Takings Clause. As such, PhRMA, PSM and CAHC are asking the Court to hold unlawful, set aside and permanently enjoin implementation of the Certification and Final Rule.

In addition to the ongoing federal litigation, PhRMA, PSM, and CAHC submitted a Citizen Petition to FDA requesting that the agency refrain from authorizing Florida's Section 804 Importation Program Proposal for the Importation of Prescription Drugs from Canada (Proposal), which Florida submitted to FDA on November 23, 2020. In addition to being issued pursuant to an invalid and legally deficient certification and Final Rule, the Proposal does not adequately demonstrate that importation will pose no additional risk to public health and safety, and it fails to show that importation will lead to any reduction—let alone a significant reduction—in the cost of prescription drugs for American consumers.

State importation programs fail to recognize the challenges of the Canadian prescription drug market.

The Canadian government is not in a position to monitor and regulate medicines that are intended for the U.S. market. Canada's former Health Minister Leona Aglukkaq said, "Canada inspects drugs for its own citizens; Canadian authorities wouldn't have the ability or resources to inspect medicines destined for the United States." [v] Therefore, the financial and practical burden would fall to U.S. authorities and local law enforcement. Kirsten Hillman, acting Ambassador to the United States, stated that "the Canadian market is too small to have a real impact on U.S. drug prices. The U.S. consumes 44% of the global prescription drug supply, compared to Canada's 2%," and that "Canada's priority is to ensure a steady and solid supply of medications at affordable prices for Canadians."[vi]

In November 2020, Health Canada issued an Interim Order stating that the distribution of certain medicines intended for the Canadian market outside of Canada is prohibited if the distribution would cause or exacerbate a shortage of the medicines in Canada. To date, no state that has submitted an application to FDA to sponsor a state importation program has secured the required foreign seller from Canada to facilitate importation.

PhRMA shares a desire to address patient affordability within the health care system and reduce consumer costs in the State of North Dakota. However, for the reasons stated above, we do not believe development of a drug importation program will produce the desired results and could significantly jeopardize patient safety.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

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[i] https://www.hhs.gov/sites/default/files/importation-final-rule.pdf

[ii] Drug Enforcement Administration (undated; viewed on July 25, 2017), DEA Warning to Police and Public: Fentanyl Exposure Kills, https://ndews.umd.edu/sites/ndews.umd.edu/files/DEA%20Fentanyl.pdf. Also, Drug Enforcement Administration (July 2016), supra.

[iii] Louis J. Freeh op-ed, "Cost of drug importation could unfairly shift to law enforcement," The Philadelphia Inquirer, May 5, 2017.

[iv] FDA. "FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries." December 2005

[v] Letter to the Washington Post, Leona Aglukkaq, Former Minister (2008-2013), Health Canada, May 12, 2017

[vi] Statement from Canada's Acting Ambassador to the United States on U.S. Importation of Pharmaceutical Drugs from Canada, December 18, 2019

#3471

SANFORD HEALTH PLAN

January 25, 2021

The purposes of this registration is to permit Daniel Weiss, Senior Executive Director – Pharmacy for Sanford Health Plan, to be available to assist the committee with questions and support NDPERS as the plan adminstrator for that program.

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

SB 2209
2/3/2021

A BILL for an Act to create and enact a new section to chapter 19-02.1 and a new chapter to title 19 of the North Dakota Century Code, relating to increased access to low-cost prescription drugs; to amend section 43-15.3-12 of the North Dakota Century Code, relating to drug wholesaler fees; to provide for a report; to provide a continuing appropriation; to provide for a transfer; and to provide a contingent effective date.

Madam Chair Lee opened committee discussion on SB 2209 at 10:19 a.m. Senators present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Prescription drug importation program
- Study resolution

[10:23] Josh Askvig, State Director, AARP. Provided the committee with opinion on study resolution language.

[10:44] Mike Schwab, North Dakota Pharmacist Association. Provided the committee with opinion on study resolution language.

Additional written testimony: N/A

Madam Chair Lee closed committee discussion on SB 2209 at 10:50 a.m.

Justin Velez, Committee Clerk

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

SB 2209
2/8/2021

A BILL for an Act to create and enact a new section to chapter 19-02.1 and a new chapter to title 19 of the North Dakota Century Code, relating to increased access to low-cost prescription drugs; to amend section 43-15.3-12 of the North Dakota Century Code, relating to drug wholesaler fees; to provide for a report; to provide a continuing appropriation; to provide for a transfer; and to provide a contingent effective date.

Madam Chair Lee opened the discussion on SB 2209 at 11:02 a.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Amendment 21.0656.03001 proposal
- SB 2212 becoming a study and fiscal impact
- SB 2170 continuing appropriations

[11:02] Senator Howard Anderson, District 8. Provided the committee with proposed amendment 21.0656.03001 (testimony #6443).

Senator Hogan moves to **ADOPT AMENDMENT 21.0656.03001**
Senator K. Roers seconded.

Voice Vote- motion passed

Senator Hogan moves **DO PASS, AS AMENDED, REREFFER TO APPROPRIATIONS.**
Senator Clemens seconded.

Senators	Vote
Senator Judy Lee	Y
Senator Kristin Roers	Y
Senator Howard C. Anderson, Jr.	Y
Senator David A. Clemens	Y
Senator Kathy Hogan	Y
Senator Oley Larsen	N

The motion passed 5-1-0
Senator Anderson will carry SB 2209.

Additional written testimony: (2)

Ariel Delouya, General Counsel, Canadian Government. Provided written testimony #5883 in opposition.

Government of Canada, Embassy of Canada. Provided comments on the proposed rule "Importation of Prescription Drugs" testimony #5882.

Madam Chair Lee closed the discussion on SB 2209 at 11:17 a.m.

Justin Velez, Committee Clerk

SV 2/4

21.0656.03001
Title.04000

Prepared by the Legislative Council staff for
Senator Anderson
February 4, 2021

PROPOSED AMENDMENTS TO SENATE BILL NO. 2209

Page 1, line 16, remove "The state board of pharmacy, in consultation with appropriate federal and state"

Page 1, line 17, replace "agencies, other states, and interested parties, shall design" with "If another state creates"

Page 1, line 20, after the underscored ending bracket insert "and this chapter"

Page 1, line 20, after "cost-savings" insert ", the state department of health may contract with the other state for the importation of prescription drugs from Canada"

Page 2, line 25, replace "state board of pharmacy" with "health council"

Page 3, after line 29, insert:

"**Drug importation fund -** "

Page 4, line 2, replace "transfer" with "deposit"

Page 4, line 5, replace "agency designated" with "department of health"

Page 5, line 1, remove "The state board of pharmacy shall submit"

Page 5, remove lines 2 and 3

Page 5, line 4, replace "Act. Section 2 of this" with "This"

Page 5, line 4, remove "president of the"

Page 5, line 5, replace "board of pharmacy" with "department of health"

Page 5, line 5, remove "approval and"

Page 5, line 6, replace "certification of the state's" with "a contract with another state for the implementation of a"

Page 5, line 6, remove "from the United"

Page 5, line 7, remove "States department of health and human services"

Renumber accordingly

REPORT OF STANDING COMMITTEE

SB 2209: Human Services Committee (Sen. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** and **BE REREFERRED** to the **Appropriations Committee** (5 YEAS, 1 NAY, 0 ABSENT AND NOT VOTING). SB 2209 was placed on the Sixth order on the calendar.

Page 1, line 16, remove "The state board of pharmacy, in consultation with appropriate federal and state"

Page 1, line 17, replace "agencies, other states, and interested parties, shall design" with "If another state creates"

Page 1, line 20, after the underscored ending bracket insert "and this chapter"

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Page 5, line 6, remove "from the United"

Page 5, line 7, remove "States department of health and human services"

Renumber accordingly

21.0656.03001

Sixty-seventh
Legislative Assembly
of North Dakota

SENATE BILL NO. 2209

Introduced by

Senator Anderson

Representatives M. Nelson, Satrom

A BILL for an Act to create and enact a new section to chapter 19-02.1 and a new chapter to title 19 of the North Dakota Century Code, relating to increased access to low-cost prescription drugs; to amend section 43-15.3-12 of the North Dakota Century Code, relating to drug wholesaler fees; to provide for a report; to provide a continuing appropriation; to provide for a transfer; and to provide a contingent effective date.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 19-02.1 of the North Dakota Century Code is created and enacted as follows:

Exception - Drug importation.

This chapter does not prohibit a manufacturer of a drug approved by the federal drug administration from importing a version of the approved drug sold in foreign countries pursuant to section 801 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 384].

SECTION 2. A new chapter to title 19 of the North Dakota Century Code is created and enacted as follows:

Wholesale prescription drug importation program.

1. ~~The state board of pharmacy, in consultation with appropriate federal and state agencies, other states, and interested parties, shall design~~If another state creates a wholesale prescription drug importation program for the importation of prescription drugs from Canada in compliance with section 804 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 384] and this chapter, including requirements regarding safety and cost-savings, the state department of health may contract with the other state for the importation of prescription drugs from Canada.

2. The program must:

a. Designate a state agency to become a licensed drug wholesaler or to contract with a licensed drug wholesaler to import safe prescription drugs and provide cost-savings to consumers in the state. The designated state agency shall implement and operate the program.

b. Use prescription drug suppliers in Canada which are regulated under the laws of Canada, one or more Canadian provinces, or both.

c. Ensure compliance with title II of the federal Drug Quality and Security Act of 2013 [Pub. L. 113-54; 21 U.S.C. 301 et seq.] for the safety and effectiveness of imported prescription drugs.

d. Limit importation to prescription drugs expected to generate substantial cost-savings for consumers in the state.

e. Ensure the program complies with the transaction and tracing requirements of sections 360eee and 360eee-1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 384] to the extent feasible and practical before the imported prescription drugs come into the possession of the licensed drug wholesaler and ensure the program complies fully after the imported drugs are in the possession of the state wholesaler.

f. Consider whether the program may be developed on a multistate basis through collaboration with other states.

g. Except as provided under subdivision f, prohibit the distribution, dispensing, or sale of imported prescription drugs outside the state.

h. Recommend a charge per prescription or another method of financing to ensure the program is adequately funded in a manner that does not jeopardize significant consumer savings.

i. Include an audit function.

Rulemaking.

The state ~~board of pharmacy~~department of health shall adopt rules to design the program in accordance with this chapter.

Implementation.

1. The state agency designated to oversee the program shall implement the program as required under this chapter.

2. The state agency designated to oversee the program shall:
   a. Become a licensed drug wholesaler or enter a contract with a drug wholesaler licensed by the state.
   b. Contract with one or more wholesale drug distributors licensed by the state.
   c. Contract with one or more licensed and regulated prescription drug suppliers in Canada.
   d. Consult with health insurance carriers, employers, pharmacies, pharmacists, health care providers, and consumers.
   e. Develop a registration process for health insurance carriers, pharmacies, and health care providers authorized to prescribe and administer prescription drugs which are willing to participate in the program.
   f. Create a publicly accessible website for listing the prices of imported prescription drugs.
   g. Develop a two-year audit work plan.
   h. Conduct any other activity the agency determines necessary to successfully implement and operate the program.

Reporting.

By June 1 of each year, the state agency designated to implement and operate the program under this chapter shall provide a report to the legislative management regarding the implementation and operation of the program during the previous calendar year. The report must include:

1. The prescription drugs included in the program.
2. The number of participating pharmacies, health care providers, and health insurance carriers.
3. The number of prescription drugs dispensed through the program.
4. The estimated cost-savings to consumers, health insurance carriers, employers, and the state during the previous calendar year and over the course of the program.
5. Information regarding the implementation of the audit work plan and audit findings.
6. Any other information the state agency designated to oversee the program considers relevant.

Drug importation fund -Transfer - Continuing appropriation.

The state board of pharmacy shall ~~transfer~~deposit six hundred dollars of every wholesaler license fee and every virtual wholesaler license fee collected by the board under section 43-15.3-12 to the drug importation program fund. All the moneys in the fund, not otherwise appropriated, are appropriated to the state ~~agency designated~~department of health to implement and operate the wholesale prescription drug importation program under this chapter for the purpose of administering the program.

SECTION 3. AMENDMENT. Section 43-15.3-12 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-12. Fees.

The board shall charge and collect the ~~following~~ fees under this chapter as follows:

Chain drug warehouse	$200
Chain pharmacy warehouse	$200
Durable medical equipment distributor, medical gas distributor, or both	$200
Durable medical equipment retailer, medical gas retailer and distributor, or both	$300
Hospital offsite warehouse	$200
Jobber or broker	~~$400~~Not to exceed $1,000
Manufacturer	~~$400~~Not to exceed $1,000
Medical gas retailer, durable medical equipment retailer, or both	$200
Medical gas durable medical equipment distributor and retailer	$300
Outsourcing facility	$200
Own label distributor	~~$400~~Not to exceed $1,000
Pharmacy distributor	$200
Private label distributor	~~$400~~Not to exceed $1,000
Repackager	~~$400~~Not to exceed $1,000
Reverse distributor	$200
Third-party logistic provider	~~$400~~Not to exceed $1,000
Veterinary-only distributor	$200
Virtual manufacturer	$400
Virtual wholesaler or distributor	~~$400~~Not to exceed $1,000
Wholesaler or distributor	~~$400~~Not to exceed $1,000

SECTION 4. CONTINGENT EFFECTIVE DATE. ~~The state board of pharmacy shall submit a request to the United States department of health and human services for approval and certification of a wholesale prescription drug importation program created under section 2 of this Act. Section 2 of this~~This Act becomes effective six months following the date the ~~president of the~~ state ~~board of pharmacy~~department of health certifies to the legislative council the receipt of ~~approval and certification of the state's~~a contract with another state for the implementation of a wholesale prescription drug importation program ~~from the United States department of health and human services~~.

Consulate General of Canada | Consulat général du Canada

701 Fourth Avenue South, Suite 900
Minneapolis, Minnesota 55415-1899

January 26, 2021

Senator Howard C. Anderson
2107 Seventh Street NW
Turtle Lake, North Dakota 58575-9667
Sent via email to hcanderson@nd.gov

Dear Senator Anderson,

I am reaching out to you regarding two bills you recently introduced, SD 2209 and 2212. The design of a wholesale prescription drug importation program from Canada into North Dakota is of significant concern to Canada.

On both sides of the border, Canadians and Americans alike worry about the rising costs of prescription drugs. In fact, Canada's drug prices are now the third highest among Organization for Economic Co-operation and Development (OECD) countries – or about 25% above the OECD median. In recent years, drug spending has accounted for an increasingly large proportion of expenditures in the Canadian health care system, growing faster than any other component of health care. Expenditures on drugs have surpassed spending on physician remuneration to become the second largest cost in the health care system, after hospitals.

As North Dakota considers policy options to lower the cost of prescription drugs, including taking steps to allow drug imports from Canada, it is important to recognize that the Canadian market, while safe and secure, is too small to make a real impact on U.S. drug prices. To put this in perspective, the U.S. consumes 44% of the global prescription drug supply, compared to Canada's 2%. One U.S. study published in 2019 predicted that if 40% of U.S. prescriptions were filled using Canadian prescription-drug sources, the Canadian drug supply would be exhausted in 118 days. As a result, Canadian stakeholders, including healthcare practitioners, patients, pharmacists and industry, have expressed their concerns about the potential impact on Canada's supply of prescription drugs, and on Canadians themselves.

Attached to this letter, you will find a copy of the comments from the Government of Canada to the United States on the proposed FDA rule "*Importation of Prescription Drugs"*, the final version of which was published by the U.S. on October 1, 2020. Following its examination of the U.S. rule, the Government of Canada determined that bulk importation by the U.S. of prescription drugs would worsen drug shortages in Canada, putting the health of Canadians at risk. The Government of Canada's priority is to ensure that Canadians have reliable and steady access to a safe, effective and affordable drug supply. Wholesale importation programs could

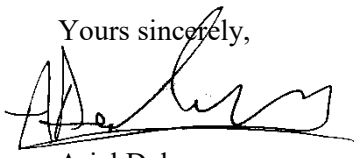
endanger the health and safety of Canadians by threatening the supply of prescription drugs. Accordingly, on November 24, 2020, the Minister of Health of Canada made an *Interim Order Respecting Drug Shortages* to allow the prohibition of exports if it this would cause or exacerbate a critical drug shortage in Canada.

In terms of pharmaceutical medicines, Canada is a price setter rather than a price taker. Canada's Patented Medicine Prices Review Board (PMPRB) sets introductory ceiling prices for brand-name drugs. It also limits the amount by which the makers of patented drugs can raise their prices every year. The maximum allowable price is determined in Canada by looking at the price of the same drug in other countries, the price of other similar drugs, or a combination of both.

Another body, the pan-Canadian Pharmaceutical Alliance (pCPA) conducts joint provincial/territorial/federal negotiations for brand name and generic drugs in Canada to achieve greater value for publicly funded drug programs and patients using the combined negotiating power of participating jurisdictions. Between 2013 and 2017, agreements reached by the pCPA have resulted in substantial savings.

I urge the North Dakota Legislative Assembly to re-examine SB 2209 and 2212 with a view to the development of domestic solutions that are more in line with those employed by other industrialised countries, including Canada. We would be happy to share with you and other legislators how we are working to address high drug prices in Canada, and connect you to relevant officials in this regard.

Yours sincerely,



Ariel Delouya
Consul General

Government of Canada
Embassy of Canada

Gouvernement du Canada
Ambassade du Canada

GOVERNMENT OF CANADA COMMENTS ON THE PROPOSED RULE 'IMPORTATION OF PRESCRIPTION DRUGS' (DOCKET NO. FDA-2019-N-5711)

INTRODUCTION

The Government of Canada welcomes the opportunity to provide comments on the Food and Drug Administration Proposed Rule on 'Importation of Prescription Drugs' (Docket No. FDA-2019-N-5711), identified as Pathway 1 in the *Safe Importation Action Plan*.

Rising drug prices and growth in the number of high-cost medicines now available on the market is a challenge faced by all governments. In response, Canada has put in place a number of domestic measures to address increasing drug prices. Ensuring that Canadians have secure and affordable access to the medicines they need is a top priority of the Government of Canada.

The proposed rule would not provide an effective solution to the problem of high drug prices in the U.S. Canada's drug market is too small to meet American consumer demand for prescription drugs or have an impact on high drug prices. Implementation of the proposed rule could exacerbate drug shortages in Canada, putting the health of Canadians at risk.

Canada will employ all necessary measures to safeguard its drug supply and preserve access for Canadians to needed drugs.

CHALLENGES OF DRUG PRICING

Pharmaceutical spending is increasing worldwide

Global pharmaceutical spending has risen consistently over the past two decades. Drug spending per capita in the U.S. and Canada has more than doubled between 2000 and 2020. According to February 2020 OECD data on pharmaceutical spending, drug expenditures represent 12% of American and 17% of Canadian total health care spending. Spending on drugs is projected to continue to rise in both countries.

High drug prices limit the affordability of drugs to the population. Patients who are unable to afford their drugs might not fill prescriptions, ration their drugs, or use less effective, but cheaper treatment alternatives. These behaviours can lead to health consequences that further burden the health care system.

Governments around the world employ a number of domestic strategies to improve drug affordability and access for their populations. Some successful strategies include:

- *International price referencing* – setting prices by considering the price of a similar medicine in a defined basket of countries.

- *Internal price referencing* – setting prices by comparing the medicine's price against others in the same therapeutic class.
- *Negotiating bulk discounts* – using the government's purchasing power to achieve lower prices.
- *Competitive bidding* – such as tendering.
- *Value-based pricing* – setting prices by taking into account both the value of a new medicine to medical advancement and its cost effectiveness in comparison with existing treatments.

Canada uses a combination of strategies to manage drug prices

Canada uses a comprehensive approach to manage drug pricing and improve the affordability of prescription drugs. The Patented Medicine Prices Review Board (PMPRB) protects Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. Under the PMPRB's current regulatory framework, the price of a patented medicine sold in Canada is assessed against the price of the same medicine sold in other countries, or the Canadian price of similar medicines in the same therapeutic class, to determine the medicine's non-excessive price ceiling.

Additionally, the pan-Canadian Pharmaceutical Alliance (pCPA) combines the collective buying power of federal, provincial and territorial governments to negotiate lower prices on brand name drugs and set price limits for generic drugs for Canada's public drug plans. As of April 1, 2019, the pCPA was estimated to have saved approximately $2.3 billion Canadian dollars annually for public drug plans, an amount equivalent to approximately 15% of total annual public drug plan spending in Canada.

Provincial and territorial governments can also control the prices of medicines reimbursed in their jurisdictions through other statutory, legal, or policy tools, such as restricting price increases.

IMPACT OF THE PROPOSED RULE ON CANADA

The implementation of the proposed rule could adversely affect the health of Canadians. The U.S. importation of prescription drugs intended for use by Canadians will cause pressure on the Canadian drug supply, exacerbating drug shortages and limiting access to needed medicines in Canada. Canada has seen a high volume of drug shortages, with 10-15% of Canadian drugs in shortage at any time in the past three years. Any increase in the occurrence and/or severity of drug shortages will have negative health impacts for Canadians.

The Canadian drug market and manufacturing capacity are too small to meet the demands of both Canadian and American consumers for prescription drugs. In 2017, Canada accounted for only 2% of global drug sales, compared to 44% in the U.S. In addition, Canada imports 68% of its drugs in their final dosage form.

Ensuring that Canadians have access to the prescription drugs they need is, and will continue to be a top priority for the Government of Canada. Canada will employ all necessary measures to safeguard its drug supply and preserve access for Canadians to needed prescription drugs.

CONCLUSION

Canada opposes the proposed rule, identified as Pathway 1 in the *Safe Importation Action Plan*, 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.

There are other domestic measures that would be more effective for the U.S to achieve its objective. Canadian officials would be pleased to meet with U.S. counterparts to share information on Canada's approach to ensuring that Canadians have access to the safe and affordable drugs they need.

2021 HOUSE HUMAN SERVICES

SB 2209

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2209
3/9/2021

Relating to increased access to low-cost prescription drugs; relating to drug wholesaler fees; to provide for a report; to provide a continuing appropriation; to provide for a transfer; and to provide a contingent effective date

Chairman Weisz opened the committee hearing at 9:30 a.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	A
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Board of Pharmacy responsibility
- Licensure fees
- Wholesale drug importation program

Sen. Howard Anderson, District 8 (9:30) introduced the bill and submitted testimony #8098.

Janelle Moos, Associate State Director-Advocacy AARP North Dakota (9:41) testified in favor and submitted testimony #8038, #8039 & #8040.

Shabbir Safdar, Executive Director Partnership for Safe Medicines (9:54) testified in opposition and submitted testimony #7944, #7945 & #9856.

Peter Fjelstad, Senior Director Public Policy PhRMA (10:01) testified in opposition and submitted testimony #8140, #8141, #8142, #8143 & #8144.

Leah Lindahl, Senior Director State Government Affairs Healthcare Distribution Alliance (10:06) testified in opposition and submitted testimony #8107 & #8108.

John Hoke, Director State Government Affairs Biotechnology Innovation Organization (10:11) testified in opposition and submitted testimony #7981.

Don Bell, Partnership for Safe Medicines (10:17) testified in opposition and submitted testimony #7984.

Mark Hardy, North Dakota Board of Pharmacy (10:21) testified neutral and submitted testimony #8058.

Additional written testimony: #7776, #7971, #8027 & #8036

Chairman Weisz adjourned at 10:24 a.m.

Tamara Krause, Committee Clerk

Senate Bill 2209

Testimony of Senator Howard C. Anderson Jr. of District 8

Chairman Weisz and members of the House Human Services Committee. This bill is also about getting access to lower prescription drug prices for the North Dakotans.

This bill still contains all the safety requirements required by the Federal rules promulgated in December 2020. Drugs must be approved by Health Canada, repackaged, relabeled, tested for quality and potency assigned a new National Drug Code (NDC) number and followed by the newest track and trace technology through the system to the final user.

This bill puts the responsibility on the Board of Pharmacy where the ability exists, with your approval, to increase licensure fees on drug manufacturers to pay for the program to import their drugs.

Most of us inherently perceive the prices for the things we buy are too high and the prices for the things we sell are too low. Prescription drugs are no different. Some of these drugs are lifesaving and we need them very badly.

Others will speak to the prices they pay for medications and the experience they have had with the same, or very similar (a conciliation to the manufacturers) medications purchased in Canada.

Manufacturers of prescription drugs do not like these bills. They say, “we are a free market country and we should be able to charge what we want to charge”. OK, then let them explain to us and the American people why they should charge us more than those across our borders. We let them advertise on television, create a market for their product, and then tell our insurance companies and Medicaid what they will charge. The patient has very little ability to shop for the best price.

The pharmacy is stuck in the middle. They are trying to serve their patient while the Government or the insurance company, perhaps through their Pharmacy Benefit Manager establishing the Maximum Allowable Cost for the drug and setting the fee the pharmacy can charge.

Way back in 2003 our then Senator Dorgan got the current law set in USC 804 allowing importation of drugs from Canada. No administration ever implemented it until in December 2020 rules were promulgated and this bill was drafted to take advantage of those rules.

This idea was developed as a model bill by the Nation Academy of State Health Policy with input from the American Association of Retired Persons and others.

Some will say, “why Canada”? Well there are many countries with lower prescription prices than the United States. But we like Canada, particularly here in North Dakota. They are our neighbors. If we go to Canada or know Canadians, we are comfortable they get good drugs and have good health care. When a drug is approved by Health Canada, we are as comfortable with it as one approved by our own Food and Drug Administration.

Most of us have never heard a good explanation of why the same drug a few miles across the border sells for 40%, 30% or even sometimes 20% of the price for the same drug in North Dakota.

Other states have adopted this approach and when they get the kinks worked out and their program approved by Health and Human Services at the Federal level this bill will allow us to join the other state and work together to bring savings to North Dakota.

Now Canada may not be happy with us importing from them and using up their drug supply. The market usually flows to where the business is so I think they will solve that over time. There is a risk, if we are successful, prices might rise north of the border. They might also go down here.

Thank you,

Howard

House Human Services Committee
SB 2209
Prescription Drug Cost Importation
March 9, 2021
Janelle Moos, AARP North Dakota
jmoos@aarp.org – (701) 355-3641

Chair Weisz and members of the House Human Services Committee,

My name is Janelle Moos, Associate State Director of Advocacy for AARP North Dakota. I appreciate your time today and look forward to working with you on an issue that is crucial to our members and one we are already seeing that they are passionate about.

Before I get into the reasons we are working so hard to fight the high cost of prescription drug prices I'd like to spend just a moment reminding you who we are and why we are here. AARP is a nonpartisan, nonprofit, nationwide organization with nearly 38 million members. 84,000 of those members live in North Dakota – a staggering number when you consider the overall population of our state.

Our story dates back 60 years, to when our founder, Dr. Ethel Percy Andrus found a former colleague of hers living in a chicken coop. I know we talk about that often, but we think it says a lot about why we fight for what we do. A lot of issues touch older Americans and their ability to live safe, independent and healthy lives. Most of our work fits into three areas; helping people choose where they live, remain financially secure and access affordable health care.

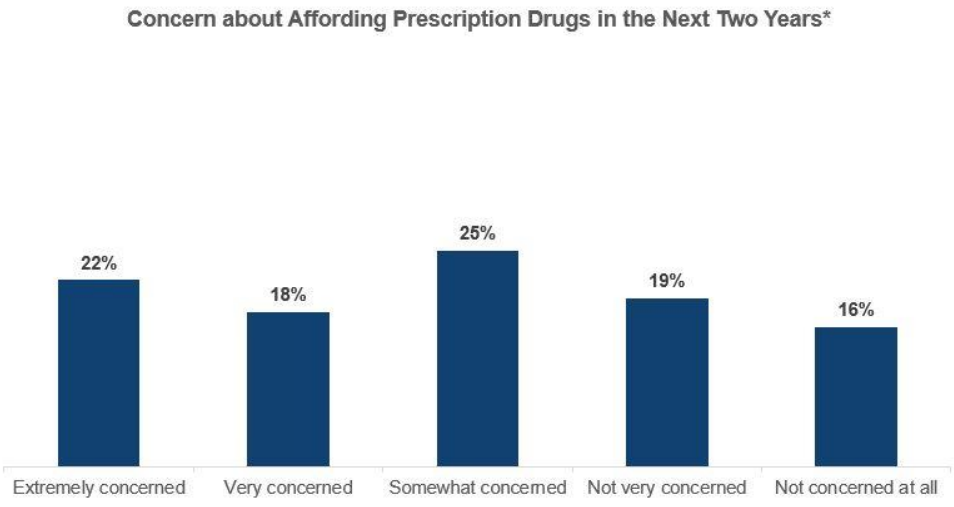
The rising cost of prescription drugs hits our members, and frankly all North Dakotans, in all three areas. It's a high priority for us, not only at the state level, but at the federal level as well. Let me outline just a couple of the reasons why.

The average older American takes 4.5 prescription drugs on a chronic basis. The average annual cost of prescription drug treatment increased 57.8% between 2012 and 2017, while the annual income for North Dakotans only increased 6.7%.

The high cost of prescription drugs doesn't just impact Medicare beneficiaries it impacts all North Dakotans, especially those age 50 and older. In AARP's 2020 survey of North Dakota adults, almost 1 in 4 individuals did not fill a prescription they were prescribed in the last two years. Of those who didn't fill a prescription, 44% of respondents said they had decided not to fill a prescription that their doctor had given them because of the **cost** of the drug. Further, 65% of them are at least somewhat concerned about being able to afford prescription drugs.

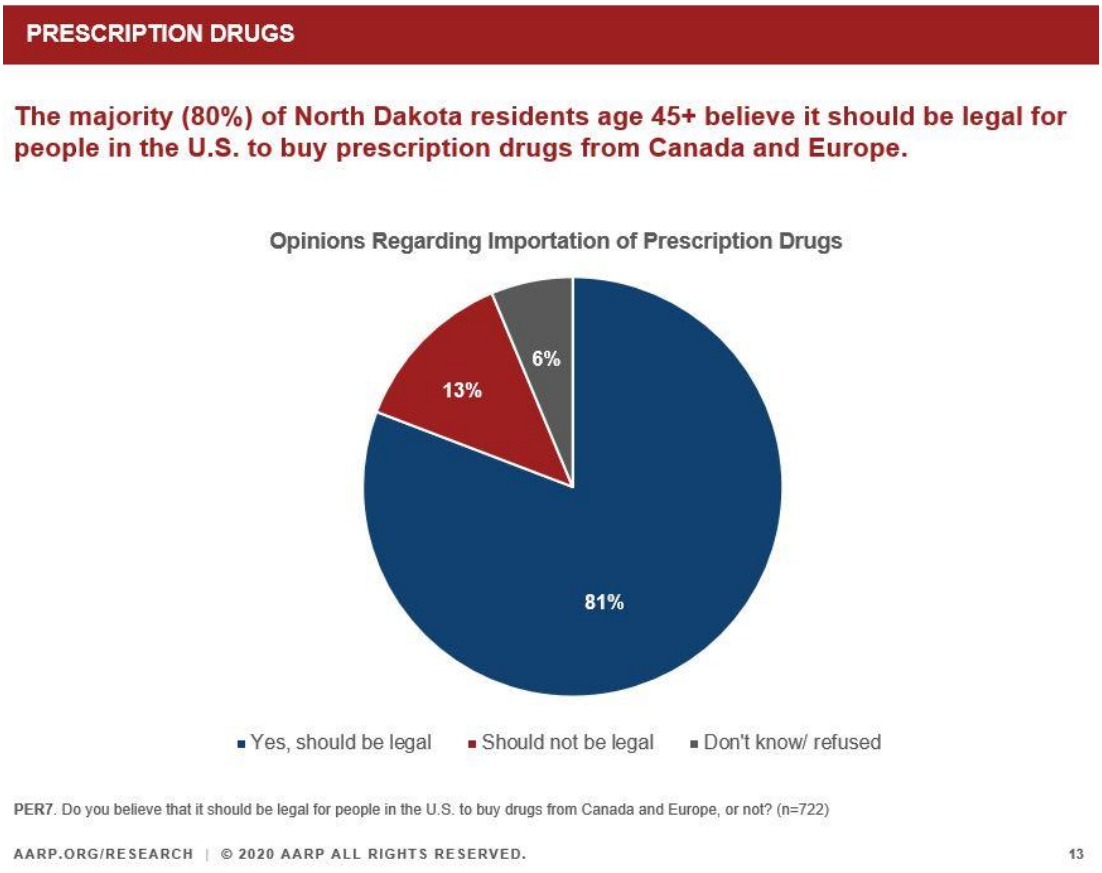
PRESCRIPTION DRUGS

Nearly two-thirds (65%) of North Dakota residents age 45+ are at least somewhat concerned about being able to afford prescription drugs over the next two years.



PER5. How concerned are you about being able to afford the cost of needed prescription drugs over the next two years? (n=722)
*Not equal to one-hundred percent due to removal of small cells; see annotation for all categories

Finally, 81% believe it should be legal for people in the U.S. to buy drugs from Canada.



Attached are two handouts along with my testimony, so you can get a good feel for why North Dakotans often have to make that crushing choice between buying medicine or buying food for themselves or their family. Near the top of the page are three common illnesses in North Dakota – cancer, diabetes and heart disease – with the number of residents of our state who have been diagnosed. More than 60,000 with cancer and nearly as many with diabetes. Below those numbers are common drugs used to treat them and their costs from 2017. Please, take note that we've included what those same drugs cost just five years earlier. **One nearly doubled, another jumped $100,000!**

Now, please take a look at the second fact sheet I included (the yellow one with the circle in the middle). It shows the average annual cost of prescription drug treatment soared more than 57 percent between 2012 and 2017. But, now, look at income. The average income in North Dakota increased just 6.7 percent. It's no wonder people are concerned.

And finally, on our Facebook page you can see some videos of North Dakotans facing these costs. There is one from Pat who told us a drug she took 10 years ago was $60. Now she pays $600! And Roger, who you will hear from today, who has found a way to import the leukemia drug he needs from Canada, saw the price of his medicine jump from 10 bucks to 24-hundred bucks in a month! Why? Because he moved from his great PERS plan to Medicare.

Prescription drug wholesale importation programs, like the one outlined in SB 2209- which would be administered by the State Board of Pharmacy- is one approach that states are considering trying to relieve consumer's financial burdens as it relates to prescription drugs.

I'd like to walk you through some of the common questions you may have heard related to wholesale prescription drug importation programs. I've included a copy of this handout along with the citations for the data and studies I will be referring to.

So, what is wholesale importation? And how is it different that personal or individual importation?

The majority of proposals moving through state legislatures intend to establish importation programs for the state to administer. This is different from personal importation, whereby an individual buys drugs directly from a pharmacy in another country. Personal importation is already allowed by the FDA under certain circumstances. A state-administered wholesale Canadian drug importation program can assure product safety, potency, and purity, as well as consumer cost savings.

Why are we focused on Canada?

The primary reason is that the safety, development and approval standards for prescription drugs in Canada are similar to standards to the U.S. Both the U.S. and Canada have strong clinical trial structure, data and reporting requirements, and post approval measures. And U.S. standards for manufacturing and handling of prescription drugs are similar to those of Canada and the two countries have a long-standing reciprocity agreement for sharing information about manufacturing and compliance.

Has the federal government outlined a process for wholesale importation?

Under the Federal Food, Drug, and Cosmetic Act, the U.S. Secretary of Health and Human Services has the authority to allow for the importation of certain drugs if safety and consumer savings can be assured. The Federal government drew on this authority when it published a final rule on importation in September 2020. The Final rule provided some broad parameters for a state importation program. A state may only import drugs that are currently marketed in the U.S. and approved by Health Canada, and, other than the labeling, meet the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA).

Under this rule, a state-administered wholesale drug importation program could be structured in a variety of ways and could:

• Be available to all state residents or just people covered under state payer programs (such as Medicaid, state employees, or prisons);
• Include all state-licensed payers, distributors, and dispensers, or just a subgroup; and
• Include many drugs or just a small number of products.

Again, the program outlined in SB 2209, would not be a program of personal importation, but instead the state itself would contract with a fully licensed,

regulated supplier from Canada or another country that is required to provide only drugs that are fully regulated and compliant with that country's laws.

Several other states have considered similar legislation including Vermont, in 2018, three other states (Florida, Colorado and Maine) in 2019, and last year New Mexico and New Hampshire passed laws. Similar bills have been introduced in another 21 states across the country.

It is no secret that the US pays the highest prices for prescription drugs in the world. By importing equally safe, less expensive drugs, North Dakota can anticipate reducing our overall expenditures on drugs and, depending on how the state program is structured, can pass on those savings on to North Dakotans who are impacted by the program. Establishing an importation program may take time but fiscal analyses estimate significant savings for the state and consumer. AARP believes that such efforts should be implemented in conjunction with other policy changes that will help reduce prescription drug prices.

Doesn't importation put research and development at risk?

Big Pharma currently spends nearly 80% on something other than research and development and there is tremendous crossover among the manufactures selling drugs in Canada and the US. Currently, there is more than 30 Canadian drug manufacturers are FDA-registered to produce drugs for US markets.

Thank you again for your thoughtful work on this issue. We wholeheartedly appreciate any effort to make medicine more affordable. North Dakota should not sit on the sideline. We should be taking action to help consumers afford their medicines. This bill is a step to do so and we look forward to working with you to make it the best possible bill for North Dakotans.

#8039

Will States Save by Importing Drugs from Canada? Yes, Here's How

States can control profit margins and make sure savings are passed on to payers and consumers:

A state can limit imported drug mark-ups and profit margins of suppliers, wholesalers, and distributors.

The state can limit what wholesalers and distributors charge for their administrative services.

Pharmacies and other dispensers must charge payers the Canadian price without any mark-up.

Pharmacies must charge uninsured people or those in their deductible period the Canadian price without any mark-up.

Health plans and other payers pay only the Canadian price without mark-up.

The state audits the program regularly to ensure consumers and payers benefit financially.

Drug Product	Price in the US* **	Price in Canada*** (in USD)
Advair-Diskus (100 mg capsule) GSK	$9.52	$3.96
Eliquis (5 mg tablet) Bristol-Myers Squibb	$6.21	$1.60
Harvoni (90/400 mg tablet) Gilead Sciences	$1,090.35	$797.62
Lyrica (25 mg capsule) Pfizer	$6.04	$0.63
Strattera (100 mg tablet) Eli Lilly	$14.81	$3.96
Tecfidera (120 mg capsule) Biogen	$119.24	$11.92
Tracleer (125 mg tablet) Actelion Pharmaceuticals Ltd.	$173.09	$47.18
Triumeq (300 mg tablet) ViiV Healthcare	$83.36	$31.51
Xarelto (15 mg tablet) Janssen Inc.	$12.44	$2.11

NASHP NATIONAL ACADEMY FOR STATE HEALTH POLICY

Center for State Rx Drug Pricing

*Centers for Medicare and Medicaid Services. Medicaid.gov. National Average Drug Acquisition Cost. Accessed online May 22, 2017 at https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html

**Drugs.com. Accessed online at https://www.drugs.com/

***Government of Saskatchewan. Saskatchewan Online Formulary Database. Accessed online May 22, 2017 at http://formulary.drugplan.ehealthsask.ca/

#8040

Is It Safe for States to Import Drugs from Canada? Yes, Here's Why

Drug manufacturing is already global.

- 80% of active ingredients used in the manufacture of drugs in the US are imported.
- 40% of prescription drugs sold in the US are produced abroad.*

Safety standards are comparable: Federal regulations already ensure the safety of foreign-produced drugs entering the US market.

- More than 30 Canadian drug manufacturers are FDA-registered to produce drugs for US markets.**
- EU regulatory inspections of drug manufacturing facilities in Europe meet US safety standards.***

Wholesale drug importation from Canada allows states to access a less expensive global drug market.

A licensed wholesaler can help a state implement a wholesale importation program to ensure product safety

- Manufacturers
- Wholesalers
- Pharmacies and Hospitals

NASHP NATIONAL ACADEMY FOR STATE HEALTH POLICY

Center for State Rx Drug Pricing

*FDA Commissioner Margaret Hamburg, "The Safety of Prescription Drugs Made Outside the U.S.", The Diane Rehm Show (Feb. 20, 2014). Transcript accessed Sept. 7, 2017. https://dianerehm.org/shows/2014-02-20/safety-prescription-drugs-made-outside-us.

**US Food and Drug Administration Database, "Drug Establishments Current Registration Site", Accessed Sept. 7, 2017. https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

***FDA press release, "Mutual Recognition promises new framework for pharmaceutical inspections for United States and European Union", (Mar. 2, 2017). Accessed Sept. 7, 2017. https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm544357.htm

Testimony of Shabbir Imber Safdar
Executive Director, Partnership for Safe Medicines
March 9, 2021 - SB 2209/2212 (Opposed)

I am testifying to explain my concerns with and opposition to SB 2209 and SB 2212 which implement and study Canadian drug importation. I am Shabbir Imber Safdar, the Executive Director of the Partnership for Safe Medicines, a seventeen-year-old not-for-profit that accepts no corporate members or donations. Our members are other nonprofits and trade associations that represent manufacturers, wholesalers, pharmacists, and patients—everyone that touches medicine from the factory floor to the patient.

I believe both bills should be combined because it doesn't make sense to study something you're implementing, but ultimately the idea is simply not safe or implementable.

Both bills are about trying to reduce prices of medicine by implementing bulk imports of Canadian medicine. The goal here is laudable: everyone wants to address healthcare costs. But the time and money we spend on proposals like this stalls more practical solutions.

Here's the problems with Canadian drug importation. For a more thorough explanation please see my written testimony.

Canada has no track and trace system
Canada doesn't have a track and trace system, so any medicine bought, even from a licensed Canadian wholesaler is not as secure as what we have in America. If you were today to go to Canadian law enforcement and ask them to trace who has handled a medicine, they could not tell you.

In the US, even though Track and Trace is not fully implemented, HHS has shown that they in many cases are able to identify every handler of medicine from the factory floor to a dispenser.

It isn't a bargain to get a cheaper medicine that you have to worry about whether its real. That's not a bargain. Nobody deserves medicine which they have to wonder is safe.

I have heard some people say that this is safer than people buying over the internet. It is definitely not safe to buy over the internet. But experts from the American Pharmacists Association to the National Association of Boards of Pharmacy to the National Sheriffs Association all agree that these schemes to buy medicine from Canada are not safe.

Canada has prohibited this practice
Canada doesn't make most of its own medicine and has enormous drug shortages. Therefore, late last year, the Canadian federal government put in place a ban on exporting medicine. Canadian pharmacists, wholesalers, and patients have all stated they are opposed to Americans taking their medication. In fact a representative of the Canadian hospital pharmacists testified to the North Dakota Senate that they were vehemently opposed to this legislation and would do everything possible to stop it.

Testimony of Shabbir Imber Safdar
Executive Director, Partnership for Safe Medicines
March 9, 2021 - SB 2209/2212 (Opposed)

The goal of reducing the cost of medication is one everyone shares. And there are ways other states have found to do it. For one, increasing generic utilization has been a big win for many states. Also, lots of states are finding that PBMs have been taking a lot of money out of the pockets of patients and state run health programs. West Virginia saved $54mm by removing their PBM from the state Medicaid program.

The money spent on this program will go to develop something that can never be implemented because of the objections of the Canadians and the safety issues. I urge you to focus on these other ideas that have actually provably shown savings.

Testimony of Shabbir Imber Safdar
Executive Director, Partnership for Safe Medicines
March 9, 2021 - SB 2209/2212 (Opposed)

I am testifying to explain my concerns with and opposition to SB 2209 and SB 2212 which study and implement Canadian drug importation. I am Shabbir Imber Safdar, the Executive Director of the Partnership for Safe Medicines, a seventeen-year-old not-for-profit that accepts no corporate members or donations. Our members are other nonprofits and trade associations that represent manufacturers, wholesalers, pharmacists, and patients—everyone that touches medicine from the factory floor to the patient.

I believe both bills should be combined because it doesn't make sense to study something you're implementing, but ultimately the idea is simply not going to work out.

SB 2209/2212 proposes to implement bulk importation of prescription medicines imported from Canada under Sec. 804 of the U.S. Food, Drug, and Cosmetics Act. Importing such medicines will put patients at risk, cost the state money to run a program that is likely to never recoup it's costs, and never be implemented over the objection of the Canadian government. Below we outline the many reasons why this proposal is unsafe and unworkable.

Canada Promises to Protect Its Limited Drug Supply

Any state looking to import prescription drugs from within the Canadian drug supply chain would need Canada to be a willing participant, which it has never been. Last year, as the Trump Administration finalized regulations to govern programs such as this, Canada imposed an order in November 2020 banning the export of prescription drugs that would cause or exacerbate drug shortages in that country.[1] There is nothing in the federal regulations or this bill that could overcome the opposition of Canada's regulators who have threatened to revoke the licenses of wholesalers who do not comply.

Drug Importation Breaks Track-and-Trace

Given that Canada has not implemented a track-and-trace system for any medical products, any drug importation plan would automatically be breaking track-and-trace. Simply slapping an identifier onto a bottle when it enters the country only gives you information as far back as that. The state would just need to trust everyone else earlier in the supply chain that the medication is what they say it is, it has been handled properly.

The proposed law requires track-and-trace compliance for any medical products before the medicine enters the state. However, there is no Track-and-Trace system in Canada to rely upon, and Canadian entities cannot be categorized as Trusted Trading Partners under the DSCSA because they do not possess state-issued wholesaler or pharmacy licenses.

[1] Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply), Government of Canada, November 27, 2020.

Testimony of Shabbir Imber Safdar
Executive Director, Partnership for Safe Medicines
March 9, 2021 - SB 2209/2212 (Opposed)

Canada Has and Continues to Experience Crippling Drug Shortages

As of January 16, 2021, Canada has over 1,500 drugs listed as currently being in shortage.[2] A report found that between 2017 and 2018, nearly 25 percent of medications in Canada were in shortage.[3] A national survey released in 2018 by the Canadian Pharmacists Association found that one in four Canadians had either personally experienced or knew someone who had experienced a drug shortage in the past three years.[4] The COVID-19 pandemic has worsened the prescription drug situation in Canada.[5]

Canada has said clearly that they will not participate in U.S. drug importation programs because it will worsen these shortages.

Negotiated Drug Prices by Canada Are Not Transferable

While Canada does have universal healthcare coverage that includes medications when administered in the hospital setting, the same is not true for any prescription drugs taken outside of a hospital.[6] Much like in the U.S., most Canadians have prescription drug coverage through a patchwork of public and/or private insurance plans. Canada's Patented Medicines Prices Review Board sets prices to ensure that brand-name medication is not priced excessively, but those prices are for Canadian citizens.[7] There is nothing that can compel any Canadian wholesaler to give those same discounted prices to a U.S. state looking to import prescription drugs from Canada. This fact was one of the items listed in Deloitte's June 30, 2020 memo to the state's Employee Benefits Programs Committee as the committee was debating this bill.[8]

Canadian Drug Importation Is Not a Sustainable Solution

In the same memo, Deloitte stated that North Dakota would see "little if any potential savings" because of Canada's limited drug supply and the price equalization that would follow even a small percentage of prescription drugs being exported to the U.S.[9] Wyoming's Department of Health (WY-DOH) came to the same conclusion. In a report released last year, the WY-DOH stated that the concept of sustained savings via the importation of Canadian drugs has a

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[2] Summary Report, Drug Shortages Canada, January 16, 2021.
[3] "Nearly a Quarter of Drugs Marketed in Canada Reported Shortages: Study," *CTV News*, September 1, 2020.
[4] "One in Four Canadians Touched by Drug Shortage in Last 3 Years," Canadian Pharmacists Association.
[5] Brooklyn Neustaeter, "Drug Shortages Could 'Imperil the Lives' of Canadians, Doctors Warn Ottawa," *CTV News*, August 13, 2020.
[6] Prescription Drug Insurance Coverage, Government of Canada, last modified December 3, 2020.
[7] Patented Medicines Prices Review Board, Government of Canada.
[8] Acturial Review of Proposed Bill 21.0068.01000, Deloitte, June 30, 2020.
[9] Idib.

fundamental economic flaw: it relies on a form of arbitrage.[10] Savings found in the exploitation of price differences are fleeting and generally cause the prices to converge, eliminating any savings.

Any Canadian Vendor Would Be Operating in a Legal Grey Area

Health Canada regulates Canadian wholesalers and pharmacies that distribute medications to Canadian citizens, and going back as far as 2004 it has said Health Canada "does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future."[11] However, the U.S. Food and Drug Administration has limited to zero say over Canadian pharmacies and wholesalers. Any state doing business with a Canadian vendor would be making a leap of faith, and that leap has not worked out very well for other states that tried to do drug importation.

Regulating a Foreign Entity Will Be an Impossible Task

Despite no secretary of HHS previously allowing a state to try a drug importation plan, states have tried and they have failed. Minnesota tried to make Canadian drug importation work for seven years. The program, RxConnect, started with a bang in 2003 and ended with a whimper in 2010.[12] Although the state envisioned tens of thousands of residents consistently using the program, in the month before the program was shuttered only 57 prescriptions were filled. Lack of participation was not the only issue the program had. In a February 2004 letter from the FDA, multiple patient safety issues were raised about the pharmacies that the state had contracted with to fill prescriptions. Some of the cited issues included **pharmacists needing to verify more prescriptions within an hour than humanly possible, a pharmacy that failed to label any prescription bottles, the failure to properly store temperature-sensitive medications, and one pharmacy re-dispensing medication that had been prevented from entering the country**, just to name a few.[13]

While Maine is currently attempting to run a state-sponsored drug importation program, the state did allow a personal drug importation program beginning in 2013. Long before a federal judge ruled that the law was in violation of federal law, counterfeit and substandard medicine was being illegally shipped into the state.[14] The former head of the Maine Pharmacy Association filed a lawsuit after testing of drugs he purchased showed that all of the drugs did not have

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[10] "Precription Drug Costs in Wyoming," Wyoing Department of Health, October 1, 2020.
[11] Report on Prescription Drug Importation, Department of Health and Human Services, December 2004.
[12] "Minnesota's Experiment With Drug Importation: RxConnect 2003-2010," The Partnership for Safe Medicines, March 11, 2019.
[13] Letter to Governor Pawlenty, U.S. Food and Drug Administration, February 23, 2004.
[14] Jackie Farwell, "Judge Overturns Maine Law Allowing Prescription Drug Imports," *Bangor Daily News*, February 24, 2015.

enough active pharmaceutical ingredients and one of them had an unknown, potentially hazardous contaminate.[15] While Maine's law required the medications to be sourced from a limited set of countries, the medications received came from unapproved countries anyway (India, Mauritius, and Turkey.[16])

If a serious violation does occur, holding a Canadian vendor responsible will not be easy. Even if the case warrants the involvement of the U.S. Department of Justice, that does not mean that justice will be easy to achieve. For example, CanadaDrugs.com was indicted in November 2014 for selling $78 million worth of unapproved, mislabeled, and counterfeit cancer drugs to doctors across the U.S.[17] including North Dakota. The Canadian defendants spent years objecting to the case until a deal was brokered. In April 2018, the CEO of CanadaDrugs.com finally stood in a U.S. courtroom and admitted to the widespread illegal sale of misbranded and counterfeit drugs. [18] No one involved received even a one-day jail sentence. The fines and forfeiture came to just over $34 million.

Drug Importation Is a Danger to Pharmacists

New Mexico's submission to HHS showed multiple ways that participating in a drug importation program is a hazard to the pharmacists of any state.[19] Space is precious in any pharmacy, but all imported medications must be separated from the normal stock, leaving some pharmacies having to juggle two or three different stocks. New Mexico's law offered no protection should a dispensed drug imported by the state turn out to be counterfeit and a patient had an adverse medical event. Pharmacies also have contracts requiring a certain percentage of drugs to be purchased from a wholesaler. Imported drugs could put those agreements at risk of being voided.

Ultimately, New Mexico had to confess that they could not prevent middlemen from marking up any drugs they imported from Canada. This is one of the reasons Wyoming chose not to proceed with this plan.

Drug Importation Will Not Help Medicaid Beneficiaries

While wanting to help constituents lower their prescription drug costs is a laudable goal, drug importation will be of no benefit to the 11 percent of North Dakotans who are on Medicaid due to

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[15] "MYTH: 'We Are Getting the Same Drugs Canadians Take,'" The Partnership for Safe Medicines.
[16] Idib.
[17] Superseding Indictment, U.S. District Court, District of Montana, Butte Division, Case No. 2:14-cr-00027-DLC.
[18] "Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States," U.S. Department of Justice, April 13, 2018.
[19] "Section 804 Drug Importation Program Application," New Mexico Department Of Health, December 15, 2020.

the discounted prices that the state is already able to get for those citizens.[20] So if drug importation cannot help the neediest in the state, who can it help? Despite the negative experiences in its attempt to do personal drug importation, Maine is currently pursuing a Canadian drug importation plan. When MaineCare, Maine's version of Medicaid, examined to see if drug importation would be a benefit for those beneficiaries, the state's analysis showed the state would lose close to $1 million because of all of the rebates the program already receives.[21]

Drug Importation Will Not Help Most North Dakotans

Ninety percent of prescriptions are filled in the U.S. are filled with generic drugs, the vast majority of which costs less than $20.[22] Seventy-seven percent of the money that U.S. patients spend is on the ten percent of prescriptions that are filled with brand-name drugs. So North Dakota's potential pool for citizens that would benefit from drug importation would be limited to people for whom there is not an FDA-approved generic option.

The Costs of Federally-mandated Testing Will Eliminate All Savings

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that any drugs imported be statistically tested to ensure the safety of all imported medicines.[23] Dr. Kristina M.L. Acri née Lybecker examined if it was possible to test cheap drugs into safety, and she found that doing the required amount of testing quickly ate up all monies saved.[24] Dr. Acri also found that if a patient were to receive substandard or counterfeit medicine, a single adverse medical event could eliminate a drug importation program's savings anywhere from days to decades.[25]

Fiscal Impact Analysis

The theory that importing drugs from Canada will allow patients to see significant savings is just that: a theory. Many states looking into drug importation have applied a blanket 45% increase to the Canadian, but no state actually knows if this number is accurate. While no state has yet to operate an HHS-approved drug importation program, some have tried and there are lessons to be learned from them. Illinois operated a program called i-SaveRx in the mid-2000s. The Office

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[20] "Medicaid in North Dakota," Henry J. Kaiser Family Foundation, October 2019.
[21] "Maine's Medicaid Program Analysis Shows the Truth: Importing Medicine from Canada Would Cost More, Not Less," The Partnership for Safe Medicines, December 1, 2020.
[22] "2018 Generic Drug Access and Savings Report," Association for Accessible Medicines.
[23] Text: H.R.1 — 108th Congress (2003-2004), U.S. Congress, December 8, 2003.
[24] Dr. Kristina M.L. Acri nèe Lybecker, "State Pharmaceutical Importation Programmes: an Analysis of the Cost-effectiveness," Journal of Pharmaceutial Health Services Research, March 18, 2020.
[25] Idib.

of the Auditor General released a report in 2006 that showed the program was expensive for the state to run[26]:

- Twenty-eight agencies reported that 521 employees provided almost 5,600 hours of assistance at an estimated payroll cost of $488,000
- Illinois had significant expenditures on the program, including travel, contractual services, marketing, and legal services.

Additionally, no state discussion importation to date has actually addressed the cost of testing outlined above. Testing alone is sufficient to make most every importation program financially unworkable.

Colorado is one of the states currently pursuing a Canadian drug importation program. In March 2020, the state released a draft of its plan that included a list of potential drugs to import. PSM did an analysis and found that nearly one-third of the drugs on the list already had a generic version on the U.S. market and that the state could save over $43 million just by switching to the generic versions of those drugs.[27] Over a two-year period, Colorado budgeted $3 million of taxpayers' money to get its drug importation program up and running. The state has still not submitted its plan to HHS and no patient has saved even a single penny. Even Florida, with its $30 million contract, is struggling to find both a Canadian and a U.S. vendor.[28]

Drug Importation Will Weaken the Security of the Drug Supply Chain

The U.S. has one of the most secure drug supply chains in the world. Drug importation will only make it less secure, not more. In a 2017 report, former FBI director Louis Freeh warned that drug importation "would deplete and overburden already limited resources. In particular, importation proposals would force law enforcement agencies to make tough prioritization decisions that leave the safety of the U.S. prescription drug supply vulnerable to criminals seeking to harm patients."[29] North Dakota is not immune to this issue. Ten doctors received warning letters between 2012 and 2016 to stop purchasing medications from known black-market suppliers.[30]

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[26] "Report Digest Management Audit of the Flu Vaccine Procurement and the I-saverx Program," State of Illinois Office of the Auditor General, September 2006.
[27] "Analysis of Draft Colorado Importation Plan," The Partnership for Safe Medicines.
[28] Phil Galewitz, "Florida Fails to Attract Bidders for Canada Drug Importation Program," *Kaiser Health News*, October 26, 2020.
[29] "Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement," Freeh Group International Solutions, LLC.
[30] "The Deadly Counterfeit Drug Trade Thrives in North Dakota," The Partnership for Safe Medicines, April 2020.

Testimony of Shabbir Imber Safdar
Executive Director, Partnership for Safe Medicines
March 9, 2021 - SB 2209/2212 (Opposed)

There Are Other Safer Ways to Bring Down Prices.

There isn't an elected official today who doesn't hear from their constituents that health care costs are an issue, and pharmaceutical spending, which is less than 20% of overall healthcare spending, is certainly a piece of the problem. But states are finding other, safer ways to address these costs. California is aggregating its spending across different healthcare programs to achieve volume discounts. Louisiana has negotiated a "Netflix" subscription model, which will allow the state to treat hepatitis C at a fixed cost. West Virginia kicked their PBM out of their Medicaid program to use a pass thru entity and saved $52 million in their first year.

Canadian drug importation sounds like a good idea, but it will feed an existing black market in poorly regulated and counterfeit drugs. Rather than simply fail, the bill will create incentives for gray market wholesalers to ship counterfeit or substandard medicine into America that will be expensive to detect, and even more expensive for patients if we fail to detect it. North Dakota could help more people access healthcare by funding programs with less risk.

THE DEADLY COUNTERFEIT DRUG TRADE THRIVES IN NORTH DAKOTA

#9856

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

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

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

These pills are disguised as real medications but made with deadly fentanyl or its even deadlier variants, and even a fraction of a single pill can mean death in less than 30 minutes of ingesting it.

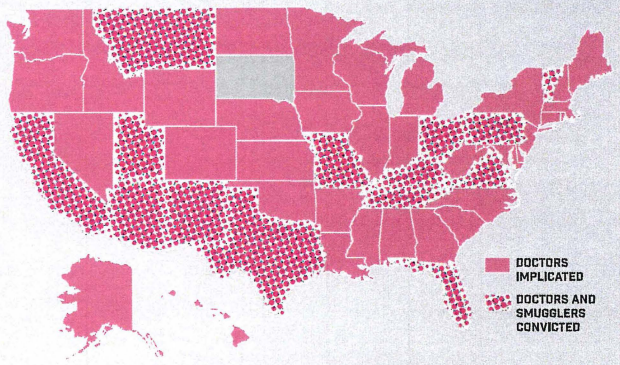
Fentanyl is a serious threat in North Dakota. Two North Dakotans suffered serious bodily harm after they ingested counterfeit pills made with fentanyl sold by a drug ring operating out of Texas. Between October 2017 and January 2018, five members of a drug ring that sold fake fentanyl pills in North Dakota and Minnesota each received prison sentences ranging from 24 to 65 months. One person in Grand Forks suffered a non-fatal overdose from a pill sold by this drug ring. In March 2020, another Grand Forks resident died after taking a fentanyl-laced counterfeit Xanax pill.

10 NORTH DAKOTA DOCTORS LINKED TO FAKE DRUG RINGS

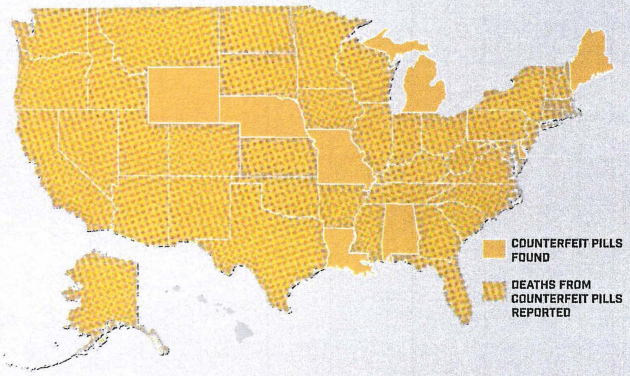
Counterfeit cancer drugs have touched North Dakota as well. 10 different medical practices in North Dakota have been implicated in various black market supply chains associated with counterfeit cancer treatments and other therapies. Families who have lost relatives to cancer will never know if their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

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

Fake Cancer Drug Crisis

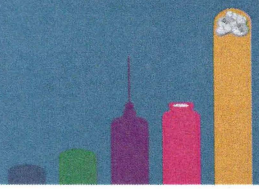


Fentanyl-Laced Counterfeits & Related Deaths



The Partnership for SAFEMEDICINES®

COUNTERFEIT AND BLACK MARKET DRUG INVESTIGATIONS IN NORTH DAKOTA (2012–2020)



BASED ON REPORTED INVESTIGATIONS.
NOTE THAT EACH INVESTIGATION COULD HAVE AFFECTED HUNDREDS OF NORTH DAKOTA RESIDENTS.

FENTANYL AND COUNTERFEIT PILLS MADE WITH FENTANYL

March 2020: A 24-year-old Grand Forks man died after he took a counterfeit Xanax made with fentanyl.[1]

October 2019: The leader of a Texas-based fake fentanyl pill drug ring received a 30-year sentence. Pills sold by this ring caused serious bodily injury to two residents of North Dakota.[2]

July 2019: Daniel Vivas Ceron pleaded guilty to operating an international drug trafficking ring while incarcerated in Canada from 2013 to 2017. The ring shipped several hundred pounds of fentanyl and fentanyl analogues across the U.S., causing 15 overdoses in North Dakota, Oregon, New Jersey, North Carolina, and Rhode Island, including four fatal overdoses, one of which was Grand Forks resident 18-year-old Bailey Henke.[3]

February 2019: The Jamestown Police Department reported seizing counterfeit oxycodone pills that contained fentanyl.[4]

June 2018: The U.S. Attorney's Office in Fargo indicted a Rhode Island man for his alleged role in a drug trafficking ring that distributed tens of thousands of counterfeit fentanyl pills throughout the U.S.[5]

October 2017: Chinese national Jian Zhang and eight other individuals were indicted in Fargo. Zhang faced multiple charges including Conspiracy to Possess with Intent to Distribute and Distribute Controlled Substances and Controlled Substance Analogues Resulting in Serious Bodily Injury and Death.[6] The U.S. Department of Justice issued a superseding indictment in April 2018, bringing the total number of defendants in this case to 28.[7]

August 2017: Police in Grand Forks issued a warning to members of the public after four people overdosed on fentanyl in just a few days.[8]

May 2017: The indictment of Aaron Shamo from Utah shows his fentanyl drug ring shipped 500 counterfeit pills into North Dakota.[9]

March 2017: The Narcotics Task Force seized hundreds of counterfeit oxycodone pills laced with fentanyl in Grand Forks and East Grand Forks.[10]

March 2017: Authorities arrested six residents of Grand Forks and East Grand Forks, Minnesota for fentanyl pill trafficking after fentanyl-laced oxycodone pills they sold caused a Grand Forks man to overdose.[11] Over the course of 2017 and 2018, six conspirators pleaded guilty in state or federal court and received sentences ranging from 24 to 65 months.[12]

BLACK MARKET AND COUNTERFEIT CANCER DRUGS

May 2013: The FDA warned 780 medical practices, two in North Dakota, to stop doing business with unlicensed drug seller Medical Device King, which had sold 31 non-FDA approved medications, including counterfeit Avastin.[13]

February–June 2012: Two North Dakota doctors were among the 136 nationwide that received warning letters indicating that they may have purchased counterfeit Avastin or Altzuan from Quality Specialty Products (QSP), a CanadaDrugs subsidiary.[14]

MISBRANDED AND COUNTERFEIT BOTOX

March 2016: The FDA warned 4 doctors and clinics in North Dakota 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.[15]

July 2013: The FDA warned four medical practices in North Dakota to stop purchasing fraudulent versions of Botox sold by Online Botox Pharmacy, Onlinebotox.com, and Onlinebotox.[16]

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FOOTNOTES

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THE AHIP PREMIUM DOLLAR: CORRECTED

America's Health Insurance Plans (AHIP) would have you believe that brand medicines are the primary driver of insurance premium costs. But AHIP's own data show that this simply isn't true. A recent AHIP infographic, "Where Does Your Premium Dollar Go?," gives the misleading impression that prescription medicines account for the largest share of insurance premiums. However, when you properly account for the share of spending that goes to brand biopharmaceutical companies vs. generic manufacturers and supply chain intermediaries, **brand medicines comprise just 10 cents of the premium dollar, or about half as much as what is spent on insurer administrative costs and profit.**[1,2]

Furthermore, by breaking hospital inpatient, hospital outpatient, and emergency room spending into separate categories, AHIP's original infographic obscures the fact that hospital spending is by far the largest contributor to insurance premium costs. Combined, hospital costs account for nearly half (48%) of the insurance premium dollar, about four times as much as brand medicines.

Both the original and corrected AHIP infographics also highlight an often overlooked fact about health care spending: **nearly 20 cents of every premium dollar is not spent on medical care, but instead goes towards administrative costs or is retained by the health plan as profit.**

[1] Berkeley Research Group. "The Pharmaceutical Supply Chain; Addendum," 2020. Available at: https://www.think-brg.com/insights/publications/the-pharmaceutical-supply-chain/

[2] This corrected infographic conservatively assumes that AHIP's original premium spending distribution was accurate. AHIP restricts its sample to patients younger than 65 years of age, who are younger and healthier than the population as a whole, and for whom spending on prescription medicines constitutes a proportionally higher percentage of total health expenditures. Spending captured in AHIP's premium dollar also excludes a significant share of health care spending, including long-term care and investments in public health. More comprehensive analysis shows that retail and non-retail prescription medicines (including brand, generic, and supply chain costs) account for just 14% of total U.S. health care spending.

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LET'S TALK ABOUT COST

#8141

10 THINGS YOU SHOULD KNOW ABOUT MEDICINE SPENDING AND COSTS

1 Today, there are more than 7,000 medicines in development, including 140 personalized medicines. And 42% of new medicines in development have the potential to be personalized therapies that can be targeted to specific patients and their individual health needs.

2 Nearly half of total spending on brand medicines – the sum of all payments made at the pharmacy or paid on a claim to a health care provider – went to the supply chain and other entities in 2018.

3 Due to negotiations in the market, net prices for brand medicines grew just 1.7%, on average, in 2019, less than the rate of inflation. And spending on medicines for one of the nation's largest pharmacy benefit managers (PBMs) grew just 2.3% last year.

4 91% of all medicines dispensed in the United States are generic copies that cost a fraction of the price of the initial brand medicine. In addition, competition from generics and biosimilars is expected to reduce U.S. brand sales by $121 billion from 2020 to 2024.

5 Unlike care received at an in-network hospital or physician's office, half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price.

6 The market-based Average Sales Price system helps control costs and spending in Medicare Part B. It is estimated that the government and seniors have saved $132 billion from 2005 to 2017 as a result of switching to this system. In 2018, Part B medicine spending was just 10% of total Part B spending and just 5% of total Medicare spending.

1.7% **The amount prices for brand medicine increased in 2019, after factoring in discounts and rebates.**

Innovative biopharmaceutical companies that research, develop and manufacture medicines retained just 54% of total point-of-sale spending on brand medicines.

7 Hospitals mark up medicine prices, on average, nearly 500%. An analysis of 20 medicines also found the amount hospitals receive after negotiations with commercial payers is, on average, more than 250% what they paid to acquire the medicine.

8 The biopharmaceutical industry spends three times more on research and development (R&D) than on marketing and promotion. To put this into context, U.S. biopharmaceutical companies spent $90.5 billion in 2016 on R&D, three times the $28.1 billion spent on marketing and promotion that year.

9 We have a responsibility to not just develop treatments and cures, but to also help patients access them. That's why we created the Medicine Assistance Tool, or MAT. This free search engine contains information on more than 900 public and private assistance programs that help patients access their prescription medicines, including some free or nearly free options. Visit **www.mat.org** for more information.

10 We are also working to fix the health care system so it works better for patients by making sure rebates and discounts are shared with patients at the pharmacy counter, eliminating barriers to innovative payment arrangements and making insurance work like insurance again. Sharing negotiated discounts could save certain commercially insured patients with high deductibles and coinsurance $145 to $800 annually and would increase premiums about 1% or less.

Learn more at LetsTalkAboutCost.org

PhRMA
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Meet MAT

#8142

medicine assistance tool.org

It's the biopharmaceutical industry's mission to find lifesaving treatments. It's also our responsibility to help patients access them.

To help provide patients with more transparency about medicine costs, PhRMA member companies created the Medicine Assistance Tool, or MAT. The platform provides patients, caregivers and health care providers with information to help them connect to financial assistance programs for the medicines patients need. MAT also links to member company websites, referenced in company direct-to-consumer television advertising, where information about the cost of the prescription medicine is available.

WHAT IS PHRMA'S MEDICINE ASSISTANCE TOOL?

The Medicine Assistance Tool (MAT) is a web platform designed to help patients, caregivers and health care providers learn more about some of the resources available to assist in accessing medicines. These include various biopharmaceutical industry programs offered to those who need financial support due to their lack of insurance or inadequate prescription medicine coverage. It also helps people learn more about the costs surrounding their medicines, as well as provides resources to help them better navigate their insurance coverage. MAT is not its own patient assistance program, but rather a search engine for many of the support programs and resources that the biopharmaceutical industry has been offering for decades.

HOW DOES MAT WORK?

MAT is a search engine that contains information on more than 900 public and private assistance programs that help patients access their prescription medicines, including some free or nearly free options. To use MAT, go to MAT.org and select whether you are a patient, loved one or health care professional. Next, enter the name of the medicines you, your loved one or your patient are prescribed and then enter your personal information or that of your loved one or patient (i.e. age, location, income, insurance coverage and household size). MAT will produce search results that identify programs and resources that might be able to help you. Any information provided is kept strictly confidential and will not be used to for any purpose other than providing the search results.

WHO IS INVOLVED IN MAT?

MAT was created by PhRMA, which represents America's top innovative biopharmaceutical research companies. There are hundreds of programs offered by PhRMA's members companies to help qualifying patients. PhRMA works in partnership on MAT with health care providers, pharmacists, patient advocacy organizations and community groups in an ongoing effort to make it easier for those with financial need to access their prescription medicines.

HOW CAN MAT HELP PATIENTS LEARN MORE ABOUT THEIR MEDICINE COSTS?

MAT provides patients, caregivers and health care providers with links to websites, referenced in company television advertising, where information about the cost of the prescription medicine is available. These websites may include information such as the list price of the medicine, out-of-pocket costs and other context about the potential costs of the medicine.

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to North Dakota
SB 2209
March 9, 2021

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes North Dakota Senate Bill (SB) 2209, which upon the successful creation of a wholesale prescription drug importation program for the importation of drugs from Canada in another state, would require North Dakota to contract with that state to create its own program, upon certain approvals. This legislation mischaracterizes importation as a tool to lower drug costs and disregards the inherent threats to patient safety associated with drug importation.

In September 2020, the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) issued its final rule (the Final Rule) implementing a provision of federal law allowing the commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs sponsored by states or Indian tribes. The Secretary concurrently offered "certification" that the program would pose no additional risk to the public's health and safety and would result in a significant reduction in the cost to the American consumer as required by law. The Rule provided no proof that importation programs will not provide additional risk to public health and safety or result in significant cost savings. Instead, the federal government placed the responsibility of ensuring public safety and proving significant cost savings on the states.

A state importation program is unlikely to produce significant cost savings and fails to recognize the additional resources needed to implement and maintain an importation program.

The Federal Rule places the onus on states to prove "significant cost savings" from a state importation program (SIP) and acknowledges that "SIP Sponsors will face costs to prepare proposals, implement authorized programs, and produce records and program reports."[i] Extensive state resources are required for the implementation and administration of an importation program including but not limited to:

- ***Start-up and Ongoing Costs:*** A state importation program would ultimately assign numerous new responsibilities to the State of North Dakota, including: the design of the importation program; compliance with existing federal laws, including track and trace; development of a wholesale prescription drug importation list; and ongoing administrative costs.

- ***Compliance with Federal Law:*** Both the Foreign Seller and the Importer, under supervision of the state, will be subject to the supply chain security requirements set forth in the Final Rule and under the federal Food, Drug & Cosmetic Act (FD&C Act).

- ***Law Enforcement Costs:*** In July 2017, the National Sheriffs Association approved a resolution opposing state importation legislation because such programs would "jeopardize law enforcement's ability to protect the public health, threaten the safety of our (U.S.) drug supply, and endanger law enforcement officers, their canines, and other first responders."[ii] As former FBI director Louis J. Freeh recently wrote, "the sheer strain that legalized drug importation would have on law enforcement agencies cannot go unappreciated…[W]e've also been faced with resource and budget challenges that force us to do more with less. Rolling the dice on a drug importation law would undoubtedly take resources away from other important law enforcement efforts."[iii]

- ***Public and Stakeholder Education:*** Any statewide prescription drug program requiring voluntary participation from supply chain entities and consumers will require training and education.

In public comments to the FDA during the rulemaking process, several states that passed importation laws expressed concern with the ability to recoup state costs, prove significant savings, achieve appropriate levels of access, and operate efficiently under the parameters outlined in the proposed rule. The Final Rule failed to address these concerns. The Colorado Joint Budget Committee approved their state's Department of Health Care Policy and Financing's FY 2020-21 recommendation to delay of the implementation of Colorado's Canadian importation program in light of budget concerns. After conducting a study on the feasibility of importation, the state of Wyoming determined in September 2020 that a state drug importation program would likely not create significant savings and would be unsustainable in the long-term.

This legislation could increase the risk to consumer health and safety by weakening the closed supply chain and opening North Dakota to increased criminal activity.

Opening our closed distribution system to importation would gravely compromise the integrity and safety of the U.S. prescription drug supply. Importation presents a huge opportunity for unscrupulous suppliers and/or criminal organizations to increase the flow of substandard, adulterated or counterfeit drugs – including pills laced with deadly fentanyl – into the U.S. FDA is the gold standard in ensuring the safety and effectiveness of medicines for the U.S. market and importation would have the same effect as repealing current FDA and consumer protections.

The legislation fails to acknowledge the complexities of setting up a state importation program that adequately protects public health and safety. Specifically, it fails to acknowledge the challenges associated with adherence to the federal "track and trace" system established under the Drug Supply Chain Security Act (DSCSA) and the inherent risk to public safety if it is compromised. Both the draft legislation and the federal Rule place significant responsibility on states to adhere to federal track and trace requirements and demonstrate that any importation program would pose no additional risk to public health.

In 2013, Congress unanimously enacted bipartisan legislation to address concerns of unsafe and counterfeit drugs entering the U.S. pharmaceutical supply chain. The Drug Supply Chain Security Act (DSCSA) established an electronic system to uniquely identify each package of drugs and trace those packages as they are distributed. Through the DSCSA and prior actions, the U.S. has established one of the most secure supply chains in the world and ensures proper protection of patients. Drug importation programs severely undercut the protections of the DSCSA, compromising patient safety. If North Dakota pursues an importation program, it will assume significant risk and potential cost in an effort to ensure public safety.

Canadian law does not prohibit the transshipment of drugs from any country—including those in the third world—into Canada and then into the United States, heightening concerns about the safety and reliability of these medicines. The FDA determined that 85 percent of the drugs sold by supposedly Canadian pharmacies come from 27 countries other than Canada.[iv]

The Importation Final Rule raises significant legal concerns and is the subject of ongoing litigation.

On November 23, 2020, PhRMA, the Partnership for Safe Medicines (PSM), and the Council for Affordable Health Coverage (CAHC) filed a complaint in the U.S. District Court for the District of Columbia against the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA). The litigation challenges the final rule on Importation of Prescription Drugs (Final Rule) and an associated "certification" made by Secretary Azar on the grounds that they suffer from fatal flaws, including failing to demonstrate that importation will pose no additional risk to public health and safety or will result in significant cost savings.

The complaint alleges that the Final Rule disregards key patient safety protections of the Federal Food, Drug, and Cosmetic Act (FDCA). Section 804 of the FDCA authorizes HHS in certain circumstances to permit both the importation of drugs by pharmacists and wholesalers for commercial distribution and the importation of drugs by individual patients. **Section 804 is effective, however, only if the HHS Secretary certifies to Congress** "that the implementation of this section will—(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer." Although this law was enacted nearly twenty years ago, no previous HHS Secretary has been willing to make this certification due to inability to ensure both public safety and cost reduction. The Final Rule and Secretary Azar's "certification" letter, which apply only to commercial distribution, contain conclusory statements as to safety and cost savings without supporting evidence and punt the responsibility for safety and cost savings to state governments.

In addition, there is no indication that the Final Rule will reduce costs to actual American patients. In the preamble to both the proposed and Final Rule, HHS has acknowledged that it cannot quantify the savings, if any, that would result from its rule, even classifying it as "not economically significant" for purposes of review by the Office of Management and Budget. Indeed, in the budget document released with the rule, the cost savings chart was left completely blank, suggesting cost savings could not be calculated.

Furthermore, aspects of the Final Rule are contrary to the FDCA, violate manufacturers' First Amendment rights and raise serious questions under the Fifth Amendment Takings Clause. As such, PhRMA, PSM and CAHC are asking the Court to hold unlawful, set aside and permanently enjoin implementation of the Certification and Final Rule.

In addition to the ongoing federal litigation, PhRMA, PSM, and CAHC submitted a Citizen Petition to FDA requesting that the agency refrain from authorizing Florida's Section 804 Importation Program Proposal for the Importation of Prescription Drugs from Canada (Proposal), which Florida submitted to FDA on November 23, 2020. In addition to being issued pursuant to an invalid and legally deficient certification and Final Rule, the Proposal does not adequately demonstrate that importation will pose no additional risk to public health and safety, and it fails to show that importation will lead to any reduction—let alone a significant reduction—in the cost of prescription drugs for American consumers.

State importation programs fail to recognize the challenges of the Canadian prescription drug market.

The Canadian government is not in a position to monitor and regulate medicines that are intended for the U.S. market. Canada's former Health Minister Leona Aglukkaq said, "Canada inspects drugs for its own citizens; Canadian authorities wouldn't have the ability or resources to inspect medicines destined for the United States." [v] Therefore, the financial and practical burden would fall to U.S. authorities and local law enforcement. Kirsten Hillman, acting Ambassador to the United States, stated that "the Canadian market is too small to have a real impact on U.S. drug prices. The U.S. consumes 44% of the global prescription drug supply, compared to Canada's 2%," and that "Canada's priority is to ensure a steady and solid supply of medications at affordable prices for Canadians."[vi]

In November 2020, Health Canada issued an Interim Order stating that the distribution of certain medicines intended for the Canadian market outside of Canada is prohibited if the distribution would cause or exacerbate a shortage of the medicines in Canada. To date, no state that has submitted an application to FDA to sponsor a state importation program has secured the required foreign seller from Canada to facilitate importation.

PhRMA shares a desire to address patient affordability within the health care system and reduce consumer costs in the State of North Dakota. However, for the reasons stated above, we do not believe development of a drug importation program will produce the desired results and could significantly jeopardize patient safety.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

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[i] https://www.hhs.gov/sites/default/files/importation-final-rule.pdf

[ii] Drug Enforcement Administration (undated; viewed on July 25, 2017), DEA Warning to Police and Public: Fentanyl Exposure Kills, https://ndews.umd.edu/sites/ndews.umd.edu/files/DEA%20Fentanyl.pdf. Also, Drug Enforcement Administration (July 2016), supra.

[iii] Louis J. Freeh op-ed, "Cost of drug importation could unfairly shift to law enforcement," The Philadelphia Inquirer, May 5, 2017.

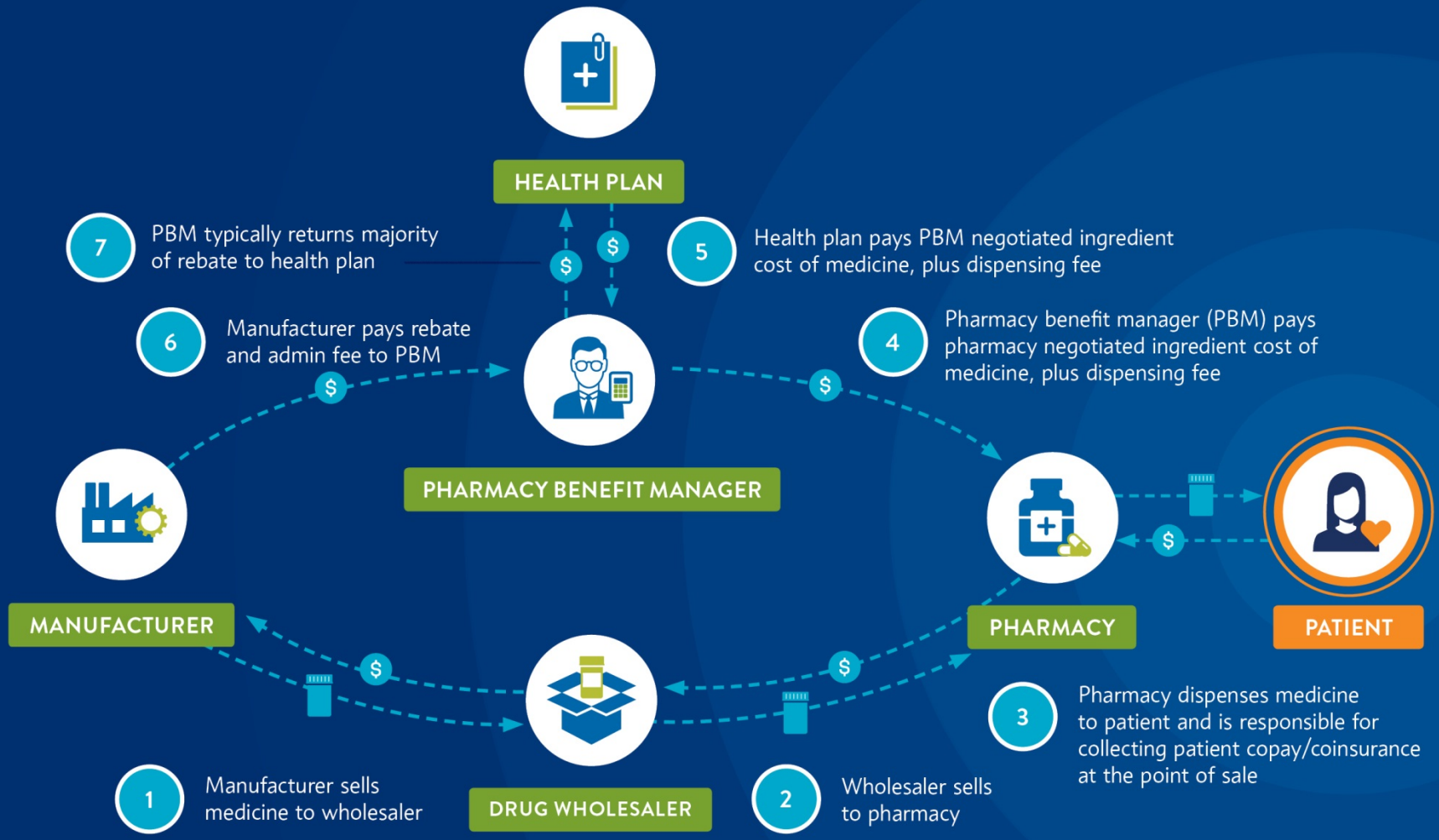
[iv] FDA. "FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries." December 2005

[v] Letter to the Washington Post, Leona Aglukkaq, Former Minister (2008-2013), Health Canada, May 12, 2017

[vi] Statement from Canada's Acting Ambassador to the United States on U.S. Importation of Pharmaceutical Drugs from Canada, December 18, 2019

Distribution and Financial Flow

FOR RETAIL BRAND DRUGS



Source: Adapted from Pembroke Consulting

HDA
Healthcare Distribution Alliance
PATIENTS MOVE US.

March 9, 2021

North Dakota Legislative Assembly
House Human Services Committee
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: Healthcare Distribution Alliance (HDA) Opposition to SB 2209

Chairman Weisz, Vice Chair Rohr and Members of the House Human Services Committee,

The Healthcare Distribution Alliance (HDA) offers this letter to indicate our opposition to Senate Bill 2209, relating to the importation of prescription drugs from Canada. HDA is the national trade association representing healthcare wholesale distributors — the vital link between the nation's pharmaceutical and healthcare manufacturers and more than 180,000 pharmacies, hospitals, and other healthcare settings nationwide. On behalf of the industry, HDA would like to express our concerns with SB 2209 due to the potential impact on pharmaceutical supply chain and risk to patient safety.

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. This will enhance the Food and Drug Administration's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve the detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Under the confines of DSCSA, any drug distributed in the U.S. must be distributed to and from an authorized trading partner and must be a serialized product incorporating the National Drug Code, Serial Number, Lot Number and expiration date. It is important to note that drugs that are sold or designated for sale in Canada as well as other countries do not conform with U.S. traceability regulations, simply affixing a new label on an imported product will not ensure the product adheres to the full FDA standards set forth by DSCSA prior to its importation. Allowing for the importation of drugs from Canada, or other countries, would hinder the intent of the DSCSA statute, and therefore increase the risk of illegitimate or counterfeit medications entering the U.S. market.

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 the tightly regulated supply chain and safeguards currently in place to ensure the efficacy and safety of prescription medications. The National Association of Pharmacy Regulatory Authorities, NABP's counterpart in Canada, has expressed concern that exportation of medicines out of Canada will threaten the supply available to its citizens. This, in turn, will increase the opportunity for counterfeit medications to enter its supply chain, endangering both US and Canadian patients."[2]

Furthermore, the legislation requires the North Dakota Board of Pharmacy to increase licensure fees on supply chain entities to fund the importation program which has yet to be established and may never come to fruition. Licensure by the Board of Pharmacy is intended to protect, preserve and promote public health and welfare of the citizens of North Dakota. Licensure fees should help the Board achieve these goals, not implement a theoretical program that would potentially harm the patients they are working to protect.

Ultimately, allowing for importation of prescription drug products increases the likelihood of counterfeit or adulterated drugs entering the country. Due to these concerns, we ask that you oppose both SB 2209. We encourage the state legislature to study the topic over the interim to determine the feasibility, cost savings and potential consequences of implementing such a program rather than rushing through a proposal allowing North Dakotans to rely on another state's pharmaceutical importation program.

In addition to my testimony, I have also included a study conducted by the Healthcare Distribution Alliance Foundation in partnership with Accenture entitled "The Risks and Realities of Commercial Drug Importation," the study concludes that "proposed importation policies likely place the integrity of the commercial supply chain at risk." Please contact me at Llindahl@hda.org or (303) 829-4121 if you have any questions or would like to discuss this issue further.

Thank you,

Leah D. Lindahl

Leah Lindahl
Senior Director, State Government Affairs
Healthcare Distribution Alliance

[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

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

#8108

THE RISKS AND REALITIES OF COMMERCIAL DRUG IMPORTATION

An End-to-End Analysis of Drug Importation Policy on Patient Safety and the Pharmaceutical Supply Chain

HDA RESEARCH FOUNDATION

SUMMARY

The impact of commercial drug importation on the pharmaceutical supply chain is not well understood. This report explores proposed drug importation policy, in general and with emphasis on proposed legislation since 2013, for commercial feasibility, operational costs to the supply chain, and impact to patients.

Multiple methods were used for qualitative and quantitative analysis as described in the appendices, including expert-panel interviews, literature reviews, and quantitative data modeling.

KEY POINTS:

- *Responsible importation relies on enacted policy achieving the current standard of drug quality and safety.*
- *Significant barriers to importation exist independent of United States (U.S.) policy proposals. These include: limited supply by the small number of countries with compatible approval and safety regulations, limits on products feasible to import, and legal and exclusivity provisions covering many high-cost medicines.*
- *Products viable for importation do not align with the greatest concerns for U.S. patients (e.g., cost and access) due to limitations imposed by handling requirements, available supply, and legality.*
- *Interviews with experts suggest that enacting moderate drug importation policy will likely lead to a 5% increase in drug-related adverse events (AEs). Further, modeling and analysis of AE data predicts a significant increase in costs to patients, conservatively estimated at $200M and potentially reaching $1.4B.*
- *Collectively, patient, regulatory, and supply chain impacts suggest a minimum threshold of $1.1B to $2.9B in costs that must be funded or accounted for in revising or implementing commercial drug importation approaches.*

This analysis concludes that the current proposed drug importation policies, as written, may not provide comprehensive guidance and funding requirements to meet current safety and quality standards for drugs in the U.S. The present realities of global drug supply and permissible product scope indicate that barriers will overshadow benefit to patients in the next three to five years. Lastly, proposed importation policies likely place the integrity of the commercial supply chain at risk.

Definitions:

Commercial Drug Importation is an activity in which a manufacturer, wholesaler, pharmacy, or third party brings drugs to the U.S. that (1) were produced outside the U.S. (2) lack Food and Drug Administration (FDA) approval, and (3) lack oversight of elements contributing to product safety and quality (i.e. ingredients, labeling, manufacturing/production, and/or handling methods) in accordance with and pursuant to a FDA approval.

Drug reimportation is a subset of approved product importation: a case where drugs manufactured and approved in the U.S., but intended for sale outside the U.S., are redirected or reimported into the U.S. commercial supply chain.

This study focuses on federal, rather than state, policies covering commercial importation.[1] Personal importation by patients physically visiting overseas pharmacies is out of scope of this analysis.[2,3]

UNCLEAR PATHS FOR PROPOSED IMPORTATION POLICY

The U.S. governance of drug standards dates to 1937 and has since been evolving (Appendix II Figure 1). This is a closed pharmaceutical system where only drugs that the FDA has reviewed and approved are permitted into the U.S. The comprehensive review and approval process includes: labeling, packaging, manufacturing, clinical data, and other information. Therefore, the system can conclude that there is substantial evidence that the benefits of the drug to U.S. patients will outweigh its risks under the FDA-approved labeled conditions of use. Maintaining these standards should be a requirement of commercial drug importation approaches.

The challenge with foreign drug imports, even if they have been approved by competent, comparable foreign authorities, is that there is no guarantee that the standards for a particular drug are the same as the FDA-approved product. This poses inherent risk to the product standards of the U.S. system and ultimately, to the patient.

In July 2018, the U.S. Department of Health and Human Services (HHS) directed the FDA to develop focused drug importation options to address access challenges. The directive was specific to single-source generics with limited patient availability while respecting patents and exclusivities.[4] This action is one example of the intent to address the increasing gap in affordability of medicines and the desire to improve patient access.

This is not the first time that changes to drug importation regulations have been considered. Lawmakers have made repeat proposals for new importation policies largely since the Medicare Modernization Act was enacted in 2003.[5] Examples of these

[1] Vermont S.175 (Act 133), enacted in 2018, permits wholesale importation of drugs from Canada pending HHS certification that this would reduce costs to consumers and pose no risk to public health. Maine's LD 171, enacted in 2013, did not require HHS certification but was overturned by the Maine District Court, which contended that federal importation provisions preempt any conflicting state laws [*(Ouellette v. Mills, 2015 WL 751760 (D. Me. Feb. 23, 2015)]*

[2] Personal importation is officially permitted only under certain circumstances, including situations in which medicines are not available within the U.S.; however, the American Bar Association notes "in practice the FDA is allowing such importation even though an equivalent drug is commercially available." *(Importing Prescription Drugs Remains Risky Business Due to FDA and DEA Regulation, American Bar Association, Mar 23, 2018)*

[3] The FDA definition of personal importation *does* include importation via courier or mail, which *is* inscope, as a party outside the U.S. is shipping product to a patient. (*"Is it legal for me to personally import drugs?" FDA*)

[4] FDA Press Announcement July 2018 webpage: https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-formation-new-work-group-develop-focused-drug

[5] In particular, the Safe and Affordable Drugs from Canada Act (S.61, 116th ; previously S.2549, 113th; S.122, 114th; S.64 and S.92, 115th); the Affordable and Safe Prescription Drug Act (S.97, 116th; previously S.469, 115th); the Affordable Medications Act (S.3411, 115th); the Improving Access to Affordable Prescription Drugs Act (S.771, 115th); the Personal Drug Importation Fairness Act (H.R. 934, 115th; previously H.R.2623, 114th, and H.R.3715, 113th); the Pharmaceutical Supply and Value Enhancement Act (S.3455, 114th). Proposals introduced in both chambers are referenced by Senate identifier only.

proposals can be reviewed in Appendix II Figure 2. Proposals can be classified by their level of restrictions on the scope of drug importation as: wide open, moderate, or restricted. Experts agree the moderate or restricted importation proposals are most likely to be enacted (Appendix III Figure 2). Supporters of drug importation approaches contend that they will reduce prices and other barriers to treatment for U.S. patients, citing lower prices for similarly branded and generic products in Canada and Europe.[6,7] While this intent is noted, these proposals have considerable variability and lack specificity for execution.

As recently as 2013, the Drug Supply Chain Security Act (DSCSA) established stringent requirements for electronic traceability for all supply chain stakeholders, creating a stricter standard for products entering the U.S. supply chain. As an example, these newer DSCSA requirements have not been accounted for in current proposed drug importation policy.

If not comprehensive enough to meet current standards and legislation, proposed drug importation policy may adversely affect the quality and safety of drugs and patient health. It will also impact the operations of the pharmaceutical supply chain, which acts to maintain the current high standards. Therefore, both patient health standards and execution pathways are at risk.

Appendix II Figure 1 shows importation-related proposals since 2003. Many proposals borrow language both from each other[8] and from related terms in the Medicare Modernization Act. However, these proposals vary in detail regarding execution, and have not been reviewed in depth by the Congressional Budget Office (CBO).[9] Proposals also vary in clarity of traceability, identification, labeling, and packaging requirements.

DEFINING RESPONSIBLE IMPORTATION

To avoid emphasis on the terms of specific proposals and to promote an objective analysis, this report used detailed interviews with experts to determine a framework and definition for responsible importation (Appendix I and Appendix II Figure 2). Most experts agree (~80%) that as written, current drug importation proposals are not detailed enough for execution. This poses inherent risk to existing U.S. processes and standards that enable the flow of drugs to the patient (Appendix III Figure 2). Therefore, a framework for minimum requirements for "responsible" commercial drug importation (1-3) and supply chain execution (4) would include:

[6] Sentiment on this topic is visible from a variety of avenues, including the Trump administration (e.g., "Remarks by President Trump on Prescription Drug Prices," October 25, 2018), the media (e.g., " High U.S. Drug Prices Fuel Outrage, Innovation Debate: QuickTake," *Washington Post*, May 11, 2018), actions from Congress (e.g., Congress holds first hearings on insulin, high drug prices," *Reuters*, Jan 29, 2019), and indicators of public sentiment (e.g., "KFF Health Tracking Poll – February 2019: Prescription Drugs," *Kaiser Family Foundation*, Mar 1, 2019).

[7] Specific reports and studies regarding pricing levels include *Kesselheim AS, Avorn J, Sarpatwari A. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. JAMA. 2016;316(8):858–871.*, and data from the Canadian Patented Medicine Prices Review Board (e.g., "Annual Report 2017," Patented Medicine Prices Review Board)

[8] For example, the Safe and Affordable Drugs from Canada Act has been reintroduced several times since 2014 (S.61, 116th; previously S.2549, 113th; S.122, 114th; S.64 and S.92, 115th). The text of the Affordable and Safe Prescription Drug Act (S.97, 116th; previously S.469, 115th) can also be found within the Affordable Medications Act (S.3411, 115th) and Improving Access to Affordable Prescription Drugs Act (S.771, 115th)

[9] "Preliminary Estimate – S.469, the Affordable and Safe Prescription Drug Importation Act (as introduced)." Congressional Budget Office, July 2017

1) Country of Origin: Comparable regulatory standards and supply conditions;

2) Product Categories: Products capable to be imported based on chemical make-up, stability, non-FDA oversight, and handling requirements;

3) Legal and Competitive Status: Transactions that abide by exclusivity, active patents, and other legal considerations; and,

4) Supply Chain Interaction: Achievement of review, tracing, and monitoring and management per the stipulations for supply chain stakeholders.

As outlined above, experts in this study recommend these minimum requirements to define "responsible importation," or importation proposals that would preserve current quality and safety standards.

COUNTRIES MATCHING U.S. REGULATORY STANDARDS HAVE LIMITED SUPPLY OF VIABLE AND NEEDED MEDICINES

Secondary research and modeling quantified the requirements for responsible imports.

Findings suggest that the supply of importable products is limited and that these products may not align to areas where U.S. patients experience the greatest difficulties with cost and access. Successful importation also depends on foreign governments' willingness to facilitate exports. Most in-scope products are expressly intended for consumption in their own market, and some sources suggest that not all countries will support exportation to the U.S.[10]

> ***"Foreign countries [will not] allow their local supply to be skimmed off, only to create local shortages of important medicines."***
>
> *- Dr. Scott Gottlieb, former FDA Commissioner* [17]

Country of Origin: Canada and the five leading economies of the European Union (EU5: Germany, the United Kingdom, France, Italy, and Spain) are the most viable sources of drug imports, as their regulations are most comparable to U.S. standards and their geographic distance might enable efficient transport. These criteria are based on expert recommendation of each country's comparable regulatory approaches, limits of transport, and analysis of their potential available supply (Appendix II Figure 4).

Product Categories: Viable products would likely be limited to oral, small-molecule drugs (Appendix II Figure 5). Biologics would be difficult and costly to import outside the current supply chain due to product complexity and handling requirements. Some proposals also exclude biologics and complex agents outright.[11] Controlled substances would also be excluded, as they are regulated separately by the Controlled Substances

[10] Lack of overseas willingness was identified as a challenge by Dr. Scott Gottlieb, FDA Commissioner 2017-2019, in a 2016 contribution to *Forbes*: "foreign countries [will not] allow their local supply to be skimmed off, only to create local shortages of important medicines." The Canadian Minister of Health for 2008-2013 previously proposed such restrictions, and voiced opposition to drug export in a 2017 contribution to the Washington Post. *Gottlieb, "What Trump should Have Said on Drug Prices," Forbes, Mar 4, 2016; Aglukkaq, "Dear Bernie Sanders: Canada is not the United States' drugstore," Washington Post, May 12, 2017*

[11] For example, The Safe and Affordable Drugs from Canada Act (S.61, 116th), the representative policy for the moderated scenario

Act of 1970.[12] The result is limited importable product supply, with little alignment to categories of need, like products of highest price and limited access.

Legal and Competitive Status: Importable drugs will most likely need to be chemically equivalent to those approved for U.S. patients to see significant demand. Drugs will also be viable to import only if they do not infringe upon any active U.S. patents or other exclusivity provisions[13], as the cost of potential lawsuits would deter importers from bringing in protected products. [14,15] Branded medicines that have already passed U.S. exclusivity remain in scope (Appendix II Figure 6)

Based on these three criteria, drugs representing $40.3B in Canadian and EU5 sales fall in scope for this analysis (22% of the $184.7B in total annual sales across the six included markets at local prices).

Applying these criteria to 2018 sales in the U.S. suggests that responsible imports would compete with 14% to 18% of U.S. sales in that year. It should be noted that these figures represent the full *potential* scope. Most of the $40.3B in international sales would be distributed in their own markets. Therefore, the volume of non-FDA approved drug imported into the U.S. would be constrained (Appendix II Figure 3).

Pharmaceutical Sales $Bn U.S. Dollar Sales revenue
Canada, UK, Germany, France, Spain, and Italy

Scope of Importation
Estimated 2018 Pharmaceutical Sales

Importation Requirements for Study	Ex-U.S.	U.S.
1 **Countries of Origin** Estimated 2018 pharmaceutical sales in proposed countries of origin	184.7 *(+/- 8.6)*	527.6 *(+/- 24.6)*
2 **Viable Product Category** Est. 2018 pharmaceutical sales of products within scope of import: chemical or biological makeup, controlled substance status, and feasibility of management and transport	84.8 *(+/- 3.9)*	217.8 *(+/- 10.0)*
3 **Legal & Competitive Status** Est. 2018 pharmaceutical sales of inscope products that are both equivalent to a product in the U.S. (left) or outside of the U.S. (right), and not blocked by an active patent	40.3 *(+/- 1.9)*	107.8 *(+/- 5.1)*

[12] The CSA was originally introduced as H.R.18583 (91st) and enacted into effective May 1, 1971; current rules are recorded in U.S. Code Title 21 Chapter 13. Proposals explicitly barring importation of controlled substances include the Affordable and Safe Prescription Drug Act (S. 97, 116th) and the Safe and Affordable Drugs from Canada Act.
[13] The FDA guarantees exclusivity of at least five years for brand-name drugs containing new chemical entities, seven years for "orphan" drugs that treat rare diseases and are unlikely to recover development costs, and three years for in some other circumstances. Pediatric drugs gain six months additional exclusivity. The first generic drug to successfully launch against a brand-name drug also receives six months of exclusivity under current policy. "*Patents and Exclusivity," FDA, May 19, 2015*
[14] U.S. law allows patent holders to exclude others from making, using, selling, or importing a product. However, these rights are only enforced if the patent holder acts on them. Many U.S. pharma patents also cover aspects besides physical composition. This suggests that *some* protected drugs may be able to physically enter the U.S., but would likely struggle to move through the supply chain, as awareness and ability to enforce likely increase as a drug gets closer to patients
[15] Reimportation has become more complicated following the Supreme Court's 2017 decision in "Impression Products vs. Lexmark," which established that authorized sales outside the U.S. still exhaust patent rights within the U.S. However, strategies have been proposed to circumvent this ruling, and the risk of litigation still presents a potential cost barrier.

PATIENT BENEFIT AND SAFETY IS PARAMOUNT

Although importation proposals aim to reduce prices and improve access to medicines for patients, patient benefit is not guaranteed due to the limited viable product scope. Given the product scope and supply requirements, lower-priced branded and generic products are the likeliest to be imported (Appendix II Figure 7). The pricing advantage for imports in these segments is likely too small to drive significant benefit to patients.[16]

There is inherent risk to patient safety when introducing overseas imports into the supply chain and thus permitting entry for counterfeit and other unsafe drugs. Likely challenges include inspecting and validating potential imports. Even with requirements for responsible importation, counterfeit or unsafe product can enter the U.S.

Precedent suggests that authorities are not confident enough in existing regulations to certify importation. For example, the Medicare Modernization Act permits importation from Canada if the HHS Secretary certifies that this would pose no risk to public health and safety and would create significant cost savings for patients. However, all secretaries since 2003 have declined to provide these certifications.[17,18] Four former FDA Commissioners voiced similar concerns regarding safety in a 2017 letter to Congress.[19]

With these concerns in mind, costs associated with patient safety were quantified by investigating rates of drug-related adverse events (AEs). Costs required for patients to seek AE-related treatment were also included. Expert analysis predicted an estimated 5% increase in drug-related AEs under moderate or restricted terms, due to increases in counterfeiting and other sources of unsafe product. While there is little research regarding the predicted costs of drug-related AEs due to possible enacted importation policy, available estimates and incidence data combined with expert estimates result in increases ranging from $200M (based on incidence data and estimates of cost *per AE*) to $1.4B (based on estimates for *total cost* from drug-related AEs, Appendix II Figure 11).

Any increase in AEs is challenging. This study finds a lack of tangible benefits (either for pricing or access) from commercial drug importation proposals, as written, with exception of certain restricted cases. In addition, there is little evidence that benefits from these imports outweigh the safety risks to patients. This analysis provides a glimpse into the patient impacts, and the opportunity exists to further assess the patient risk/benefit through future proposals.

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[16] This is expected generally, but not universally. For example, insulin has attracted attention due to price differences between the U.S. and Canada; while insulin's status as a biologic excludes it from most importation proposals, permissive regulations could see some importation as the price difference drives importers to look past the higher logistics costs.

[17] The Medicare Modernization Act directs HHS Secretaries to permit "pharmacists and wholesalers to import prescription drugs from Canada into the United States[…]only if the Secretary certifies to the Congress that the implementation of this section will (A) pose no additional risk to the public's health and safety; and B) result in a significant reduction in the cost of covered products[…]" (H.R.1, 108th, Sec. 1121). All Secretaries since 2003 have declined to make this certification.

[18] Reliable estimates of potential savings are hard to come by. The Pew Charitable Trusts notes, "The Congressional Budget Office (CBO) estimated that potential savings from a similar policy - the Pharmaceutical Market Access Act of 2003, which would have allowed pharmacists, wholesalers, and individuals to import drugs from 25 countries, among them Australia, Canada, Japan, and a number in Europe - could have produced total savings of $40 billion over ten years in the U.S., including savings of $2.9 billion for the federal government […] *CBO also estimated that savings from the policy would be minimal if imports were permitted only from Canada*" (emphasis ours).

[19] Letter to Congress from Robert Califf (2016 - 2017), Margaret Hamburg (2009-2015), Andrew Von Eschenbach (2006 – 2009), and Mark McClellan (2002 - 2004), March 17, 2017. Accessed at https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final_signed.pdf

THE FDA WILL BE RESPONSIBLE FOR THE QUALITY AND SAFETY OF IMPORTED MEDICINES

The challenge of regulating safety in a globalized and technological economy is already formidable.[20] Expert interviewees agreed that the burden of defining processes and ensuring the quality and safety of imported drugs would fall on the FDA. This means that the FDA will lead the planning and funding for responsible importation. Former FDA commissioners have echoed this sentiment.[21] Given the FDA's relationships with government and regulatory bodies in Canada and the European Union, the agency is well positioned for this task.

Despite having the technical expertise, added responsibility would increase the FDA's operational costs and overhead. Interviewees estimated that a moderate importation policy would lead to an eight to ten times increase in costs, including domestic and foreign inspection, headcount, staff training, quality assurance, and traceability technology. These increases would collectively triple the FDA's existing cost to operate foreign offices, inspect foreign facilities, and screen imports.

Quantitative analysis based on these estimates and published FDA budgets suggest that at least $270-350M annually would be required for the agency to handle these new responsibilities. This range aligns with estimates from interviewees with intimate knowledge of FDA processes[22](Appendix II Figure 8).

These additional costs and responsibilities to regulate importation would fall on an agency that is already experiencing capacity constraints. The Government Accountability Office (GAO) has reported on the FDA's activity overseas since 1998 and consistently identifies concerns with the program.[23] One recent report notes that almost 50% of overseas positions were vacant as of July 2016 and that inspections had yet to be conducted at over 1,000 facilities already involved in the U.S. supply chain.[22,23] The GAO's findings suggest that current funding is insufficient for the targeted volume of inspections. The FDA will likely need to address these deficits before expanding efforts to manage commercial drug importation.

Responsible importation should specify the processes, funding, authority, and timeline for expanded FDA oversight and ensure that adequate contingencies are in place.

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[20] The National Academy of Sciences, for example, notes that safety concerns and recalls even of U.S.-approved drugs present a challenge for the FDA (Pray and Robinson, "Challenges for the FDA: The Future of Drug Safety, Workshop Summary," National Academy of Sciences). Fraud and counterfeiting also remain global concerns, with data published by the Pharmaceutical Security Institute suggesting that worldwide incidents of pharmaceutical crime rose nearly 63% from 2013 to 2017 (Pharmaceutical Security Institute Incident Trends. Accessed April 3, 2019)

[21] Letter to Congress from Robert Califf (2016-2017), Margaret Hamburg (2009-2015), Andrew Von Eschenbach (2006-2009), and Mark McClellan (2002-2004), March 17, 2017.

[22] Additionally, a 2016 GAO report estimated $92m for foreign drug inspections in 2015; inspections of conventional and biologic drugs have collectively increased from 1139 in 2015 to 1407 in 2018, suggesting that the figure has increased since then. "FDA Has Improved Its Foreign Drug Inspection Program but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices." Government Accountability Office, Dec 16, 2016; FDA 2017 and 2019 Budget Summaries

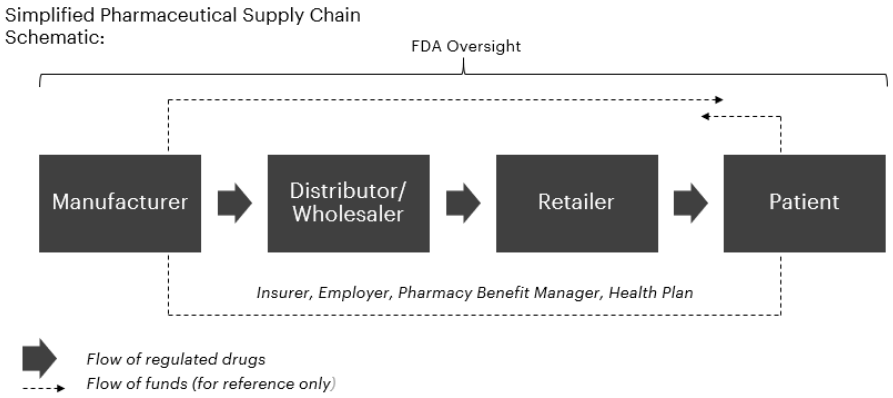
[23] The GAO has issued several reports on overseas FDA activity starting in 1998 ("Improvements Needed in the Foreign Drug Inspection Program," GAO, Mar 17, 1998) and continuing in 2008 ("Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program," GAO, Sep 22, 2008), 2009 ("High Risk Series: An Update," GAO, Jan 22, 2009), 2010 ("FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed," GAO, Oct 25, 2010), and 2016 (see previous)

This study recognizes the FDA's continued efforts to innovate, create international drug transparency, and raise quality standards. In the longer term, these global partnerships could pave the way for co-evaluation and co-approval measures for importable product.[24] This is likely a sustainable alternative to the current proposals on this topic.

THE COST TO STAKEHOLDERS EXCEEDS $1B

The standards set by regulators are implemented by supply chain stakeholders. This stakeholder analysis focuses on manufacturers, who develop and produce finished products; distributors and wholesalers,[25] who facilitate the storage and efficient transportation of product; and retail pharmacies, who dispense product and educate patients in obtaining product.

Manufacturers are important partners to the FDA to ensure product quality and patient safety. It is in their interest to preserve these standards for medicines in their market space for competitiveness and innovation. Nevertheless, some branded and generic manufacturers would see greater near-term risk, due to high overlap between their products and product scope suggested by a responsible importation policy.



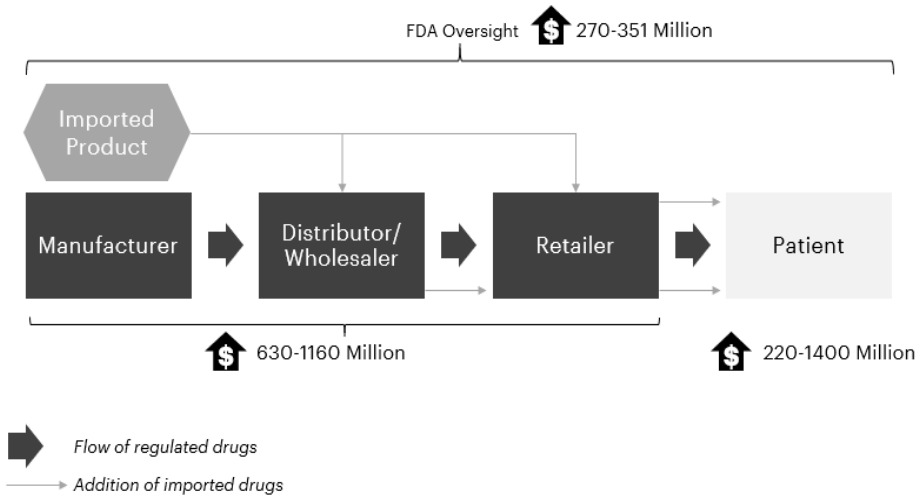
Manufacturers may also decide to protect their products and increase investments to defend patents and channels. If importers choose to challenge exclusivity provisions, litigation costs across the entire manufacturing segment could reach as high as $390-$430M per year (Appendix I Methods and Appendix II Figure 9a).

Distributors have greater flexibility and, if permitted, could choose to import product directly by collaborating with overseas suppliers. The additional costs revolve around the logistics of moving and storing imported product (e.g., warehousing and shipping). However, distributors would also need to absorb losses from product returned by retail pharmacies (e.g., recalls or overstocks); these returns likely would not be eligible for the manufacturer credits currently covering 90% of U.S. returns.[26] This analysis estimates that these would drive $240-$730M in added costs per year, depending on volume of product imported (Appendix II Figure 9b).

[24] Regarding safety, the FDA would ideally have access to foreign clinical trial reports discussing the actual effects of a drug on its biological pathway. Intellectual property confidentiality, however, may still present a significant barrier.
[25] For the remainder of the paper, "Distributor" will refer to companies in both the distribution and wholesaling sectors.
[26] 89th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (2018-2019), Table 47

Pharmacies have closer relationships with patients and may be more cautious with imports in the near term. However, costs could be incurred in protecting brand credibility and filling any gaps in compliance or pharmacovigilance. Estimated costs for regulatory oversight and supply chain stakeholders are a significant hurdle – a minimum of $900M per year – to execute a moderate importation proposal (Appendix II Figure 10). Combined with the cost to patients related to AEs, there is an estimated minimum threshold of more than $1.1B annually to overcome.

Simplified Pharmaceutical Supply Chain with Commercial Drug Importation Schematic:
TOTAL COST THRESHOLD MINIMUM: $1120 Million



SHIFTS ARE IMMINENT

If implemented, expanded importation will shift pricing models, stakeholder revenues, therapeutic dynamics, drug pricing models, and supply chain pathways.

Pricing Models: The combination of revenue disruption and impacted therapeutic categories may reshape pricing. Under manufacturers' current pricing structures, the higher prices charged in wealthier countries are used to subsidize sales in other economies and to help fund research on new therapeutics. If overseas prices spread to the U.S., manufacturers may respond by raising prices elsewhere or restricting international supply.[27] Importation could therefore interfere with the global benefits afforded by the current approach and prompt negative reactions from foreign governments concerned about their own drug prices and availability.

Stakeholder Revenues: Manufacturers (both brand and generic) may see the greatest revenue losses for a given level of adoption. For example, if 33% of in scope importable drugs replace U.S. sales, there would be an annual revenue impact of roughly $7.9B. Distributors and pharmacies may buffer lost sales of U.S. product by buying and selling the new imports. Distributors may therefore experience a smaller decrease of around $5.3B and pharmacies a decrease of around $6.1B, per year (Appendix II Figure 12).

[27] U.S. manufacturers are likely to mitigate the impact of importation on their pricing models by limiting the amount of product they sell to foreign countries and, thus, the amount of their product that could be reimported back into the U.S., at cheaper international prices.

Therapeutic Dynamics: Analysis suggests that imports will compete most heavily in the cardiovascular (62% of sales exposed), gastrointestinal (40%), and genitourinary (33%) segments (Appendix II Figure 13). These therapeutic areas differ from those identified by experts as the highest-need areas for U.S. patients, like oncology, orphan and rare disease categories. This further suggests that areas of highest viability for importation may differ from U.S. populations with the highest need and potential adoption.[28] Importantly, the issue of patient trust in medicines should be considered. Experts say that despite any decline in revenues, quality of medicines and patient safety is the mission of supply chain stakeholders.

Supply Chain Pathways: Introducing competing products may squeeze already-low margins in the generics space. This potentially reduces the number of viable players, further driving the endemic shortages and drastic price increases in the segment. On the other hand, innovative biopharmaceutical companies, may stop competing for these types of products and shift their focus to more complex and personalized drugs. Some industry leaders contend that lower prices in impacted product categories will lead to reduced investment in R&D to preserve existing margins, though other parties question the extent of this effect.[29]

Distributors may choose to maintain their traditional logistics roles or expand their capabilities and start buying directly from companies beyond U.S. governance and FDA oversight. Similarly, U.S. pharmacies could choose to partner with global pharmacies and evolve to become direct providers to patients. Non-traditional players are also likely to enter the mix. These factors change interactions across the supply chain in the longer term.

Overall, mismatches between importable supply and patient needs, potential revenue loss, and new investment requirements make commercial drug importation a challenging proposition for supply chain stakeholders. The interlock of stakeholders - which today enables appropriate delivery of medicines to patients - will face disruption.

EXPLORING ALTERNATIVES

The drug approval system in the U.S. sets a standard of quality and safety unlikely to be preserved by current proposals on commercial drug importation. For this reason, alternatives should be explored for addressing patient access and high drug costs. It should be noted that the price of a new medicine aims to reflect its value. Pricing systems try to consider therapeutic, economic, demographic, epidemiologic, and other factors that differ across countries and change over time. This flexibility aims to balance access to medicines and ongoing investment in research and development.[30]

Therefore, measures that maintain standards while reducing patient challenges and preserve flexibility for investment in innovation are preferred. For example, modifications to the "Safe Harbor" for manufacturer rebates and progress on drug

[28] It bears reiterating that some therapeutics of note, including insulin, are outside the scope of this analysis due to handling requirements and exclusion from many proposals.
[29] For example, Bach et. al. argue against the position that U.S. pricing is necessary to subsidize global R&D investment ("R&D Costs for Pharmaceutical Companies Do Not Explain Elevated U.S. Drug Prices," *Health Affairs Blog*, March 7, 2017.DOI: 10.1377/hblog20170307.059036). PhRMA and the U.S. Chamber of Commerce have expressed dissenting views (https://catalyst.phrma.org/government-imposed-price-controls-threaten-innovation-and-access)
[30] Global Pricing Flexibility for New Medicines. Global Policy and International Public Affairs, *Pfizer Inc*. October 2017

pricing transparency may be viable paths to channeling savings to patients by 2020.[31,32] The administration and Congress have proposed other initiatives targeted at price reductions,[33] approaches to increase supply and access to generic drugs,[34] and additional price transparency measures.[35,36]

The longer term challenge for the U.S. supply chain will be to strategically evolve global partnerships and regulatory mechanisms to maximize shared benefits and improve global drug approval and review standards. It is important for architects of drug importation approaches to improve their understanding of global economics of product supply, costs of aging populations, shortages, and chronic disease burden that are likely to be issues beyond U.S. borders. These must be considered for sustainable relationships with other governments.

Responsible and transparent standards, traceability, and supply are necessary for global drug standards, approval, and trade. Importantly, systems must be in place to guarantee globalized product quality and safety. Medicines are unique: patients have no easy way to ascertain the authenticity of a given drug, and supply chain disruption can have unintended consequences. Future progress should consider the terms of responsible importation as proposed and aim to address the requirements demonstrated by this study to ensure patient safety.

[31] https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html
[32] Actual patient impact of rolling back Safe Harbor protections is out of scope for this analysis. However, the measure is *intended* to reduce patient cost burden.
[33] Trump Administration proposals, and part of the Prescription Drug Price Relief Act, S.102 (116th) (PDPRA)
[34] Core component of the CREATES Act (S.340, 116th) and associated proposals
[35] PDPRA HR1035 the Prescription Drug Price Transparency Act, and HR1034 the Fair Pricing Act
[36] ANPRM International Pricing Index Model for Medicare Part B Drugs; CREATES Act; Medicare Prescription Drug Price Negotiation Act (H.R. 275, 116th). Implied under public option and Medicare expansion proposals such as the Medicare-X Choice Act (S.981, 116th).

ACKNOWLEDGEMENTS:

A SINCERE THANK YOU TO OUR SPONSORS FOR MAKING THIS STUDY POSSIBLE.

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ABOUT THE HDA RESEARCH FOUNDATION

The HDA Research Foundation is the 501(c)(3) non-profit charitable organization of the Healthcare Distribution Alliance (HDA). The Foundation serves the healthcare industry by providing research and education focused on healthcare supply chain issues. The Foundation's mission is to conduct research and disseminate information that will enhance the knowledge base, efficiency and effectiveness of the total healthcare supply chain; and to provide thought leadership to further enhance the safety and security of the healthcare supply chain through future-focused study and programming.

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APPENDICES:

APPENDIX I: METHODS SUMMARY

This analysis was conducted through a combination of literature review, expert interviews, and quantitative modeling.

The policy baseline was defined through review of existing commentary on importation published by the Congressional Research Service ("Prescription Drug Importation: A Legal Overview," 2008) and FDA summaries ("Milestones in U.S. Food and Drug Law History").

Legislative proposals were identified using the records at Congress.gov, filtering for legislative proposals in the 113th-116th Congresses with the health subject-policy area. Approximately 4,400 bill titles were reviewed to identify those related to pharmaceuticals, and those bills were then reviewed individually to identify twenty-three entries with terms covering importation, representing ten unique proposals. The terms of these policies were also leveraged to shape prompts and questions to be further validated by experts. These were direct inputs into the importation scenarios framework.

Further literature analysis was conducted via review of reports from the last five years produced or sourced via FDA.gov, HHS.gov, the Government Accountability Office, the Congressional Research Service, PubMed, the European Medical Association, and supported by other key sources of perspectives on the topics investigated throughout the analysis. The references of materials leveraged for this research are within the end-notes section.

In parallel, a group of experts were identified as respondents to structured interviews, scenario prompts for consensus development, and validation of assumptions on data (n=22 completed the interview process). These experts satisfied screening questions requirements on experience, depth of knowledge on drug importation and direct experience on elements of execution relating to drug importation. Interviewees were selected such that there was balanced representation from regulators, policy makers, manufacturers, distributors, retail pharmacies and medical advisors.

Interviews were structured, presenting the same prompts and questions to each interviewee. These interviews were conducted by phone and averaged 60 to 90 minutes each. Interviewee answers were logged and if the answer was ambiguous, the input on that question was removed from the final analysis. Interviews were conducted across five areas: regulatory baseline and proposed policy/bills, requirements for responsible importation, regulatory impacts/costs, supply chain stakeholder impacts/costs, patient impact, and general questions about the topic of drug importation.

Literature, data, and interview results were used to develop inputs into the quantitative analysis to model the impacts as outlined in this paper and the appendices.

Quantitative analysis was conducted in four phases.

First, markets of interest and countries of origin were identified by interviewees and validated based on investigation into their history of drug exports and similarity to the U.S. in both approval processes and traceability requirements. Pharmaceutical spending in these countries and in the U.S. were then estimated using data published by IQVIA.

Second, spending was segmented between branded and generic products using data from IHS Markit. These expenditures were then allocated between "in-scope" and "out-of-scope" based on product-level data from EvaluatePharma and the U.S. Drug Enforcement Agency (DEA). Out-of-scope drugs were identified based on route of administration, classification as small molecule or biologic, and presence on the DEA list of controlled substances as of December 2018. In-scope drugs were then filtered to exclude products still under U.S. patents or lacking ex-U.S. competition based on their active ingredients. In-scope dollars were further allocated between market segments based on their target markets and between therapeutic areas. An average conversion factor between international and U.S. pricing was also generated for generic and branded drugs, based on data published by the Canadian Patented Medicine Prices Review Board.

Third, revenue impact analysis was conducted using a simplified model of the U.S. supply chain, under which U.S. manufacturers sell to distributors a discount against their official wholesale acquisition cost (WAC) and distributors sell to pharmacies at a lower discount based on the same official WAC. Pharmacy pricing was simplified to a percentage upcharge against official WAC, as explicit modeling of pharmacy benefit managers was out of scope for this analysis. Total U.S. sales based on IQVIA reports were assumed to represent pharmacy revenues. Manufacturer and distributor sales were then calculated based on a 5%-off-WAC manufacturer discount to distributors and a 4%-off-WAC distributor discount to pharmacies. Potential impacts were estimated based on assumptions that overseas markets could export at most 20% of their in scope sales volume to the U.S., that all *adopted* imports would directly replace sales of existing U.S. products, and average pricing of remaining U.S. products in affected segments would decline at a level proportional to level of adoption. Distributors and pharmacies were assumed to benefit from sales of imported products. Estimates of potential adoption of imports by U.S. patients were not available, so calculations were conducted for a range of adoption levels from 0% (no patients accepting commercial imports) to 100% (patients accept all available commercial imports).

Fourth, operational cost analyses were conducted by first consulting experts as to potential areas of increased cost and then identifying cost metrics that could be used to estimate potential changes. Regulator costs were estimated using FDA budget data and GAO estimates. Manufacturer costs were estimated using product-level data from EvaluatePharma, and cost of patent litigation cases published by the American Intellectual Property Law Association. Distributor costs were estimated based on benchmarks published by the Healthcare Distribution Alliance. Patient costs were estimated using a combination of expert estimates regarding increased AE rates, data from the FDA AE Reporting System (FAERS) and estimates of per-AE and total AE-related costs identified during literature review.

APPENDIX II: REPORT FIGURES

Figures include literature and policy analysis, and quantitative modeling also informed by expert interviews outlined in Appendix III.

Figure 1: Policy Baseline[37,38]

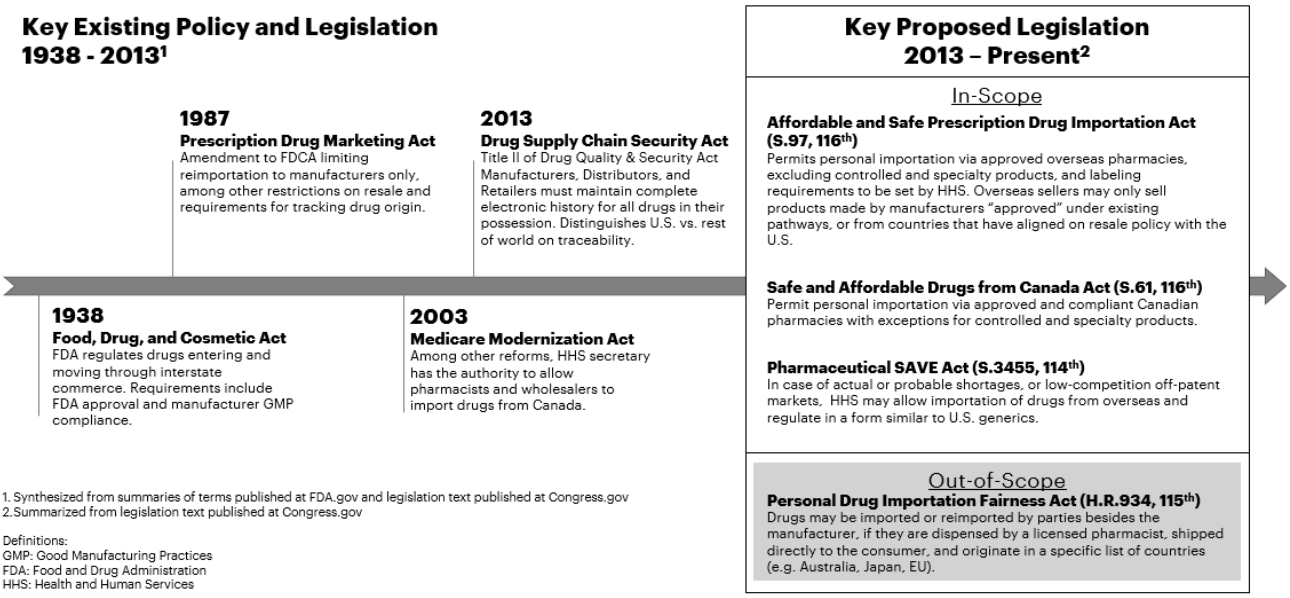


Figure 2: Importation Scenario Framework

"Wide Open"	"Moderated"	"Restricted"
Some restrictions on origin and product type, subject to specific approvals	Subject to specific and well-defined restrictions by product type and country of origin	Only in specific circumstances, subject to restrictions beyond product type and origin
Representative Policy: Affordable and Safe Prescription Drug Importation Act (S.97, 116th) • Permitted from a range of countries at HHS discretion, with options for further expansion • Few restrictions on types of products • No special requirements e.g., patent status, etc. • Importation into all parts of the supply chain, with specific licensure requirements for distributors and pharmacies	**Representative Policy: Safe and Affordable Drugs from Canada Act (S.61, 116th)** • Permitted from a set list of countries at HHS discretion, with no options for expansion • Products largely restricted to non-biologic drugs with no handling requirements • No special requirements regarding patent status, etc. • Drugs may be imported only by end consumers and in limited quantities	**Representative Policy: Pharmaceutical Supply and Value Enhancement Act (S.3455, 114th)** • Minimal country-level guidance; left to HHS discretion regarding country of origin • Products largely restricted to non-biologic drugs with no handling requirements • Specifically excludes drugs that would compete with any existing patented product

[37] Synthesized from summaries of terms published at FDA.gov and legislation text published at Congress.gov
[38] Summarized from legislation text published at Congress.gov

Figure 3: Potential Product Supply Estimation

Figure 4: Key Characteristics of Permitted Countries for Feasibility

	Canada	Germany	U.K.	France	Italy	Spain	EU (All)
History of Exporting to U.S.?	Yes (Personal)	No	No	No	No	No	No
Regulatory comparability (expert panel)?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Significant Shortages (as indicator of supply challenges)?	Yes[39]	Yes[6,40]	Yes[7]	Yes[7,41]	Yes[7,8]	Yes[7,8]	Yes[7,8]
Ability to Export (Est. % volume)	*20%*	*5-15%*	*5-15%*	*5-15%*	*5-15%*	*5-15%*	*NA*

[39] Canadian sources reported as many as 400 drug shortages per month in 2017 following the rollout of the new shortage tracking system. The average duration of known shortages in 2016 was 80 days with a maximum of 414. *Donelle et al, "Assessing Canada's Drug Shortage Problem," C.D. Howe Institute, 2018*

[40] 26% of German outpatient pharmacists surveyed by ABDA in Oct. 2016 reported that shortages had caused a disruption in treatment, and that most shortages impact generics. French shortages increased 30% in 2017 compared to 2016, with similar changes seen in other European (e.g., Netherlands). *"Drug Supply Shortages in Germany," IHS Markit,* 2018

[41] Among pharmacists surveyed by the EAHP in 2018, >75% of Italian, >90% of Spanish, and>95% of U.K., French, and German hospital pharmacists responded that shortages significantly disrupted their ability to provide care or run the hospital pharmacy. >50% of Italian, >70% of Spanish, >85% of English and French, and >95% of German pharmacists also stated that these shortages happened on a weekly or daily basis. 77% of respondents across the EU found generics frequently in short supply, and 65% likewise for branded. Average shortage duration was approximately or at least 2 months for all five countries. *European Association of Hospital Pharmacists 2018 Medicines Shortage Survey*

Figure 5: Out-of-Scope vs. In-Scope Sales[42,43]

Market	Classification	Branded* (2018 est., $b)	Generics (2018 est., $b)	Total (2018 est., $b)
Canada + EU5	***Total***	***138.5 (+/- 6.6)***	***46.2 (+/- 2.0)***	***184.7 (+/- 8.6)***
	Out of Scope *Biologics, Non-Orals, Controlled Substances*	77.8 (+/- 3.7)	22.1 (+/- 1.0)	99.9 (+/- 4.7)
	In Scope *Conventional, Oral*	60.7 (+/- 2.9)	24.1 (+/- 1.1)	84.8 (+/- 3.9)
U.S.	***Total***	***381.8 (+/- 15.1)***	***145.8 (+/- 5.8)***	***527.6 (+/- 20.9)***
	Out of Scope[9,10] *Biologics, Non-Orals, Controlled Substances*	240.9 (+/- 9.6)	68.9 (+/- 2.7)	309.8 (+/- 12.3)
	In Scope *Conventional, Oral*	140.9 (+/- 5.6)	76.9 (+/- 3.1)	217.8 (+/- 8.6)

*Brand covers all products approved in the U.S. as NMEs and covers both patent-protected and off-patent branded drugs

Figure 6: Intellectual Property Considerations

	Segment	Total Inscope Sales	No Off-Patent* U.S. Competitors	Competes with Off-Patent US Product
Canada + EU5	Branded	60.7 (+/- 2.9)	35.4 (+/- 1.7)	25.3 (+/- 1.2)
	Generic	24.1 (+/- 1.1)	9.1 (+/- 0.4)	15.0 (+/- 0.7)
	Total	**84.8 (+/- 3.9)**	**44.5 (+/- 2.1)**	**40.3 (+/- 1.9)**

	Segment	Total Inscope Sales	On-Patent* or no Ex-U.S. Equivalent	Off-Patent with Ex-U.S. Equivalent
U.S.	Branded	140.9 (+/- 5.6)	114.6 (+/- 4.5)	26.3 (+/- 1.0)
	Generic	76.9 (+/- 3.1)	18.1 (+/- 0.7)	58.8 (+/- 2.3)
	Total	**217.8 (+/- 8.6)**	**132.7 (+/- 5.3)**	**85.1 (+/- 3.4)**

U.S. Patent Status and product-level sales estimates from EvaluatePharma

Figure 7: Commercial Segmentation[9,10]

	Segment	Branded	Generics	Total
Canada + EU5	**Hospital Focus** *Conventional, Oral*	4.3 (+/- 0.2)	1.3 (+/- 0.1)	5.6 (+/- 0.3)
	Mixed Focus *Conventional, Oral*	5.1 (+/- 0.3)	2.3 (+/- 0.1)	7.3 (+/- 0.4)
	Primary Care and DTC *Conventional, Oral*	15.9 (+/- 0.8)	11.5 (+/- 0.5)	27.4 (+/- 1.3)
	Total	25.3 (+/- 1.3)	15.0 (+/- 0.7)	40.3 (+/- 1.9)
U.S.	**Hospital Focus** *Conventional, Oral*	5.5 (+/- 0.2)	4.9 (+/- 0.2)	10.4 (+/- 0.4)
	Mixed Focus *Conventional, Oral*	8.5 (+/- 0.3)	10.7 (+/- 0.4)	19.1 (+/- 0.8)
	Primary Care and DTC *Conventional, Oral*	12.3 (+/- 0.5)	43.2 (+/- 1.7)	55.5 (+/- 2.2)
	Total	26.3 (+/- 1.0)	58.8 (+/- 2.3)	85.1 (+/- 3.4)

[42] IQVIA Global Outlook for Medicines Through 2021
[43] Generic and Brand shares from IHS Markit; formulation/makeup and target markets from EvaluatePharma; controlled substances from DEA

Figure 8: Estimated Regulatory Costs[44]

All cost figures in $m	Approach 1	Approach 2
Total FDA Human Drugs Budget and Fees	197.8	
Est. Domestic Inspection Allocation	107.7	80.8
Est. Foreign Inspection Allocation	45.1	72.0
Est. Import Inspection Allocation	45.1	45.1
Total Foreign + Import	90.2	117.1
Est. Cost Increase Factor	3	3
Est. Final Cost	**270.5**	**351.3**

Figure 9: Summary Costs for Manufacturers and Distributors

9a: Manufacturers	Approach 1	Approach 2
Customer Education	Insufficient Data	
Damage Control	Insufficient Data	
IP Litigation[45,46]	$390	$430
Total	$390	$430

9b: Distributors	Approach 1	Approach 2
Inventory[13,47] *Includes Product Recalls*	$210	$630
Warehousing and Shipping[13,14]	$31	$93
Customer Education	Insufficient Data	
Total	$240	$730

9c: Pharmacies
Insufficient Data
NB: No pharmacy cost increases currently identified ***Experts agreed that in the one to three year time frame, pharmacies would not see significant changes in operational cost***

Figure 10: Total Stakeholder Cost Summary

All cost figures in $m	Approach 1	Approach 2
Regulators	270	350
Manufacturers	390	430
Distributors	240	730
Pharmacies	N/A	
Total	900	1,510

[44] 2019 FDA Budget Estimates (retrospective to 2018)
[45] Bloomberg Law, American Intellectual Property Law Association
[46] IQVIA, IHS Markit, DEA, EvaluatePharma
[47] 89th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (2018-2019)

Figure 11: Patient Impact Estimates – Two Methods

	Approach 1 *FAERs; Watanabe et al*	Approach 2 *NEHI*
Adverse Events (AE) (2018) *Excludes Foreign-Reported AEs*	1.4M[48]	N/A
Average Cost per Event (2018) *Adjusted from 2014*[49]	$3.1K[50]	N/A
Cost of Adverse Events	$3.6B	$27.3B[51,52]
Estimated Increase in AEs (expert panel)	~5%	
Estimated Patient Impact	$200M	$1.4B

Figure 12: Estimated Revenue Impact by Stakeholder

Modeling assumes that all importation goes through U.S. distributors and includes the impact of both declining U.S.-origin sales and replacement sales from imported drugs. Sample cases assume that only 33% of in scope ex-U.S. product will be imported.

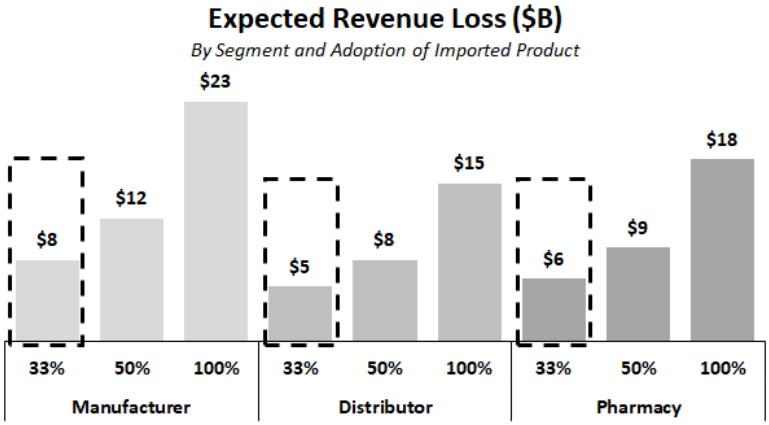


Figure 13: Therapeutic Area Impacts[53]

Therapeutic Area (TA)	"Safe" Sales	Sales "At Risk"	% of TA "At Risk"	Example "At-Risk" Products
Neurology	70.6	18.3	21%	Lamictal (Epilepsy), Abilify (Antipsychotic)
Cardiovascular	11.6	18.6	62%	Ranexa (Chest Pain); Multaq (Arrhythmia)
Genitourinary	19.6	9.7	33%	Cialis, Viagra (ED)
Gastrointestinal	11.9	7.9	40%	Nexium (GERD), Pentasa (IBD)
Endocrine	39.4	8.1	17%	Medrol (inflammatory issues)
Other TAs	289.5	22.6	7%	

Other therapeutic areas: Hematology, Dermatology, Immunodilators, Musculoskeletal, Oncology, Respiratory, Sensory Drugs (e.g., Ophthalmology), Anti-Infectives, and miscellaneous uncategorized products

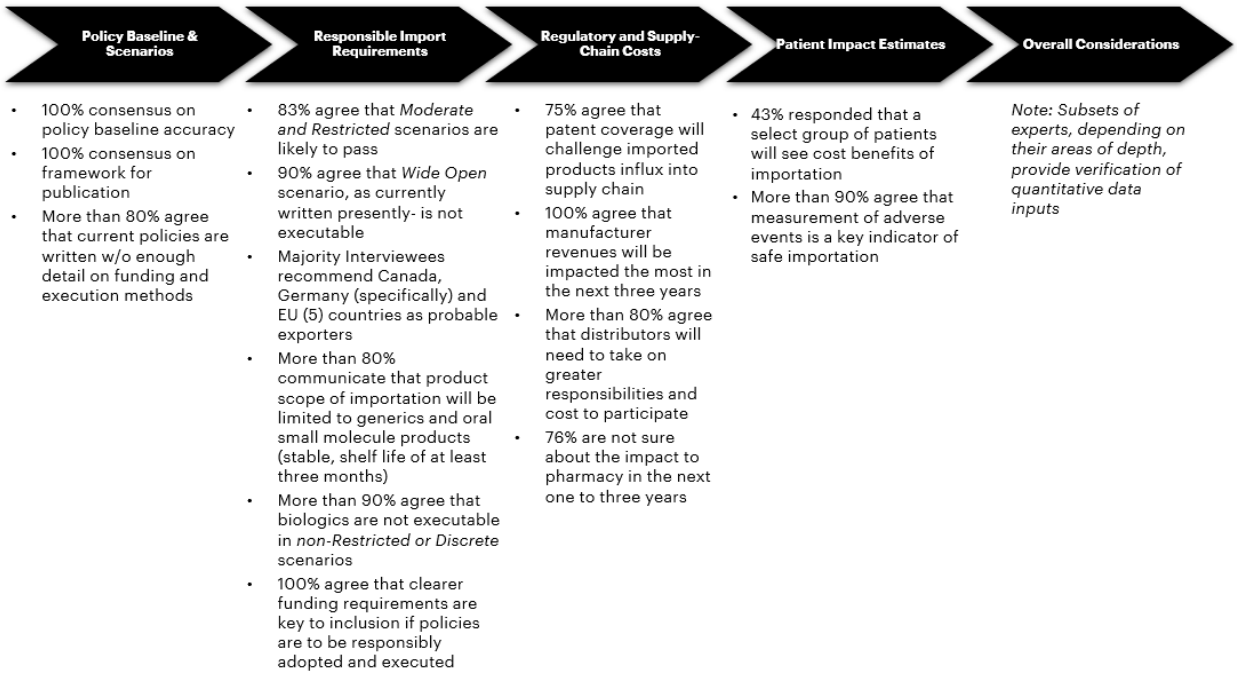
[48] FDA Adverse Event Reporting System
[49] Adjusted from 2014 to 2018 based on health expenditure values from CMS Office of the Actuary
[50] Watanabe, J. H., McInnis, T., & Hirsch, J. D. (2018). Cost of Prescription Drug–Related Morbidity and Mortality. Annals of Pharmacotherapy, 52(9), 829–837. https://doi.org/10.1177/1060028018765159
[51] New England Health Institute. Preventing medication errors: a $21 billion opportunity
[52] Adjusted from 2012 to 2018 dollars based on health expenditure values from CMS Office of the Actuary
[53] Therapeutic area data provided by EvaluatePharma

APPENDIX III: INTERVIEWEE EXPERT PANEL SUMMARY

Figure 1: Expert Credential Summary

• 22 Expert Interviews • Requirements – Minimum 20 years in relevant roles with direct authority and influence over decisions or execution in drug importation-related topics • Structured expert interviews were conducted to enable qualitative and quantitative assessment of consensus • Semi structured interviews were conducted to validate data assumptions	3	Former Lead Advisor, CDER, FDA
	3	Former Global Head, Pharmaceuticals
	2	Former Head of Pharmacovigilance, Pharmaceuticals
	1	Former CMC Review, FDA
	1	Former C-Level Advisor, Regulatory Affairs (cross-stakeholder)
	1	Former Senior Regulatory Lead, Pharmaceuticals
	2	Former Head and General Counsel, Generics Pharmaceuticals
	3	Security/Distribution/Global Ops Lead, Distributor/Wholesaler
	2	Director of Health Policy, Major Pharma Association(s)
	1	Former Director of Policy and Regulatory
	2	Chief Medical Officer, Life Science Industry
	1	Senior Health Policy Advisory to Life Science and Health Industries

Figure 2: Interview Key Points- Top 15



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BIO ISSUE BRIEF

Biotechnology Innovation Organization

DRUG IMPORTATION

#7981

Issue Background

The Food and Drug Administration (FDA) was created to ensure food and medicines sold in the United States are safe for consumers. Today, the FDA's regulatory and enforcement policies are recognized globally as the "gold standard" for safety and efficacy. Some have proposed that to address the cost of prescription drugs, the U.S. should import medicines manufactured in foreign countries, like Canada and China. However, trusted law enforcement and health officials have expressed strong concerns with importing drugs from foreign countries that do not meet the gold standard for health and safety.

Judge Louis Freeh, former director of the Federal Bureau of Investigation (FBI), has warned that legalized drug importation would expose patients to counterfeit or adulterated drugs. He has also said it would strain law enforcement resources and exacerbate the opioid epidemic. According to the National Sheriffs Association, drug importation would "jeopardize law enforcement's ability to protect the public health; threaten the safety of our drug supply; and endanger law enforcement officers, their canines, other first responders."

Additionally, in March 2017, a bipartisan group of former FDA commissioners warned Congress that importation is "likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products." They also noted that importation "will not achieve the aim of [lowering costs]," a view that has been largely reaffirmed by both the nonpartisan Congressional Budget Office and the U.S. Department of Health and Human Services.

Furthermore, drug importation would impose artificial foreign price controls on America's highly innovative drug development ecosystem, which is produces more new drugs than the rest of the world combined. Disrupting that successful ecosystem of biomedical innovation would be devastating to future drug discovery.

Policy Position

The United States is the standard-bearer for ensuring drug safety and efficacy, as well as the world leader in innovative drug development. Importing medicines from foreign countries would undermine public health and do little to reduce prescription drug costs. Policymakers should reject proposals that would endanger the well-being of patients, families and communities or stifle the discovery of new cures and treatments. Instead, policymakers should seek to strengthen a system that encourages biomedical innovation and gives patients peace of mind knowing the medicines they need are safe and effective.

Key Points

- ✓ While Canadian regulators ensure the safety and authenticity of medicines entering their market that are intended for use by patients in Canada, **they do not apply those standards for medicines intended for export only.**
- ✓ Former FDA Commissioner Robert Califf has testified that "while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, **85 percent of such drugs were actually from different countries**."
- ✓ The global market for counterfeit drugs is estimated to be as large as **$75 billion a year.**
- ✓ **96 percent of online drug retailers** are operating out of compliance with U.S. health and safety standards.
- ✓ Any improved access or cost savings for consumers resulting from importation are likely to be minimal — estimates suggest this number would be **less than 1 percent.**

Written Testimony by

Don Bell
Chief Superintendent Ontario Provincial Police (ret.)
Director of Enforcement and Intelligence Canada Border Service Agency (CSBA) (ret.)
Orillia, Ontario, Canada

Submitted on behalf of the Partnership for Safe Medicines
To the North Dakota House Human Services Committee

On Senate Bill SB 2209

Mr. Chairman and members of the committee, I submit this testimony to express my concerns and opposition to passage of SB 2209, which aims to legalize the importation of prescription drugs from Canada. I encourage you to continue your due diligence in studying the issue as is proposed through SB 2212, to examine the public health and safety concerns and the unintended consequences of prescription drug importation.

My concerns and resulting opposition to prescription drug importation is based on my experience as a former Canadian law enforcement officer, combating organized crime groups operating in Canada and along the border with the United States for over three decades. I was a Chief Superintendent in the Ontario Provincial Police and a Director of Intelligence and Enforcement for the Canada Border Services Agency.

While prescription drug importation proposals are well-intentioned to help lower drug prices for average Americans, they are likely to trigger significant, long-lasting and dangerous unintended consequences by greatly expanding the illicit trade in adulterated, substandard and counterfeit drugs.

The Government of Canada has repeatedly stated opposition to any importation proposals, due to the devastating impact this would have on our domestic supply. Our government most recently enacted an interim order on export restrictions for prescription medicines to counter importation proposals and avoid worsening drug shortages.[i]

This lack of genuine supply for any importation program will open the door to foreign and domestic criminals willing to fill the unmet demand with adulterated, substandard or counterfeit drugs. This will include the transshipment of illicit prescription medicines through Canada to make them appear legitimate.

Transshipments provide a significant challenge to law enforcement, since Canadian prescription drugs do not have a Track and Trace system. As such, there is no system in place to trace prescription drugs back to their supply source to verify authenticity and avoid counterfeits, grey market products, adulterated or substandard drugs.

While Canada's pharmaceutical supply chain is very safe, it was built to ensure the safety of drugs entering and being consumed in Canada. Canadian law enforcement and Canadian border agents are resourced to secure the Canadian drug supply, not to protect the safety of prescription drugs for

export or transshipment to the United States. The priority of Canadian law enforcement and border protection is to maintain the safety on inbound packages destined for domestic use.

Canadian Law Enforcement and Border Protection do not routinely inspect outgoing or transshipped packages and cargo, unless presented with actionable intelligence from other law enforcement units or third parties. Transshipments into the United States, including those through Canada already present an avenue for illegal, dangerous, and counterfeit drugs. Legalizing importation schemes from Canada is going to exacerbate this issue.

Criminals are already in the business of supplying fake medicines and have repeatedly shown a disregard for human life and public safety by operating fraudulent Canadian pharmacies, transshipping counterfeit medicines and trafficking in illicit medical supplies. Operation Pangea, an annual global law enforcement operation designed to investigate the online sale of counterfeit and illicit medicines highlights the extent of the issue. During Operation Pangea XIII (conducted March 2020), law enforcement seized over 4.4 million units of counterfeit, adulterated or substandard medicines, medical supplies and devices worth over USD$14 million and took over 2,500 illegal websites offline.[ii] Seized fake medical products related to the COVID 19 pandemic, including unauthorized anti-viral medicines and fake PPE, provided a stark reminder that criminals will exploit every opportunity and every loophole, especially if driven by a lack of genuine supply.

Since legitimate medicines will be unavailable from Canada in sufficient quantities for North Dakota's importation program, criminals will fill that void. Criminals driven by greed will offer medicines that they will claim are Canadian but are anything but. This is not some hypothetical future scenario but has already happened multiple times before.

CanadaDrugs.com is an example of a Canadian online pharmacy operated by two Canadian licensed pharmacists, which was prosecuted by law enforcement for illicit activity. From 2009 – 2012, they sold $78 million worth of unapproved, misbranded, and counterfeit drugs to the U.S. clinics and patients. These drug products included Avastin, a counterfeit cancer medication, which had zero active pharmaceutical ingredients.

And while the impact of the fraud was significant, the prosecution outcome was minimal. The DOJ and the FDA pursued the criminals with the full range of federal tools available, yet none of the ring leaders went to jail. The DOJ had to settle on a penalty of $34 million in fines and six-months of house arrest, commensurate with Canadian sentencing guidelines.[iii] The lure of high profits combined with minimal risk is too attractive for bad actors not to capitalize on.

It may seem appealing to try and address drug pricing with drug importation, but we need to worry about the unintended consequences of such policies for the United States, as well as Canada. In the interest of the public safety of both or our nations I urge you to dismiss SB 2209 and continue your due diligence by studying the issue first, as proposed by SB 2212. Thank you for allowing me to raise my concerns.

Sincerely,

Don Bell

[i] "Health Canada issues new Interim Order to prevent bulk exportation of prescription drugs from Canada", accessed at https://www.pharmainbrief.com/2020/11/health-canada-issues-new-interim-order-to-prevent-bulk-exportation-of-prescription-drugs-from-canada/

[ii] https://www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations

[iii] Volz, M. (2018, April 13). *Canadian pharmacy fined $34 million for illegal imports*. https://www.usnews.com/news/news/articles/2018-04-13/canadian-pharmacy-to-be-fined-millions-for-illegal-imports.

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Doug Burgum, Governor

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Mark J. Hardy, PharmD, R.Ph.
Executive Director

Senate Bill No 2209 – Prescription Drug Importation

House Human Services Committee – Pioneer Room
9:30 AM - Tuesday – March 9th, 2021

Chairman Weisz, members of the House Human Services Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today about Senate Bill 2209 and offer our perspective on this bill, as well as discuss the fiscal aspect of the bill and answer any questions you may have about this legislation.

Certainly, the Board of Pharmacy stands ready and willing to act on any legislation that you determine to be appropriate to be implemented for the State of North Dakota and will assist in whatever capacity needed.

The concept of a *Drug Importation Plan* is certainly not new to the Board of Pharmacy, as previous Executive Director, now Senator Howard Anderson was instrumental in working with Senator Dorgan on some of the efforts back in the early 2000s, to put the legislation in place which is now being acted upon Federally. The model was termed the "*Prairie Prescription Project*."

There is a deep layer of complexity with how this importation may work for the State of North Dakota. We certainly understand and appreciate the need for legislative solutions relative to the pricing of prescription medications. Our Office hears about the issues in pricing models from the public entities, patients and even our pharmacists. The current broken model of drug pricing with the many players involved continues to be a bone of contentious. We also must deal with the flip side, the illicit transportation of medications, purported to be Canadian Drugs that flow to consumers of our State. Often, in fact, these medications are actually adulterated and are shipped from third-world countries that are only marketing themselves as Canadian Drugs, often on the internet.

The proposal in SB2209 sets forth the ability to contract with another state who operates a legitimate process for importation of prescription medications to flow from approved Canadian Wholesalers to the State of North Dakota and sets a fairly complex process for how those medications would actually get to the consumers in our State.

Of note, this legislation is going to place the authority with the Department of Health to determine if it would move forward with a *Drug Importation Program.* To fund the program, the Board of Pharmacy is tasked with providing an appropriation, based on license fee increases set in Section 3 of the bill.

In the prepared fiscal note you will see the revenue associated with the license fee collected by the Board of Pharmacy, which is a fairly accurate representation of increasing licensing fees on the specific business license types in section 3 of the bill from $400 to $1,000.

The Board is requesting an amendment to clarify the appropriation section starting on page 3, line 28. We do not believe the intent is to raise and collect the increase license fees unless a *Drug Importation Program* is planned to be implemented. We do not need to increase these fees for any operations of the Board. We would recommend changing “shall” to “may” on line 29 as well as making it contingent upon initiating a contract with another state.

To be completely transparent, our office sees a difficult path to implement and enforce such a program, both in a process perspective and in the ability to garnish a working model of importation with a Canadian Wholesaler. Our contacts with our counterparts in Canada indicate a deep resistance within the legitimate wholesale channels of Health Canada to assist states developing a *Drug Importation Program*. The Canadian Government has already taken preemptive steps to make exportation from Canada illegal for any medication that could be in a shortage. Furthermore, states that have been more actively soliciting, to our knowledge, have not found suitable partners for a working program.

The Board of Pharmacy will continue to closely monitor other states for any developments, especially if SB2212 and the resulting study are enacted. Certainly, choosing a wholesaler that may not be a legitimate source is definitely *NOT* an option for North Dakota as the health and welfare of our citizens is paramount. The proven integrity of those products must be assured.

We stand ready to assist the State in whatever capacity it determines to move forward.

If you have any questions, I would be happy to answer them at this time.

SB 2209 – Testimony by Dustin Gawrylow (Lobbyist #266) North Dakota Watchdog Network

The North Dakota Watchdog Network opposes efforts this session to create price controls that interfere with the free market - either directly, or by referencing prices in Canada. We also oppose placing North Dakota's economic value in the hands of other states.

We do support the idea of studying ways the state can amend its own laws to help industry make prescription drugs and healthcare generally more affordable. (refer to support of SB 2212)

If that study (SB 2212) goes forward, it is our hope that the committee will bring in experts from industry to discuss in depth the various factors involved that increase the cost of prescriptions.

On the issue of re-importation, the committee should also invite experts from Canada to ask them how their system works as well as if their government would actually let North Dakota or any other state implement such policies.

Again, we support a study as long as it is complete and not just for show - one way or another.

We oppose immediate policy changes until a full study can be completed.

Extra-credit for legislators: Take 45 minutes to watch a discussion I had with Peter Fjelstad, Senior Director of Public Policy of PHARMA on this subject:
https://www.youtube.com/watch?v=7aUQfQ7rX48

March 9, 2021

Chair Weisz and Members of the House Human Services Committee,

My name is Ellen Schafer. I live in Bismarck and I am an advocacy volunteer and member of AARP North Dakota's Executive Council. I am testifying this morning in support of SB 2209 that outlines the process for the safe, legal wholesale importation of prescription drugs from Canada.

The rising cost of prescription drugs impacts all North Dakotans but hits older North Dakotans particularly hard. Most Medicare beneficiaries live on relatively modest incomes. Their ability to absorb increasingly expensive prescription drugs is nearly impossible. Many of my friends, neighbors and family talk about the difficult decisions about how to live because of the price of those drugs.

My sister was diagnosed with chronic lymphocytic leukemia. The medication used to treat her leukemia is called Sprycel. When I testified in support of the drug importation bill in the Senate Human Services Committee, her medication cost $15,000 per month. As of January, this year, the medication she now needs costs $18,000. She is retired and cannot afford this medication. The doctor placed her on a catastrophic list and which has helped her obtain a grant to pay for this medication. The dollar amount of her grant is a total of $8,000.00 per calendar year which only helps her cover 5 months of this medication. After her insurance and the grant loan she still will have to pay $5,677 out of her pocket.

She is very worried if she can't obtain another grant how she will pay for this medication. If she is required to pay for the medication herself, she will have to quit this life saving medication. She is retired and cannot afford this medication. The doctor placed her on a catastrophic list and which has helped her obtain a grant to pay for this medication. The cost of her medication will now be covered until December of 2021. After that she is not sure what will happen. If she is required to pay for the medication herself, she will have to quit this life saving medication.

Another drug the doctor has ordered for her is a respiratory inhaler called Trilogy to help her breathing. This medication currently costs $450.00 a month. She had to quit taking it because she cannot afford to pay for it.

My sister is not alone, AARP research shows that between 2012 and 2017, the average annual cost of prescription drug treatment increased 57.8%, while the annual income of North Dakotans only increased 6.7%. In AARP's 2020 survey of North Dakota adults, 44% of respondents decided not to fill a prescription that their doctor had given them because of the drug's cost. We cannot afford higher drug prices and bills like these would provide more affordable options to bring down the price.

Thank you again for listening to mine and other AARP members concerns as you work on this issue. I wholeheartedly appreciate any effort to make medicine more affordable. These bills are a step in the right direction and I hope you give at least one of these bills a favorable recommendation.

Thank you.

Testimony Prepared for
House Human Services
Donnell Preskey, NDACo
3/9/2021

Chair Weisz and committee members, I'm Donnell Preskey with the North Dakota Association of Counties. One of my roles at NDACo is serving as the Executive Director for the North Dakota Sheriffs and Deputies Association (NDSDA). NDSDA is in opposition to SB 2209 as we feel the issue of importation should be studied first as proposed by SB 2212.

While prescription drug importation proposals are well-intentioned to help lower drug prices for average Americans, they are likely to trigger significant and dangerous unintended consequences by greatly expanding the illicit trade in adulterated, substandard and counterfeit drugs. This in turn will increase the black-market, will require more enforcement and create an unfunded mandate for law enforcement in North Dakota. Studying the issue as proposed in SB 2212 will help flush out some of the concerns raised by stakeholders, including law enforcement, before passing this legislation.

We are members of the Western States Sheriffs' Association (WSSA and the National Sheriffs' Association (NSA) which both have resolution opposing prescription drug importation.

Our reasoning for our concerns are based on the lack of genuine Canadian prescription drug supply, the lack of law enforcement resources and the difficulties for U.S. law enforcement to pursue foreign nationals who violate our laws. Since Canada has stated that it is unlikely to supply U.S. importation programs, the lack of genuine supply opens the door to foreign criminals willing to fill unmet demand with adulterated, substandard or counterfeit drugs.

Most importantly, SB 2209 does not provide any resources for inspections or enforcement. With criminal organizations ready to expand their operations within North Dakota, this creates a significant interior enforcement issue and an unfunded mandate for North Dakota law enforcement. Even if caught by law enforcement, extradition proceedings for Canadian or foreign suspects are very cumbersome and often ineffective for U.S. law enforcement due to jurisdictional limitations.

Law enforcement from across the state is already reporting significant counterfeit prescription drug issues. Communities across North Dakota have been experiencing a significant increase in fatal and near-fatal overdoses, due to counterfeit pills.[i] These Counterfeit pills look identical to legitimate medications, such as oxycodone, hydrocodone, Xanax and other pain and anxiety medication. Importation is likely to make his issue worse, especially without an increase in law enforcement funding, resources, training or specialized equipment.

[i] Dickinson: https://www.kxnet.com/news/local-news/dickinson-police-believe-recent-overdoses-stem-from-counterfeit-medication/
Fargo: https://www.inforum.com/news/crime-and-courts/6595149-Fargo-police-warn-of-potentially-deadly-counterfeit-pills
Devils Lake: https://www.valleynewslive.com/content/news/Devils-Lake-Police-warn-of-fake-prescription-drugs-laced-with-fentanyl-571317651.html
DEA: https://www.dea.gov/press-releases/2020/08/12/dea-reports-significant-increase-counterfeit-pills-minnesota

March 8, 2021

Members of the House Human Services Committee:

On behalf of the organizations below and the thousands of North Dakota patients we represent, we urge you to proceed with caution when considering SB 2209 and other similar Canadian drug importation proposals. Meanwhile, we urge you to support SB 2212 and study these extremely complex issues.

Ensuring patients have access to affordable medicines is critical. However, permitting wholesalers and pharmacists to import medications from Canada — or elsewhere in the world — poses a serious risk to the public's health and safety that should not be ignored. Such proposals undermine important regulatory protections provided by manufacturer oversight and could lead to a host of unintended consequences, including opening our borders to a dangerous supply of counterfeit drugs. Additionally, there is no guarantee that any potential cost savings from these proposals will be passed on to patients.

The patients we work with on a daily basis rely on their medications to keep them healthy. The possible dangers of importing drugs without manufacturer authorization, even from seemingly safe places such as Canada, simply carry too great a risk. Nor is importation the solution to lowering patient costs. We urge you to focus on real solutions that protect the safety of the drug supply and directly address out-of-pocket costs for North Dakota patients.

Sincerely,

Community Liver Alliance

North Dakota Nurses Association

WomenHeart Jamestown

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2209
3/31/2021

Relating to increased access to low-cost prescription drugs; relating to drug wholesaler fees; to provide for a report; to provide a continuing appropriation; to provide for a transfer; and to provide a contingent effective date

Chairman Weisz opened the committee meeting at 10:16 A.M.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Committee Action

Rep. Todd Porter (10:16) moved **Do Not Pass**

Rep. Bill Tveit (10:16) second

Representatives	Vote
Representative Robin Weisz	Y
Representative Karen M. Rohr	Y
Representative Mike Beltz	Y
Representative Chuck Damschen	Y
Representative Bill Devlin	Y
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	Y
Representative Dwight Kiefert	Y
Representative Todd Porter	Y
Representative Matthew Ruby	Y
Representative Mary Schneider	N

Representative Kathy Skroch	Y
Representative Bill Tveit	Y
Representative Greg Westlind	Y

Motion Carried Do Not Pass 13-1-0

Bill Carrier: Rep. Kathy Skroch

Chairman Weisz adjourned at 10:20 a.m.

Tamara Krause, Committee Clerk

REPORT OF STANDING COMMITTEE

SB 2209, as engrossed: Human Services Committee (Rep. Weisz, Chairman) recommends **DO NOT PASS** (13 YEAS, 1 NAY, 0 ABSENT AND NOT VOTING). Engrossed SB 2209 was placed on the Fourteenth order on the calendar.