2021 SENATE HUMAN SERVICES

SB 2170

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

SB 2170
1/27/2021

A BILL for an Act to create and enact chapter 19-03.7 of the North Dakota Century Code, relating to prescription drug costs; and to provide a penalty.

Madam Chair Lee opened the hearing on SB 2170 at 9:00 a.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- States with similar prescription drug systems
- Restrictions on government/manufacturer negotiations
- Drug price fixing
- Free/reduce drug pricing
- Vaccine development
- Pharmaceutical research and development

[9:01] Senator Howard Anderson, District 8. Introduced SB 2170 and provided testimony #3671 in favor.

[9:13] Josh Askvig, State Director, AARP, North Dakota. Provided testimony #3641, #3642, and #3643 in favor.

[9:26] Drew Gattine, Senior Policy Fellow, National Academy for State Health Policy. Provided neutral testimony #3636.

[9:39] Chrystal Bartuska, North Dakota Insurance Department. Provided oral neutral testimony.

[9:43] Scott Miller, Executive Director, North Dakota Public Employees Retirement System (NDPERS). Provided neutral testimony #2293.

[9:53] Roger Roehl, North Dakota Citizen. Provided testimony #3428 in favor.

[10:06] Peter Fjelstad, PhRMA. Provided testimony #3666, #3667, #3668 in opposition.

[10:19] Leah Lindahl, Senior Director, Government Affairs, Healthcare Distribution Alliance. Provided testimony #3702 in opposition.

[10:22] Brett Michelin, Senior Director, State Government Affairs, Association for Accessible Medicines (AAM). Provided testimony #3591 in opposition.

[10:30] John Hoke, Biotechnology Innovation Organization. Provided testimony #3191 in opposition.

Additional written testimony: (8)

Ellen Schafer, Volunteer, AARP. In favor testimony #2993.

Dr. Michael Worner, Fargo Citizen. In favor testimony #3509.

Tom Schatz, President, Council for Citizens Against Government Waste. Opposition testimony #3385.

Richard Glynn, Executive Director, Bioscience Association of North Dakota. Opposition testimony #3534

Rebecca Fricke, Chief Benefits Officer, NDPERS. Neutral testimony #2295.

Derrick Hohbein, Chief Operating & Financial Officer, NDPERS. Neutral testimony #3394.

Daniel Weiss, Senior Executive Director, Sanford Health Plan. Neutral testimony #3465.

Alex Sommer, Lobbyist, Prime Therapeutics. Neutral testimony #3675.

Madam Chair Lee closed the hearing on SB 2170 at 10:33 a.m.

Justin Velez, Committee Clerk

,Senate Bill 2170

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 Dakota Public Employee Retirement System and the North Dakota Workers Compensation Program and then, by design, the rest of North Dakotans when and if the plan works for those programs.

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.

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. This is not price controls, this is a negotiating tool to put pressure on manufacturers to give us a good price. Much like the person who goes to Bill at Bill's Ford to bargain for a car. Bill gives him a price and he goes to Joe's Ford down the street and says, "gee I can get the same car at Bill's ford for one thousand dollars less, how about a deal".

Reference pricing is built on the ability to get data on the published prices paid by the four most populated provinces in Canada, getting the average or perhaps taking the lowest one and then saying, "This is the maximum North Dakota will pay for these drugs".

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.

Oklahoma was the first state to adopt this approach and I have heard some Oklahomans express that they need others to get on board so the manufacturers will decide they need everyone's business and not refuse to sell to our small states, which is one of the risks. There are penalties in the bill for a manufacturer withdrawing products, but we would hope that will not become necessary.

Now Canada may not be happy with us piggybacking on their successful efforts to hold prescription drug prices down in their country. There is a risk, if we are successful, prices might rise north of the border. They might also go down here. Perhaps we could get President Biden to trade lower drug prices for the Keystone XL pipeline.

I did see a recent article where 93 Canadian drug company executives were complaining that Canadian efforts to lower drug prices even more were going to cause delays in new product launches, etc. Just like we hear on this side of the border.

Here is how the Canadians look at their pricing system: Based on a letter from Counsel General Delouya

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 industrialized 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.

This bill seeks to give North Dakotans the same power over pricings as reflected above in a letter from Ariel Delouya the Counsel General of Canada.

Thank you,

Howard

#3641

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.

#3642

How North Dakota Residents Are Impacted By High Rx Costs

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

House Human Services Committee
SUPPORT - SB 2170
Prescription Drug Price Indexing
January 27, 2021
Josh Askvig, AARP North Dakota
jaskvig@aarp.org – (701) 355-3642

Chairwoman Lee and members of the Senate Human Services Committee, my name is Josh Askvig, State Director 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. 88,000 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 right now, not only at the

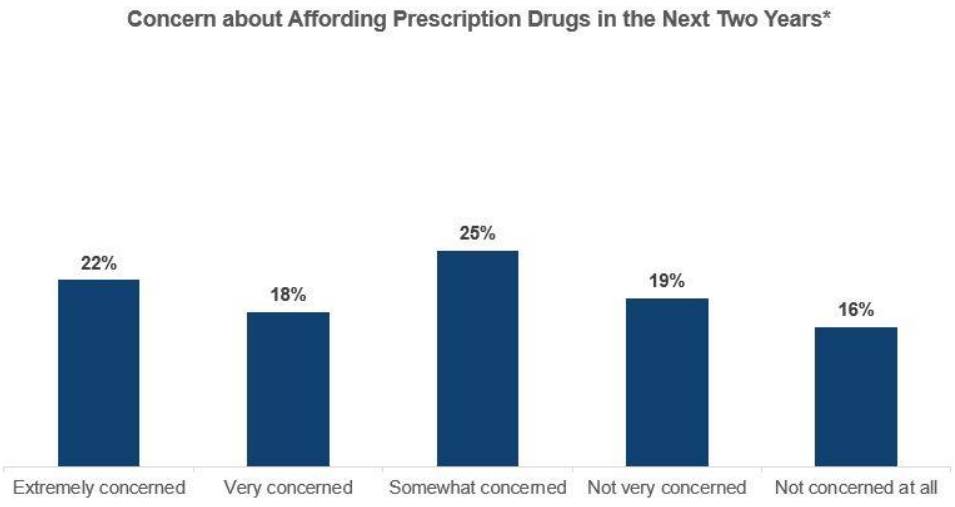
state level, but at the federal level as well. Let me outline just a couple of the reasons why.

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.

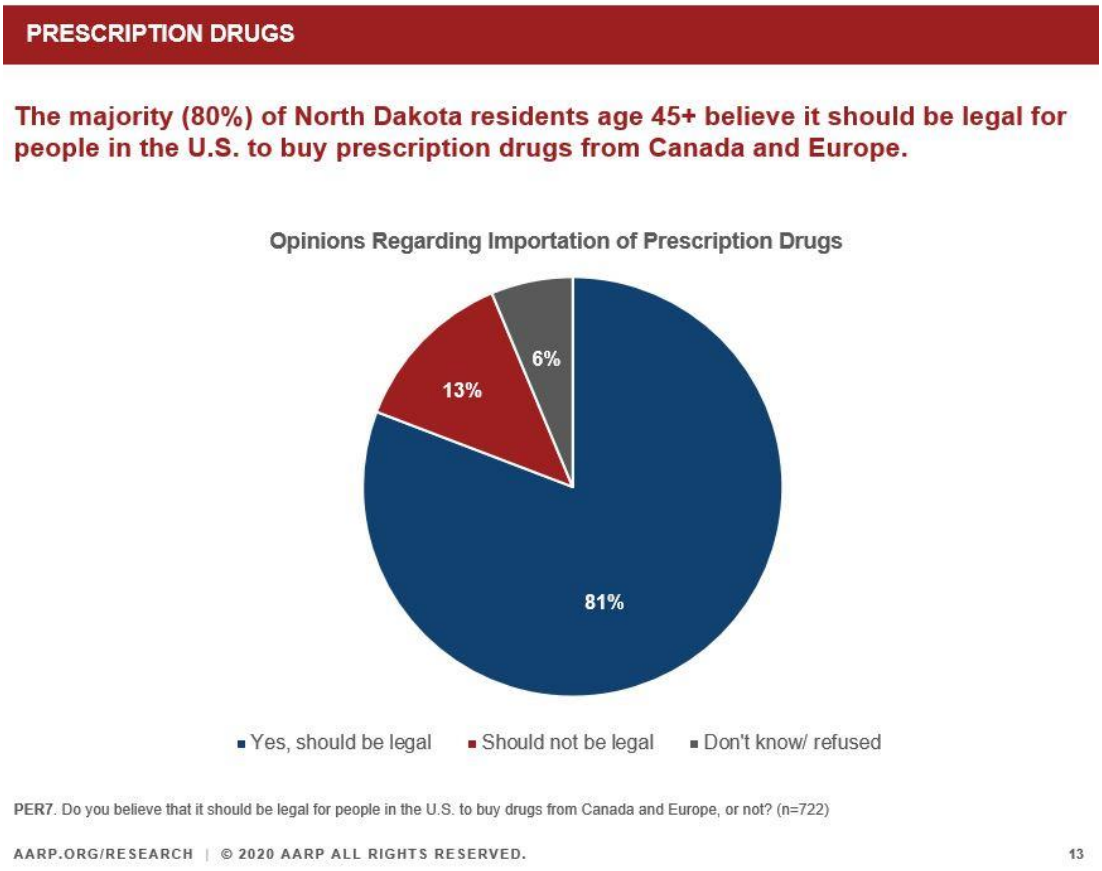
PRESCRIPTION DRUGS

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 self-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? Simply because he moved from his PERS plan to Medicare.

Drug prices in other countries are often many times lower than in the United States. SB 2170 which is based on a model bill developed by the National Academy for State Health Policy or NASHP, determines payment rates for certain prescription drugs based on international prices, and establishes the referenced rate as the upper payment limit for payers within a state.

SB 2170- which would outline a process for setting a payment rate in reference to international prices does not dictate what a manufacturer can charge for a drug – but it does limit how much payers in a state pay- is one approach that some states are considering to relieve consumer's financial burdens. This bill proposes using price data from the four most populous Canadian provinces (Ontario, Quebec, British Columbia, and Alberta) to compare drug prices between the United States and Canada. After that comparison the bill uses the lowest price as the referenced rate for payers in a state. If prices are not available for the provinces, the model act instead refers to the ceiling price set by Canada's Patented Medicine Prices Review Board (PMPRB) for referenced rates, which are posted online.

Prices in Canada can be dramatically lower than in the United States. While a number of states have passed laws to import drugs from Canada in order to

capture those savings, this model act allows a state to “import” the drugs’ prices instead of the actual drugs.

For example, the drug Xeljanz is $76.07 for a 5-mg tablet in the United States, while the lowest price for the drug across Canada’s four largest provinces is $16.96. The table below from NASHP provides additional comparisons, with savings ranging from 60 to 85 percent off US prices, for an average savings of 75 percent for these examples.

Drug*	US (NADAC)**	Quebec	Alberta	Ontario	British Columbia	Canadian PMPRB Maximum Price
Xeljanz [5 mg] *(rheumatoid arthritis)*	**$76.07**	$16.96	$ 17.49	$17.59	$ 18.47	$21.28
Eliquis [2.5 mg] *(anticoagulant)*	**$7.53**	$1.17	$1.19	$1.19	$1.29	$2.78
Eplcusa [400/100 mg] *(hepatitis C)*	**$869.05**	$521.43	$521.43	$521.43	$531.86	$722.86
Zytiga [250 mg] *(cancer)*	**$87.63**	$20.68	+	+	+	$36.96

* Prices, effective as of June 2020, represent unit cost (i.e., per tablet, pill, etc.) in US dollars, converted at an exchange rate of $1 CAN = 73 cents USD.

+ Price not available online.

International referenced rates is a cost savings strategy, allowing states to import more affordable drug payment rates from Canada as an alternative to importing

actual drugs. Furthermore, federal law prohibits the importation of several major classes of drugs, such as controlled substances, biological products, infused and parenteral drugs, intravenously injected drugs, and drugs inhaled during surgery. International referenced rates can help reduce costs for drugs that are ineligible for importation – for example Humira, a medication for rheumatoid arthritis.

Rate setting is already in use. For example, determining maximum payment levels or payment rates for health care and other public goods is a practice that has existed for decades. States regulate insurers and other public goods and services in markets with little or no market competition and set payment rates for health services through their public purchasing. This bill extends that precedent to prescription drugs by using Canadian prices as reference points to set fair payment rates.

Under SB 2170, as outlined on page 3, lines 16-25 directs participating plans to utilize savings to reduce costs for their members. Participating plans must submit a report to the Insurance Commissioner indicating how much they saved by participating and how they passed those savings on to consumers. Self-insured plans that elect to opt-in to the program must also accept these terms as conditions for their voluntary participation.

Thank you again for your thoughtful work on this issue. We wholeheartedly appreciate the effort to make medicine more affordable. This bill is a step in the right direction and we look forward to working with you to make it the best possible bill for North Dakotans.

NASHP NATIONAL ACADEMY FOR STATE HEALTH POLICY Center for State Rx Drug Pricing

Testimony of the National Academy for State Health Policy on SB 2170 - An Act to Create and Enact Chapter 19-03.7 of the North Dakota Century Code, Relating to Prescription Drug Costs; and to Provide a Penalty

Madam Chair and Members of the Committee,

My name is Drew Gattine and I am a Senior Policy Fellow at the National Academy for State Health Policy (NASHP). NASHP is a non-partisan forum of state policy makers that works to develop and implement innovative health care policy solutions at the state level. At NASHP we believe that when it comes to health care, the states are a tremendous source of innovative ideas and solutions. We approach our work by engaging and convening state leaders to solve problems. We conduct policy analysis and research and we provide technical assistance to states.

In 2017 NASHP created its Center for Drug Pricing to focus attention on steps that states can take to tackle the spiraling costs of prescription drugs and the impact it has on consumers, the overall cost of health care and state budgets. NASHP's Center for Drug Pricing develops model legislation for states and provides technical assistance and support to legislators and executive branch leaders who wish to move them forward. When these bills pass, NASHP continues to support states as they are implemented.

The bill before the Committee today, SB 2170, is based on one of NASHP's model bills. Because NASHP is not an advocacy organization we do not take a position "for" or "against" a bill but we do stand by to answer questions and provide technical support for sponsors and legislative committees.

I think we are all aware that when compared to citizens of other countries, Americans pay a lot more for prescription drugs and that the rising cost of prescription drugs is a huge driver in the overall annual increase in health care costs that Americans experience routinely. Other countries spend less for the same drugs because they set rates for prescription drugs. In the United States, rate setting is the norm for many health care services. Public programs like Medicaid or Medicare, and commercial payers routinely negotiate rates. But when it comes to prescription drugs, the United States has a very complicated payment and distribution system that is fundamentally rooted in the manufacturers dictating the price.

States could undertake to do this work themselves but the process of rate setting is complicated, labor intensive and would require a lot of work and up-front investment in resources. Most states don't have the infrastructure to do that work and for many it would be a barrier to build it, even though there is a potentially big pay-off. The good news is that other countries are already doing this analytical work and the results of that work are readily and publicly available for states to use.

NASHP Center for State Rx Drug Pricing

This bill directs North Dakota's Insurance Commissioner to determine the top 250 costliest drugs, using a list from the North Dakota Public Employees Retirement System as the benchmark. This list is then compared to publicly available information from the four most populous Canadian provinces (Ontario, Quebec, British Columbia, and Alberta) and directs that the lowest price becomes the reference rate for payers (state entities other than Medicaid, commercial payers and ERISA plans that chose to participate).

Referencing North Dakota rates to Canadian rates should lead to significant savings to the state and to commercial payers. NASHP stands willing to work with North Dakota to develop state specific savings estimates, but the chart below, using national data, demonstrates the magnitude of the possible savings:

Drug Name & Dosage Source: National Average Drug Acquisition Cost (NADAC) data	US Price (NADAC)	Canadian Reference Rate*	Price Difference	Savings off US Prices
Humira syringe (40 mg/0.8 ml) (arthritis, psoriasis, Crohn's)	$2,706.38	$541.29	$2,165.09	80%
1 ml of Enbrel (50 mg/ml syringe) (arthritis, psoriasis, Crohn's)	$1,353.94	$272.28	$1,081.66	80%
1 ml of Stelara (90 mg/1 ml syringe) (arthritis, psoriasis, Crohn's)	$21,331.28	$3,267.64	$18,063.64	85%
1 ml of Victoza (2-pak of 18 mg/3 ml pen)* (diabetes)	$103.44	$17.30	$86.14	83%
Truvada tablet (200 mg/300 mg) (PrEP for HIV)	$59.71	$19.78	$39.93	67%
Xeljanz tablet (5 mg) (rheumatoid arthritis)	$76.07	$17.50	$58.57	77%
Epicusa tablet (400 mg/100 mg) (hepatitis C)	$869.05	$541.32	$327.73	38%
Zytiga tablet (250 mg) (cancer)	$87.63	21.47	$66.16	75%

The bill requires that any savings generated by implementing the reference rates – whether generated by state entities or commercial health plans – be used to reduce the health care costs of the people of North Dakota.

As the Committee continues its work on this bill NASHP is available to support your work as necessary. Prior to drafting its latest round of model legislation, NASHP engaged with a team of legal experts to design legally sound approaches that can withstand the inevitable challenges from manufacturers and their allies. NASHP has made our legal analysis available on our website. (https://www.nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/). The NASHP website also contains other materials (Written Q&A, Blog Articles, etc.) that may be useful material for the Committee. Thank you.

Drew Gattine
NASHP Senior Policy Fellow
Email: dgattine@nashp.org
Phone: (207) 409-3477

TESTIMONY OF SCOTT MILLER

Senate Bill 2170 – Canadian Reference Drug Pricing

Good Morning, my name is Scott Miller. I am the Executive Director of the North Dakota Public Employees Retirement System, or NDPERS. I am here to testify in a neutral position regarding Senate Bill 2170.

SB 2170 would impose price controls on prescription drugs sold in North Dakota by implementing reference-based pricing using prevailing drug prices in Canada as the reference price. The Insurance Commissioner will be required to set a list of the top 250 drugs each year based on cost data provided by NDPERS, and then must determine the referenced rate for each drug by comparing to Canadian provincial drug costs. The Bill goes on to impose penalties on sellers who violate those prices, or who pull out of North Dakota. This bill does not comply with the statutory requirement that mandates first apply to the NDPERS group insurance plan.

Unfortunately, our consultant, Deloitte, was unable to estimate the actuarial impact of this bill based on the information available, the number of assumptions that would need to be made, and the uncertainty of how the bill could be implemented and administered. They noted that if the price controls required by this legislation cause companies to lose money, it is likely they will withdraw from the state and jeopardize access to needed medications for North Dakota residents.

There could also be questions as to the availability and willingness for the Canadian supply chain to provide cost details to the Insurance Department as the basis of the reference price. Further, all participants in the American supply chain would need to reduce pricing enough so that the total cost to pharmacies is below the reference rate, or local pharmacies may ultimately end up being reimbursed by payors less than their cost to acquire those drugs. This could put local North Dakota pharmacies in jeopardy.

Deloitte also noted that the reference rates required by this bill may conflict with federal most favored nation (MFD) requirements which restricts manufacturers from offering rates lower than what the federal government pays for Medicaid.

Finally, there are a few very large wholesalers that distribute the majority of drugs throughout the country, and they are unlikely to establish offices in North Dakota as required by this bill. If so, this could significantly reduce the availability of medications.

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.

21.0611.01000

FISCAL NOTE

Requested by Legislative Council
01/11/2021

Bill/Resolution No.: SB 2170

1 A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2019-2021 Biennium		2021-2023 Biennium		2023-2025 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues						
Expenditures						
Appropriations						

1 B. **County, city, school district and township fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

	2019-2021 Biennium	2021-2023 Biennium	2023-2025 Biennium
Counties			
Cities			
School Districts			
Townships			

2 A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

SB 2170 would impose price controls using RX drug prices from Canada as the reference using a list of the 250 top NDPERS drugs.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

NDPERS consultants are unable to estimate the actuarial impact based on the information available.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*

A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

N/A

B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

The fiscal impact can not be determined.

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation or a part of the appropriation is included in the executive budget or relates to a continuing appropriation.*

The fiscal impact can not be determined.

Name: BRYAN REINHARDT
Agency: NDPERS
Telephone: 17013283919
Date Prepared: 01/13/2021

#3667

Comparing the Availability of New Medicines in the United States and Other Countries

	New Medicines Available	Average Delay in Availability of New Medicines
Greece	16%	31 months
Ireland	41%	20 months
Belgium	44%	22 months
Czech Republic	44%	24 months
Canada	46%	15 months
France	50%	18 months
Finland	51%	16 months
Italy	51%	20 months
Japan	51%	16 months
Netherlands	53%	7 months
Denmark	54%	12 months
Austria	58%	11 months
United Kingdom	59%	18 months
Germany	63%	10 months
United States	87%	0-3 months

Source: PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data. June 2020. Note: New Ac ive Substances (NASs) approved by the FDA, EMA and/or PMDA and first launched in any country between January 2011 and December 2019. Average delay represents the ime in months since global first launch among NASs that have launched in a given country. IQVIA reports only the retail channel for Greece. Updated July 2020

Comparing the Availability of New Cancer Medicines in the United States and Other Countries

	New Cancer Medicines Available	Average Delay in Availability of Cancer Medicines
Greece	16%	41 months
Ireland	53%	23 months
Belgium	55%	25 months
Czech Republic	55%	24 months
Italy	58%	21 months
Japan	58%	23 months
Canada	59%	14 months
Finland	61%	14 months
Netherlands	63%	9 months
Denmark	64%	11 months
France	67%	16 months
Austria	68%	11 months
United Kingdom	70%	12 months
Germany	73%	11 months
United States	96%	0-2 months

Source: PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data. June 2020. Note: New Ac ive Substances (NASs) approved by the FDA, EMA and/or PMDA and first launched in any country between January 2011 and December 2019. Average delay represents the time in months since global first launch among NASs hat have launched in a given country. IQVIA reports only the retail channel for Greece. Updated July 2020

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to North Dakota
SB 2170 – Canadian Reference Pricing
January 20, 2021

Position: PhRMA respectfully opposes Senate Bill 2170 – Canadian Reference Pricing because it would place a price control on prescription drugs which could stifle innovation, limit patient access to medicines, and raises significant legal concerns.

This proposed legislation requires state-regulated commercial insurance plans to cap the amount they pay for prescription medicines at a reference price, essentially placing a price control on these medicines. This kind of legislation will not benefit patients and can jeopardize the competitive market that works to drive down drug prices. Proposals such as this that arbitrarily cap pharmaceutical prices fail to recognize the complexity of the pharmaceutical supply chain.

Implementing price controls, at a time when the industry has been tirelessly dedicated to finding treatments and vaccines for COVID-19, diverts industry resources elsewhere and risks current and future innovation. We are in a new era of medicine that is bringing revolutionary, innovative treatments, therapies, and cures to patients. Last year alone, the cancer death rate saw the biggest one-year drop in history.[1] Unfortunately, this radical policy would freeze new, life-saving innovation and force patients to face the uncertainty of a health care system where the government sets prices for critical medicines, similar to what is done in foreign countries.

International reference pricing could threaten drug development and replaces market competition with government price setting.

This legislation replaces market competition with government price setting or price controls, basing U.S. medicine prices on the policies of foreign governments that ration care in their own countries. The legislation threatens to drastically reduce development of new medicines at a time of remarkable scientific promise, undermining U.S. global leadership in biopharmaceutical innovation. Price controls diminish the incentive for biopharmaceutical manufacturers to invest in the research and development of new medicines. By requiring state-regulated commercial insurance plans to cap the amount they pay for the prescription medicines at a reference price, this creates a price control on these medicines that could have the long-term effect of decreasing access to medications.

On average, it takes more than 10 years and $2.6 billion to research and develop a new medicine. Just 12% of drug candidates that enter clinical testing are approved for use by patients. Efforts to impart price

[1] Facts and Figures 2019: US Cancer Death Rate has Dropped 27% in 25 Years, Cancer.org, https://www.cancer.org/latest-news/facts-and-figures-2019.html.

controls on innovative manufacturers could chill the research and development of new medicines by taking away the incentives that allow manufacturers to invent new medicines. Price controls also could severely reduce patients' access to medicines, as is seen abroad.

For years, Canada has imposed price controls and other measures that significantly undervalue innovative medicines developed in the United States. Research shows that U.S. patients enjoy earlier and less restrictive access to new therapies,[2] a finding that is reinforced by the United States Department of Health and Human Services' own analysis of Medicare Part B drugs which showed that only 11 of the 27 drugs examined (41 percent) were available in all 16 comparator countries, nearly all of which have single payer health care systems.[3]

In fact, American patients have faster access to more medicines than patients anywhere else in the world, and doctors and patients work together to decide which medicine is right for them. In countries that use international reference pricing and other government price controls, patients can access fewer new medicines and face long treatment delays. Nearly 90% of new medicines launched since 2011 are available in the United States compared to just 50% in France, **46% in Canada** and 41% in Ireland – countries that use some form of international reference pricing.[4] Even the medicines available in these countries take much longer to reach patients. On average, patients must wait at least 18 months longer in France, **15 months longer in Canada**, and 20 months longer in Ireland than in the U.S.

By importing prices set in other countries, this legislation also imports cost-effectiveness analyses that are known to be discriminatory.

Studies using cost-effectiveness analysis (CEA) relies on the use of discriminatory Quality Adjusted Life Years (QALYs) and cost-per-QALY thresholds. Developed from population averages, QALYs ignore important variability in patients' individual needs and preferences. Experts have identified that QALYs discriminate against people with disabilities by placing a lower value on their lives. A report issued by the National Council on Disability in 2019 "found sufficient evidence of the discriminatory effects of QALYs to warrant concern, including concerns raised by bioethicists, patient rights groups, and disability rights advocates about the limited access to lifesaving medications for chronic illnesses in countries where QALYs are frequently used."[5]

Value frameworks can be useful decision-support tools, but should not be viewed as providing a single, universally applicable answer to questions about a treatment's value. Value frameworks typically emphasize one of several perspectives (e.g., payer, patient, society, or innovator) and conclusions may not apply to individual patients. In addition, as with any economic model, value frameworks involve making choices about methods, assumptions and data that can yield important differences in results depending on the choices made. This is reflected in the disparate assessments produced by different frameworks. These factors, combined with lack of consensus on best practices and inconsistency in level of transparency, underscore the need to construct and use value frameworks appropriately. Experience in some countries outside the U.S. illustrates how value frameworks can be used in ways that deny access to care options that clinicians and patients recognize as highly valuable.

[2] IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost, May 2017.
[3] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018.
[4] https://catalyst.phrma.org/setting-the-record-straight-on-international-reference-pricing
[5] National Council on Disability, "Quality-Adjusted Live Years and the Devaluation of Life with Disability." November 6, 2019 (cite cover memo).

In countries that rely on CEA to determine coverage and payment, many patients face significant restrictions on access to treatments, including those diagnosed with cancer, diabetes, and rare diseases. A recent analysis noted that these types of cost-effectiveness assessments and recommendations, based on population-averages, fail to properly adjust to the demands of an evolving health care system and do not reflect the rapid pace of the science, or the needs and preferences of the patients.[6]

This legislation raises significant legal concerns.

This legislation raises a number of constitutional concerns.

The proposed legislation specifically caps prices payors and pharmacies may pay for a drug at an international benchmark (Canadian prices) which raises federal patent preemption concerns. Price controls have historically been found unconstitutional. Specifically, in the case of *BIO v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 1997), the court overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the D.C. law conflicted with the underlying objectives of the federal patent framework by undercutting a company's ability to set prices for its patented products. The court's decision stated, "The underlying determination about the proper balance between innovators' profits and consumer access to medication …is exclusively one for Congress."

This legislation gives the Superintendent of Insurance broad discretion to determine which products will be subject to a price control, and biopharmaceutical manufacturers are not provided due process at any stage of the Superintendent's determinations. In addition, there is no clear mechanism for a biopharmaceutical company to appeal a penalty from the Superintendent of Insurance and/or Attorney General.

Finally, this legislation regulates extraterritorial transactions and discriminates against manufacturers that sell patented products in foreign nations, raising Dormant Commerce Clause and Foreign Commerce Clause concerns respectively.

This legislation fails to recognize the role of the pharmaceutical supply chain in setting prices and fails to address patients' barriers to accessing care, particularly the costs patients pay at the pharmacy counter.

This legislation fails to recognize the role the pharmaceutical supply chain plays in the net price of a medicine. Biopharmaceutical companies that research, develop and manufacture medicines retain only 54% of total point-of-sale spending on brand medicines, with the remaining 46%, a staggering $166 billion in 2018, going to other members of the supply chain in the form of rebates and discounts.[7] This bill is affixing price controls without addressing actors within the supply chain who set the price a patient pays.

Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as making monthly costs more predictable, making cost sharing assistance count toward meeting plan out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients.

[6] Context Matters. NICE Limits Reimbursement for Oncology Products beyond EMA Product Labeling. May 2014.

[7] BRG: Revisiting the Pharmaceutical Supply Chain 2013-2018. January 2020

Discounts to plans and PBMs are growing while net prices remain under the rate of inflation, yet patients are being asked to shoulder a greater burden.

- Half (49%) of commercially insured patients' out-of-pocket spending for brand medicines in 2019 was based on the full list price.[8] This means that cost sharing did not consider any rebates or discounts in that scenario.
- The use of four or more cost-sharing tiers is becoming more common by rising from just 4% of all employer plans in 2005 to 45% by 2019.[9]

Sharing negotiated discounts could save patients a significant amount of money at the pharmacy counter. A recent report by Milliman estimates some patients would save over $1,000 per year on their prescription drug costs of rebates were shared with patients.[10] Any attempts at addressing drug affordability should start there.

The biopharmaceutical sector is committed to bringing new treatments and cures to patients. This commitment to innovation supports high-quality jobs and is a vital part of North Dakota's economy and its economic competitiveness. The biopharmaceutical sector directly accounted for more than 800 jobs in North Dakota through 2019. These jobs generate over $10 million in state and federal tax revenue. This bill could place these jobs, and tax revenue, in jeopardy.

PhRMA recognizes the access challenges faced by patients in North Dakota with serious diseases. **However, this legislation will stifle innovation and does nothing to address patient access and affordability.** In addition, this legislation raises a number of constitutional concerns including due process and patent preemption. PhRMA stands ready to work with the legislature to develop market-based solutions that help patients better afford their medicines at the pharmacy counter.

We respectfully oppose SB 2170 and ask for an unfavorable vote.

8 IQVIA. Medicine Spending and Affordability in the U.S. August 2020. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us

[9] Id.

[10] Point of Sale Rebate Analysis in the Commercial Market: Sharing Rebates May Lower Patient Costs and Likely has Minimal Impact on Premiums. Milliman, Inc. October 2017

Healthcare Distribution Alliance

PATIENTS MOVE US.

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

January 26.2020

Re: Healthcare Distribution Alliance (HDA) Opposition to SB 2170

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

On behalf of the Healthcare Distribution Alliance (HDA), representing 35 primary pharmaceutical wholesale distributors, I am writing in opposition to Senate Bill 2170 and the inclusion of pharmaceutical wholesale distributors within the legislation.

Wholesale distributors serve as the critical logistics provider within the healthcare supply chain. As a patient enters a pharmacy, there is a level of expectation that your prescription, or any number of over-the-counter medications and medical supplies, will be readily available when you arrive. Wholesale distributors are the reason patients can take that process for granted. HDA members work 24 hours a day, 365 days a year to ensure over 15 million healthcare products are delivered to more than 180,000 pharmacies, hospitals, nursing homes and other healthcare settings nationwide.

Distributors are unlike any other supply chain participants – their core business does not involve manufacturing, marketing, prescribing or dispensing medicines, nor do they set the list price of prescription drugs, influence prescribing patterns or determine patient-benefit design. Their key role is to serve as a conduit for medicines to travel from manufacturer to the provider while making sure the supply chain is fully secure, fully functional, and as efficient as possible. Due to these efficiencies, HDA member companies generate between *$33 and $53 billion in estimated cost savings each year* to our nation's healthcare system.[1]

HDA and our member companies appreciate the legislation's intent to decrease healthcare costs for patients, however we believe Senate Bill 2170 fails to accurately reflect the complexity of the healthcare supply chain. A wholesale distributor is responsible for fulfilling pharmacy customer orders. Wholesale distributors have no insight into patient-level data, nor are they privy to how products are dispensed at the patient-level by the pharmacy. Similarly, at the time of the purchase from the wholesale distributor, a retail pharmacy is unaware of which patient would receive the medication and what coverage that individual would have. Establishing a cap on the purchase price of a pharmaceutical product by the retail

[1] The Role of Distributors in the US Health Care Industry Report; https://www.hda.org/resources/the-role-of-distributors-in-the-us-health-care-industry

pharmacy does not accurately reflect the supply chain, as health plans reimburse retail pharmacies for drugs when they are dispensed to enrollees in their plan.

Furthermore, the determination not to sell a product to a state would fall outside of the wholesale distributor's authority, this determination would occur at the direction of the manufacturer who could impose such conditions on the sale of the product to the wholesaler. Wholesale distributors should not be subject to the penalty provided within section 19-03.7-07. Enforcement-Penalty if they are acting at the direction of the manufacturer.

Ultimately, the services provided by the healthcare wholesale distribution industry result in benefits to healthcare system, patients and consumers while also making the U.S. pharmaceutical supply chain one of the safest and most efficient in the world. The industry has accomplished these objectives without impacting the overall cost of prescription drugs. Due to the reasons stated above, HDA opposes SB 2170 and we respectfully request an unfavorable vote.

Thank you,

Leah Lindahl
Sr. Director, State Government Affairs
Healthcare Distribution Alliance
LLindahl@hda.org
(303) 829-4121

#3591

January 26, 2021

Senator Judy Lee
Chair, Senate Human Services Committee
1822 Brentwood Court
West Fargo, ND 58078-4204

Dear Chairwoman Lee and Committee Members,

The Association for Accessible Medicines (AAM) is opposed to Senate Bill 2170, which establishes price controls in the United States based on reference pricing from four Canadian provinces. AAM represents the manufacturers and distributors of generic and biosimilar medications and works to ensure generic and biosimilar medicines are more accessible to the people who need them. Generic medications represent 90% of all prescriptions filled but only 20% of prescription drug spending in the United States. In 2019, the use of generic medicines saved $313 billion nationwide, while use of biosimilar medications saved US patients $2.2 billion.

AAM is opposed to SB 2170 primarily based on its effect on the competitive generic and biosimilar marketplace. While AAM supports the goal of lowering prescription drug costs, the use of reference pricing would not achieve that goal. Instead, reference pricing would undermine savings already delivered through generic competition as well as future savings promised by biosimilar medicines. In fact, biosimilars are projected to save more than $100 billion over the next 4 years alone as generic savings also continue to increase.

The U.S. has the most competitive generic market in the world, with generic savings that increase each year and exceed $2.2 trillion over the past ten years. Generic and biosimilar medicines are developed under a statutory and regulatory framework that provides that once approved by the FDA, they compete against the brand products as well as other approved generics and biosimilars. This direct price competition benefits patients and payers, saving North Dakota almost $915 million in 2019 alone. The use of reference pricing would undermine the competitive market that has worked so well in the U.S. It could also potentially stunt the developing market for biosimilars. These complex drugs offer competition for some of the most expensive disease states to treat, but manufacturers must balance the potential market post-launch before investing the significant research and development costs – which can range from an estimated $100 million to $300 million per drug.

For this and other reasons the AAM is opposed to Senate Bill 2170. Please feel free to contact me at brett.michelin@accessiblemeds.org if you have any questions regarding the AAM or its position on this bill.

Sincerely,

Brett Michelin

Brett Michelin
Senior Director, State Government Affairs

BIO Opposes North Dakota SB 2170– Canadian Reference Pricing
January 22, 2021

Position: BIO respectfully opposes SB 2170 that would import Canadian price controls on medications in the United States. Price controls are discriminatory and would jeopardize patient access to innovative biopharmaceuticals.

Critics of the biopharmaceutical industry often condemn the industry for charging higher prices in the United States than abroad. The fact is that nearly all foreign countries operate on nationalized healthcare systems where prices are set and controlled by the government. When imposed on medicines, government price controls suppress innovation and access to new medicines. This deters the development and supply of new life saving and life improving medicines to the detriment of patients and doctors.

Pegging prescription drug prices in the United States to lower foreign prices will limit prescription drug prices and jeopardize patient access to innovative medicines here in the United States.
Lack of access to innovative medicines presents real dangers to patients. In a study conducted by the National Bureau of Economic Research estimated that cutting prescription drug prices in the United States will lead to between 30% to 60% fewer early-stage research and development project being undertaken.[1]

Another recent study highlighted these risks, comparing differences in health outcomes for patients being treated for locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC).

- The researchers found that, if the access conditions for five ex-U.S. comparator countries (Australia, Canada, France, South Korea, and the United Kingdom) were to replace the actual U.S. access conditions between 2006 and 2017, aggregate survival gains due to innovative medicines would have been cut in half for U.S. patients diagnosed with locally advanced and metastatic NSCLC.

- According to the authors, this reduction in health gains is due to the access delays experienced by patients in other countries compared to patients in the U.S.

- Across all cancers, the 5-year survival rate is 42% higher for men and 15% higher for women in the U.S. compared to Europe.

Importing Canadian prices controls to the United States will jeopardize the innovative health care ecosystem that produces life-saving therapies.
More than 57% of all drugs come from the United States. Implementing price controls of any kind will have a chilling effect on innovation. Economists have estimated that a 50% drop in drug prices in the United States could see the number of drugs in the development pipeline reduced by 14-24 percent,[2] decreasing the hopes of patients

[1] Abbott, Thomas and John Vernon, "The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions," NBER Working Paper Series, NBER, 2005.
[2] "The Effect of Price on Pharmaceutical R&D," *The B.E. Journal of Economic Analysis and Policy,* 2009.

seeking new cures and treatments. The impact would be felt far greater by patients with one of the more than 7,000 rare diseases only 5% of which have FDA-approved treatment options.[3]

The average biopharmaceutical costs $2.6 billion to bring from research and development to market.[4]
On average, prescription drug development takes more than a decade. Only one drug candidate out of thousands will receive regulatory approval. The overall probability is less than 12% for a drug or compound in clinical testing to reach final approval.[5] These research and development failures are part of pricing strategies so that companies have the ability to reinvest revenues into new research and development projects.

Canadian style prices controls discriminate against patients with chronic disease and disability.
Canadian prices are governed by price controls that are based on the use of quality-adjusted life years (QALYs). The federal government recognizes that QALYs are inherently discriminatory to patients with chronic disease and disability. In its November 2019 report on QALYs, the National Council on Disability (NCD) "found sufficient evidence of QALYs being discriminatory (or potentially discriminatory) to warrant concern." It called on Congress to pass legislation prohibiting the use of QALYs in Medicare and Medicaid. In addition, it encouraged CMS to use alternative measurements of value when "the exact cost and benefits of a drug or treatment are not known."

The NCD report also notes that basing prices in the US on foreign prices imports a discriminatory system and jeopardizes patient care. Studies have shown that countries that use QALYs have severe restrictions on patient access to innovative medicines in other countries. For example, one study has shown that between 2002 and 2014, 40% of medicines that treat rare diseases were rejected for coverage in the United Kingdom. Another study demonstrates that only 55% of new drugs approved globally for respiratory illnesses between 2011 and 2017 were available in Canada versus 100% in the United States.

The premise that establishing upper limits does not impose price controls is a false narrative.
Whether you call it establishing "Upper Limits" or a price control the effect is the same. This policy still regulates free-market prices and creates a price ceiling based upon a metric from Canadian health system that establishes their prices at a much lower level than in the US.

We ask for an unfavorable vote on SB 2170.

[3] Kaufman, Petra, et al., From scientific discovery to treatments for rare diseases – the view from the National Center for Advancing Translational Sciences – Office of Rare Diseases Research, Orphanet Journal of Rare Diseases, 2018.
[4] DiMasi, JA, et al., Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. February 12, 2016.
[5] Biopharmaceutical Research and Development, The Process Behind New Medicines. PhRMA, 2015. http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf

#2993

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 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.

Dr. 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 Dr. 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 2170 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 2170.

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

COUNCIL for CITIZENS AGAINST GOVERNMENT WASTE

Thomas A. Schatz, *President*
1100 Connecticut Ave., N.W., Suite 650
Washington, D.C. 20036
ccagw.org

January 27, 2021

The Honorable Judy Lee
Chairwoman
North Dakota Senate Human Services Committee
600 East Boulevard
Bismarck, ND 58505-0360

Dear Chairwoman Lee and Members of the Senate Human Services Committee,

On behalf of the 4,460 members and supporters of the Council for Citizens Against Government Waste (CCAGW) in North Dakota, I urge you to oppose SB 2170.

SB 2170 adopts price controls, which throughout history are known to distort markets, hurt innovation, and never solve the problem they were created to fix. The Legislative Council fiscal note states that SB 2170 would impose price controls using prescription drugs prices found in Canada as the reference price for a list of the top 250 prescription drugs utilized by the North Dakota Public Employees Retirement System (NDPERS) drugs. The legislation gives the insurance commissioner wide decision-making ability should a specific reference price not be available in Canada.

Not only is it unwise to adopt Canadian price controls for drugs sold in North Dakota, the legislation also raises significant legal issues. If the insurance commissioner determines that a pharmaceutical company is withdrawing a referenced drug from sale or distribution to avoid the rate limitations, or refuses to negotiate prices "in good faith," the commissioner can assess a penalty of $500,000 or the amount of "annual savings determined by the commissioner," whichever is greater. This vague and arbitrary standard will be challenged in court, along with the potential taking of intellectual property in violation of the U.S. Constitution.

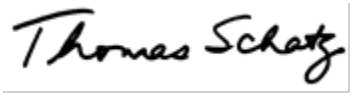
CAGW has long opposed using price controls to lower drug prices. For example, we have strongly objected to President Trump's effort to adopt a "most favored nation" (MFN) policy that has been a topic of controversy since July 24, 2020. Under the interim rule, the U.S. would be paying no more than the lowest price found in 22 countries, including Canada. These countries have socialized, government-controlled healthcare that utilize price controls and rationing to keep costs down. Neither North Dakota nor the United States should adopt such policies.

A better way to lower drug costs is for legislators to contact North Dakota's federal representatives and encourage them to hold the Food and Drug Administration's feet to the fire for faster generic drug approvals, and create an environment that encourages more "me too" drugs that will foster competition among branded pharmaceuticals that are in the same class and still under patent.

Officials in Washington should also implement trade policies that would require Canada, Europe, and other allies to pay their fair share of U.S. biopharmaceutical research and development and adopt policies that would encourage, not stifle, biopharmaceutical research and development in their countries. Not only would that help their biopharmaceutical companies, it also would lead to the creation of more new, innovative drugs and increase competition, which is a far more effective way to reduce costs.

Again, I urge you to vote against HB 2170.

Sincerely,



#3534

Bioscience Association of North Dakota
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January 26, 2021

The Bioscience Association of North Dakota opposes North Dakota SB 2170– Canadian Reference Pricing

Position: BIO ND respectfully opposes SB 2170 that would import Canadian price controls on medications in the United States. Price controls are discriminatory and would jeopardize patient access to innovative biopharmaceuticals and violates the concept of a "Free Market System".

It is no secret that both the State and Federal Governments are trying to find ways to reduce the cost of prescription medications. One of the ways that the Government is trying to reduce the cost of prescription medications is 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, but it disregards the inherent threats to patient safety associated with drug importation and it "kills" innovation. But one of the biggest reasons not to implement this program is the fact SB 2170 will require extensive state resources for the implementation and administration of an importation program!

In the opinion of the Association, it would require the creation of a whole new bureaucracy to carry out a drug importation program. Such a program would ultimately assign new responsibilities to the State of North Dakota such as designing the program to comply with State and Federal Laws; development of a drug importation list; law enforcement problems such as jurisdictional questions, litigation, and increased costs. It is the Associations belief that such a program will not provide significant savings, achieve appropriate levels of accessor operate efficiently.

North Dakotans are believers in the "Free Market System". They believe in an economic system based on supply and demand with little or no government control. It contributes to economic growth and transparency. It ensures competitive **markets**. Consumers' voices are heard in that their decisions determine what products or services are in demand. Supply and demand create competition, which helps ensure that the best goods or services are provided to consumers at a lower price.

The "system" being proposed in SB 2170, is not a "Free Market System", rather it is the **opposite** of a **market economy** — i.e, a "non-**market**" or "planned" **economy** — one that is heavily

regulated or controlled by the government. The sale of Prescriptions Drugs in this State is going to be controlled by the Insurance Commissioner and enforced by the Insurance Commissioner in collaboration with the Attorney General. Violate the provisions of this act and in specific instances a company can be fined up to $500,000.00.

The way I interpret this law, and I could be wrong, but I do not think I am, let us say, I am the manufacturer of a specific referenced drug, as defined in the act. I determine that I no longer wish to "sell" that drug in our State because the price I am allowed to charge does not cover the cost of my manufacture and distribution costs. If it is determined by the Insurance Commissioner that this constitutes a ". . . purpose of avoiding the impact of the rate limitations set forth in section 19 - 03.7 – 02, I can be "fined" five hundred thousand dollars or the amount of annual savings determined by the insurance commissioner as described in subsection 4 of section 19 - 03.7 - 04, whichever is greater.

Hardly a "free market system". I wonder how this would go over if this was "beef cattle" and a law is passed saying beef producers must sell their cattle at a price determined to be fair by the Commissioner of Agriculture? Or they can be fined out of existence.

We ask for an unfavorable vote on SB 2170.

Richard Glynn
Executive Director
Bioscience Association of North Dakota

TESTIMONY OF REBECCA FRICKE

Senate Bill 2170 – Canadian Reference Drug Pricing

Good morning, my name is Rebecca Fricke. I am the Chief Benefits Officer of the North Dakota Public Employees Retirement System, or NDPERS. I appear before you today in a neutral position on Senate Bill 2170. I am available should there be any questions related to the impact of the bill on any of the NDPERS benefits.

TESTIMONY OF DERRICK HOHBEIN

Senate Bill 2170 – Canadian Reference Drug Pricing

Good morning, my name is Derrick Hohbein. I am the Chief Operating & Financial Officer of the North Dakota Public Employees Retirement System, or NDPERS. I appear before you today in a neutral position on Senate Bill 2170. I am available should there be any questions related to the impact of the bill on any of the NDPERS benefits.

#3465

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.

PRIME THERAPEUTICS®

January 26, 2020

The Honorable Judy Lee, Chair
Senate Human Services Committee
North Dakota State Legislature
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: Senate Bill 2170

Dear Madame Chair Lee:

Thank you for the opportunity to comment on Senate Bill 2170. I represent Prime Therapeutics, a pharmacy benefit manager (PBM) owned by 18 not- for-profit Blue Cross and Blue Shield insurers, subsidiaries or affiliates of those insurers, including Blue Cross and Blue Shield of North Dakota (BCBSND). The policies embodied in this bill – namely, asking purchasers of drugs to acquire those drugs at the lowest possible price – align with Prime's long-standing business practices. We believe this bill represents a positive step in understanding and addressing the cost-drivers in the prescription drug market.

Moving ahead, we look forward to working with the committee to discuss how we work to make prescription drugs more affordable for North Dakotans. We appreciate the bill sponsor's recognition that the price of a drug remains unaddressed by North Dakota law. Prime Therapeutics has been and will continue to be committed to helping North Dakotans get the drugs they need to feel better and live well at the best possible price – this represents a step in the right direction to help us further that mission.

Sincerely,

Alex Sommer, J.D.
Prime Therapeutics
Alexander.Sommer@primetherapeutics.com

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

SB 2170
2/3/2021

A BILL for an Act to create and enact chapter 19-03.7 of the North Dakota Century Code, relating to prescription drug costs; and to provide a penalty.

Madam Chair Lee opened the discussion on SB 2170 at 2:35 p.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Top 250 prescription drugs
- Negotiating on prescription drug prices
- Prescription drug manufacturer rebates

[2:35] Chrystal Bartuska, Director, Life and Health/Medicare Division, ND Insurance Department. Advised the committee on working with the Board of Pharmacy to develop amendment language.

Additional written testimony: N/A

Madam Chair Lee closed the discussion on SB 2170 at 2:42 p.m.

Justin Velez, Committee Clerk

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

SB 2170
2/16/2021

A BILL for an Act to create and enact chapter 19-03.7 of the North Dakota Century Code, relating to prescription drug costs; and to provide a penalty.

Madam Chair Lee opened the discussion on SB 2170 at 3:03 p.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Spending authority of Insurance Depratment
- ND Board of Pharmacy partnership
- PBM licensing
- Prescription drug manufacturers negotiation process

[3:04] Senator Howard Anderson, District 8. Introduced Jon Godfread.

[3:05] Jon Godfread, North Dakota Insurance Commissioner. Provided the committee with concerns on SB 2170.

[3:27] Senator Judy Lee, District 13. Provided the committee with an overview of amendment 21.0611.01001 (testimony #6773)

Senator Anderson moves to **ADOPT AMENDMENT** 21.0611.01001
Senator Hogan seconded.

Voice Vote – motion passed

Senator Anderson moves **DO PASS, AS AMENDED.**

Senator Hogan seconded.
The motion passed 4-2-0.
Senator Anderson will carry SB 2170.

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

Additional written testimony: (1)

Brett Michelin, Senior Director, State Government Affairs, Association for Accessible Medicines. Provided written testimony #6909 in opposition.

Madam Chair Lee closed the discussion on SB 2170 at 3:43 p.m.

Justin Velez, Committee Clerk

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

PROPOSED AMENDMENTS TO SENATE BILL NO. 2170

Page 2, line 17, after the underscored comma insert "on a form established by the insurance commissioner,"

Page 2, line 18, remove "two hundred fifty"

Page 2, line 23, replace "two hundred fifty" with "the"

Page 2, line 24, after the underscored period insert "The insurance commissioner shall identify the number of reference drugs subject to the referenced rate."

Page 2, line 25, replace "determine the referenced rate" with "establish a rate to be used as a basis to begin negotiation. The insurance commissioner shall establish this rate"

Page 3, remove line 1

Page 3, line 2, remove "among those resources and the wholesale acquisition cost."

Page 3, line 3, after "within" insert "the identified"

Page 3, line 3, remove "described in subsection 3"

Page 3, line 4, replace "shall" with "may"

Page 3, line 5, remove "referenced"

Page 3, line 5, replace "a reference such as" with "used as a basis to begin negotiation"

Page 3, after line 6, insert:

"4. The insurance commissioner shall negotiate with manufacturers and distributors of referenced drugs to set a reference rate for each of the identified drugs."

Page 3, line 13, remove "**and office within the state**"

Page 3, line 15, replace "be" with "have"

Page 3, line 15, replace "and maintain an office within" with "in"

Page 3, line 16, after "**savings**" insert "**- Referenced drug fund**"

Page 3, line 17, replace "Any" with "A health plan or participating Employee Retirement Income Security Act plan shall use any"

Page 3, line 17, remove "must be"

Page 3, line 18, remove "used"

Page 3, line 18, replace "consumers" with "their members"

Page 3, line 18, remove "state entity,"

Page 3, line 18, remove the second underscored comma

Page 3, line 21, remove "2."

CJ 2/16 2 of 2

Page 3, line 21, remove "state entity."

Page 3, line 21, remove the third underscored comma

Page 3, line 25, replace "achieve the requirements of subsection 1" with "reduce costs to its members"

Page 3, after line 25, insert:

"2. A state entity shall deposit any savings generated as a result of the requirements in section 19-03.7-02 into a referenced drug fund in the state treasury. Subject to legislative appropriation, the money in the fund must be used by the public employees retirement system and the insurance commissioner to administer this chapter and to reduce health plan premiums of state entities."

Page 3, line 30, after the underscored period insert "The insurance commissioner and state board of pharmacy shall work with the attorney general in enforcing this chapter."

Page 4, line 3, after "**sale**" insert "**- Penalty**"

Page 4, line 9, after "commissioner" insert ", to the state board of pharmacy,"

Page 4, line 12, after "commissioner" insert ", working in consultation with the state board of pharmacy,"

Page 4, line 23, after "commissioner" insert ", working in consultation with the state board of pharmacy,"

Page 4, line 28, replace "4" with "5"

Renumber accordingly

REPORT OF STANDING COMMITTEE

SB 2170: Human Services Committee (Sen. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (4 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). SB 2170 was placed on the Sixth order on the calendar.

Page 2, line 17, after the underscored comma insert "on a form established by the insurance commissioner,"

Page 2, line 18, remove "two hundred fifty"

Page 2, line 23, replace "two hundred fifty" with "the"

Page 2, line 24, after the underscored period insert "The insurance commissioner shall identify the number of reference drugs subject to the referenced rate."

Page 2, line 25, replace "determine the referenced rate" with "establish a rate to be used as a basis to begin negotiation. The insurance commissioner shall establish this rate"

Page 3, remove line 1

Page 3, line 2, remove "among those resources and the wholesale acquisition cost."

Page 3, line 3, after "within" insert "the identified"

Page 3, line 3, remove "described in subsection 3"

Page 3, line 4, replace "shall" with "may"

Page 3, line 5, remove "referenced"

Page 3, line 5, replace "a reference such as" with "used as a basis to begin negotiation"

Page 3, after line 6, insert:

"4. The insurance commissioner shall negotiate with manufacturers and distributors of referenced drugs to set a reference rate for each of the identified drugs."

Page 3, line 13, remove "**and office within the state**"

Page 3, line 15, replace "be" with "have"

Page 3, line 15, replace "and maintain an office within" with "in"

Page 3, line 16, after "**savings**" insert "**- Referenced drug fund**"

Page 3, line 17, replace "Any" with "A health plan or participating Employee Retirement Income Security Act plan shall use any"

Page 3, line 17, remove "must be"

Page 3, line 18, remove "used"

Page 3, line 18, replace "consumers" with "their members"

Page 3, line 18, remove "state entity,"

Page 3, line 18, remove the second underscored comma

Page 3, line 21, remove "2."

Page 3, line 21, remove "state entity,"

Page 3, line 21, remove the third underscored comma

Page 3, line 25, replace "achieve the requirements of subsection 1" with "reduce costs to its members"

Page 3, after line 25, insert:

"2. A state entity shall deposit any savings generated as a result of the requirements in section 19-03.7-02 into a referenced drug fund in the state treasury. Subject to legislative appropriation, the money in the fund must be used by the public employees retirement system and the insurance commissioner to administer this chapter and to reduce health plan premiums of state entities."

Page 3, line 30, after the underscored period insert "The insurance commissioner and state board of pharmacy shall work with the attorney general in enforcing this chapter."

Page 4, line 3, after "**sale**" insert "**- Penalty**"

Page 4, line 9, after "commissioner" insert ", to the state board of pharmacy,"

Page 4, line 12, after "commissioner" insert ", working in consultation with the state board of pharmacy,"

Page 4, line 23, after "commissioner" insert ", working in consultation with the state board of pharmacy,"

Page 4, line 28, replace "4" with "5"

Renumber accordingly

Sixty-seventh
Legislative Assembly
of North Dakota

SENATE BILL NO. 2170

Introduced by

Senator Anderson

Representative M. Nelson

A BILL for an Act to create and enact chapter 19-03.7 of the North Dakota Century Code, relating to prescription drug costs; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. Chapter 19-03.7 of the North Dakota Century Code is created and enacted as follows:

19-03.7-01. Definitions.

As used in this chapter:

1. "Employee Retirement Income Security Act plan" means a plan qualified under the federal Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002 et seq.].
2. "Health plan" has the same meaning as accident and health insurance policy under section 26.1-36-02.
3. "Participating Employee Retirement Income Security Act plan" means an Employee Retirement Income Security Act plan that has elected to participate in the requirements and restrictions of this chapter as described in section 19-03.7-03.
4. "Prescription drug" has the same meaning as stated in section 43-15.1-01.
5. "Referenced drugs" means prescription drugs subject to a referenced rate.
6. "Referenced rate" means the maximum rate established by the insurance commissioner utilizing the wholesale acquisition cost and other pricing data described in section 19-03.7-04.
7. "State entity" means any agency of state government that purchases prescription drugs on behalf of the state for an individual whose health care is paid for by the state, including any agent, vendor, fiscal agent, contractor, or other party acting on behalf of the state. The term does not include the medical assistance program established under 42 U.S.C. section 1396 et seq.

8. "Wholesale acquisition cost" has the meaning stated in 42 U.S.C. section 1395w-3a.

19-03.7-02. Payment in excess of referenced rate prohibited.

1. It is a violation of this chapter for a state entity, health plan, or participating Employee Retirement Income Security Act plan to purchase referenced drugs to be dispensed or delivered to a consumer in the state, whether directly or through a distributor, for a cost higher than the referenced rate as determined in section 19-03.7-04.
2. It is a violation of this chapter for a retail pharmacy licensed in this state to purchase for sale or distribution referenced drugs for a cost that exceeds the referenced rate to an individual whose health care is provided by a state entity, health plan, or participating Employee Retirement Income Security Act plan.

19-03.7-03. Employee Retirement Income Security Act plan opt-in.

An Employee Retirement Income Security Act plan may elect to participate in the provisions of this chapter. Any Employee Retirement Income Security Act plan that desires its purchase of prescription drugs to be subject to the prohibition described in section 19-03.7-02 shall notify the insurance commissioner in writing by October first of each year.

19-03.7-04. Referenced drugs determined.

1. As of October first of each year, on a form established by the insurance commissioner, the public employees retirement system shall transmit to the insurance commissioner a list of the ~~two hundred fifty~~ most costly prescription drugs based upon net price times utilization. For each of these prescription drugs, the public employees retirement system also shall provide the total net spend on each of those prescription drugs for the previous calendar year.
2. Utilizing the information described in subsection 1, as of January first of each year, the insurance commissioner shall create and publish a list of ~~two hundred fifty~~the referenced drugs subject to the referenced rate. The insurance commissioner shall identify the number of reference drugs subject to the referenced rate.
3. The insurance commissioner shall ~~determine the referenced rate~~establish a rate to be used as a basis to begin negotiation. The insurance commissioner shall establish this rate by comparing the wholesale acquisition cost to reference costs such as the cost from the Ontario ministry of health and long-term care and most recently published on the Ontario Drug Benefit Formulary; régie de l'assurance maladie du Québec and

most recently published on the Quebec Public Drug Programs List of Medications; British Columbia ministry of health and most recently published on the BC PharmaCare Formulary; and Alberta ministry of health and most recently published on the Alberta Drug Benefit List.

~~4. The referenced rate for each prescription drug must be calculated as the lowest cost among those resources and the wholesale acquisition cost.~~ If a specific referenced drug is not included within the identified resources ~~described in subsection 3~~, the insurance commissioner ~~shall~~may utilize as a reference for the purpose of determining the ~~referenced~~ rate ~~a reference such as~~used as a basis to begin negotiation, the ceiling price for drugs as reported by the government of Canada patented medicine prices review board.

4. The insurance commissioner shall negotiate with manufacturers and distributors of referenced drugs to set a reference rate for each of the identified drugs.

5. The insurance commissioner shall calculate annually the savings expected to be achieved by subjecting prescription drugs to the referenced rate. In making this determination the commissioner shall consult with the public employees retirement system and the state board of pharmacy.

6. The insurance commissioner may adopt rules to implement fully the requirements of this chapter.

19-03.7-05. Registered agent ~~and office within the state~~.

An entity that sells, distributes, delivers, or offers for sale any prescription drug in the state must ~~be~~have a registered agent ~~and maintain an office within~~in the state.

19-03.7-06. Use of savings - Referenced drug fund.

1. ~~Any~~A health plan or participating Employee Retirement Income Security Act plan shall use any savings generated as a result of the requirements in section 19-03.7-02 ~~must be used~~ to reduce costs to ~~consumers~~their members. A ~~state entity, health plan,~~ or participating Employee Retirement Income Security Act plan shall calculate the savings and utilize the savings directly to reduce costs for its members.

~~2.~~ No later than April first of each year, each ~~state entity, health plan,~~ and participating Employee Retirement Income Security Act plan subject to this chapter shall submit a report to the insurance commissioner describing the savings achieved for each

referenced drug for the previous calendar year and how those savings were used to ~~achieve the requirements of subsection 1~~reduce costs to its members.

2. A state entity shall deposit any savings generated as a result of the requirements in section 19-03.7-02 into a referenced drug fund in the state treasury. Subject to legislative appropriation, the money in the fund must be used by the public employees retirement system and the insurance commissioner to administer this chapter and to reduce health plan premiums of state entities.

19-03.7-07. Enforcement - Penalty.

Each violation of this chapter is subject to a fine of one thousand dollars. Every individual transaction in violation of section 19-03.7-02 is determined to be a separate violation. The attorney general may enforce this chapter on behalf of any state entity or consumers of prescription drugs. The insurance commissioner and state board of pharmacy shall work with the attorney general in enforcing this chapter. The refusal of a manufacturer or distributor to negotiate in good faith as described in subsection 4 of section 19-03.7-08 is a valid affirmative defense in any enforcement action brought under this chapter.

19-03.7-08. Prohibition on withdrawal of referenced drugs for sale - Penalty.

1. It is a violation of this chapter for a manufacturer or distributor of a referenced drug to withdraw the referenced drug from sale or distribution within this state for the purpose of avoiding the impact of the rate limitations set forth in section 19-03.7-02.
2. A manufacturer that intends to withdraw a referenced drug from sale or distribution from within the state shall provide a notice of withdrawal in writing to the insurance commissioner, to the state board of pharmacy, and to the attorney general at least one hundred eighty days before the withdrawal.
3. The insurance commissioner shall assess a penalty on a manufacturer or distributor that the insurance commissioner, working in consultation with the state board of pharmacy, determines has withdrawn a referenced drug from distribution or sale in the state in violation of subsection 1 or 2. With respect to each referenced drug for which the insurance commissioner has determined the manufacturer or distributor has withdrawn from the market, the penalty must be equal to five hundred thousand dollars or the amount of annual savings determined by the insurance commissioner as described in subsection 5 of section 19-03.7-04, whichever is greater.

4. It is a violation of this chapter for a manufacturer or distributor of a referenced drug to refuse to negotiate in good faith with a payor or seller of prescription drugs a price that is within the referenced rate as determined in section 19-03.7-04.

5. The insurance commissioner shall assess a penalty on a manufacturer or distributor the insurance commissioner, working in consultation with the state board of pharmacy, determines has failed to negotiate in good faith in violation of subsection 4. With respect to each referenced drug for which the insurance commissioner has determined the manufacturer or distributor has failed to negotiate in good faith, the penalty must be equal to five hundred thousand dollars or the amount of annual savings determined by the insurance commissioner as described in subsection 4 of section 19-03.7-04, whichever is greater.

#6909

February 17, 2021

Dear Senator,

The Association for Accessible Medicines (AAM) is opposed to Senate Bill 2170, which establishes price controls in the United States based on reference pricing from four Canadian provinces. AAM represents the manufacturers and distributors of generic and biosimilar medications and works to ensure generic and biosimilar medicines are more accessible to the people who need them. Generic medications represent 90% of all prescriptions filled but only 20% of prescription drug spending in the United States. In 2019, the use of generic medicines saved $313 billion nationwide, while use of biosimilar medications saved U.S. patients $2.2 billion.

AAM is opposed to SB 2170 primarily based on its effect on the competitive generic and biosimilar marketplace. While AAM supports the goal of lowering prescription drug costs, the use of reference pricing would not achieve that goal. Instead, reference pricing would undermine savings already delivered through generic competition as well as future savings promised by biosimilar medicines. In fact, biosimilars are projected to save more than $100 billion over the next 4 years alone as generic savings also continue to increase.

The U.S. has the most competitive generic market in the world, with generic savings that increase each year and exceed $2.2 trillion over the past ten years. Generic and biosimilar medicines are developed under a statutory and regulatory framework that provides that once approved by the FDA, they compete against the brand products as well as other approved generics and biosimilars. This direct price competition benefits patients and payers, saving North Dakota almost $915 million in 2019 alone. The use of reference pricing would undermine the competitive market that has worked so well in the U.S. It could also potentially stunt the developing market for biosimilars. These complex drugs offer competition for some of the most expensive disease states to treat, but manufacturers must balance the potential market post-launch before investing the significant research and development costs – which can range from an estimated $100 million to $300 million per drug.

For this and other reasons the AAM is opposed to Senate Bill 2170. Please feel free to contact me if you have any questions regarding the AAM or its position on this bill.

Sincerely,

Brett Michelin

Brett Michelin
Senior Director, State Government Affairs
Association for Accessible Medicines

2021 HOUSE INDUSTRY, BUSINESS AND LABOR

SB 2170

2021 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

SB 2170
3/22/2021

Prescription drug costs.

(2:51) Chairman Lefor called the hearing to order.

Representatives	Attendance	Representatives	Attendance
Chairman Lefor	P	Rep Ostlie	P
Vice Chairman Keiser	P	Rep D Ruby	P
Rep Hagert	P	Rep Schauer	P
Rep Kasper	P	Rep Stemen	P
Rep Louser	P	Rep Thomas	P
Rep Nehring	P	Rep Adams	P
Rep O'Brien	P	Rep P Anderson	P

Discussion Topics:

- Lower prescription drug prices
- Insurance & pharmacy Benefit managers

Sen Anderson~District 8 introduced the bill. Attachment #10206.

Rep Satrom~District 12. Testified in support.

Rep Nelson~District 9. Testified in support.

Josh Askvig~State Director-AARP North Dakota. Attachments #10304, 10305 & 10306.

Roger Roehl~Self. Attachment #10228.

Kathi Schwan~Volunteer State President-AARP North Dakota. Attachment #10271.

Matt Gardner~Director of Government Affairs-Greater ND Chamber. Attachment #10317.

Kristen Dvorak~Executive Director-The Arc of ND. Attachments # 10298 & 10299.

Brett Michelin~Senior Director-Association for Accessible Medicines. Attachments #10147 &10146.

Leah Lindahl~Senior Director-State Government Affairs-Healthcare Distribution Alliance. Attachment #10264.

John Hoke~Biotechnology Innovation Organization. Attachment 10185.

Peter Fjelstad~PhRMA. Attachments # 10241, 10237, 10238, 10239 & 10240.

Jon Godfread~ND Insurance Commissioner. Testified in support. Attachment #10412.

Mike Schwab~Executive Vice President-ND Pharmacists Association. Testified in neutral.

Chairman Lefor closed the hearing.

Vice Chairman Keiser moved a Do Not Pass.

Rep Kasper second.

Representatives	Vote
Chairman Lefor	Y
Vice Chairman Keiser	Y
Rep Hagert	Y
Rep Jim Kasper	Y
Rep Scott Louser	Y
Rep Nehring	Y
Rep O'Brien	Y
Rep Ostlie	A
Rep Ruby	Y
Rep Schauer	N
Rep Stemen	Y
Rep Thomas	Y
Rep Adams	N
Rep P Anderson	N

Vote roll call taken Motion carried 10-3-1 & Vice Chairman Keiser is the carrier.

Additional written testimony: #10138, 10141, 10184, 10199, 10203, 10221, 10242, 10259, 10296 & 10307.

(4:37) End time.

Ellen LeTang, Committee Clerk

REPORT OF STANDING COMMITTEE

SB 2170, as engrossed: Industry, Business and Labor Committee (Rep. Lefor, Chairman) recommends **DO NOT PASS** (10 YEAS, 3 NAYS, 1 ABSENT AND NOT VOTING). Engrossed SB 2170 was placed on the Fourteenth order on the calendar.

Senate Bill 2170

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

Chairman Lefor and members of the House Industry Business and Labor Committee. This bill is about getting access to lower prescription drug prices for the North Dakota Public Employee Retirement System and the North Dakota Workers Compensation Program and then, by design, the rest of North Dakotans when and if the plan works for those programs.

This is actually a great opportunity for drug manufactures if they would just open their eyes. They complain about insurance and pharmacy benefit managers getting rebates and how much that takes from them. I say "get on board with North Dakota and cut the middle men out of the system and just give us a good price".

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, or other countries. This is a very real risk to our citizens as we are forcing them out of the country to get medications they must have.

This idea was developed as a model bill by the National Academy of State Health Policy with input from the American Association of Retired Persons and others. This is not price controls, this is a negotiating tool to put pressure on manufacturers to give us a good price. Much like the person who goes to Bill at Bill's Ford to bargain for a car. Bill gives him a price and he goes to Joe's Ford down the street and says, "gee I can get the same car at Bill's ford for one thousand dollars less, how about a deal".

There is no importation required in this scenario. Reference pricing is built on the ability to get data on the published prices paid by the four most populated provinces in Canada, getting the average or perhaps taking the lowest one and then saying, "This is what North Dakota would like to pay for these drugs".

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. Therefore comparing our price to theirs is comparing apples to apples.

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.

Will lower drug prices stifle innovation? The evidence says no. Look here for an enlightening article.

https://www.nashp.org/will-laws-to-lower-drug-prices-harm-innovation-the-evidence-says-no/

19 billion of Federal money for vaccines. The drug industry relies heavily on public funding for all forms of drug development. Taxpayer-funded research for each of the 356 drugs approved by the US Food and Drug Administration in the last decade totals $230 billion. Despite this level of public investment in drug development,

manufacturers face few restrictions on what they can charge for their drugs in the United States despite taxpayers' investments.

Oklahoma was the first state to begin this approach and I have heard some Oklahomans express that they need others to get on board so the manufacturers will decide they need everyone's business and not refuse to sell to our small states, which is one of the risks. There are penalties in the bill for a manufacturer withdrawing products, but we would hope that will not become necessary.

Now Canada may not be happy with us piggybacking on their successful efforts to hold prescription drug prices down in their country. There is a risk, if we are successful, prices might rise north of the border. They might also go down here. Perhaps we could get President Biden to trade lower drug prices for the Keystone XL pipeline.

I did see a recent article where 93 Canadian drug company executives were complaining that Canadian efforts to lower drug prices even more were going to cause delays in new product launches, etc. Just like we hear on this side of the border.

Here is how the Canadians look at their pricing system: Based on a letter from Counsel General Delouya

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 industrialized 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.**

This bill seeks to give North Dakotans the same power over pricings as reflected above in a letter from Ariel Delouya the Counsel General of Canada.

We obtained a list of the top drugs in spending from our PERS system. I asked the analysist from the National Academy of State Health Policy to run the possible savings based on the bills design and for the top 25 in the list. They came up with a potential savings of $21,228,212.15 over just those 25 drugs.

Thank you,

Howard

10304

House Human Services Committee
SUPPORT - SB 2170
Prescription Drug Price Pricing
March 22, 2021
Josh Askvig, AARP North Dakota
jaskvig@aarp.org – (701) 355-3642

Chairman Lefor and members of the House Industry, Business and Labor Committee, my name is Josh Askvig, State Director 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.

Before I get into the details of the why lowering the cost of prescription drugs is so important to older North Dakotans, I'd like share Roger's story. Roger, like many other North Dakotans, have found ways to self-import the drugs they need from Canada. SHOW VIDEO

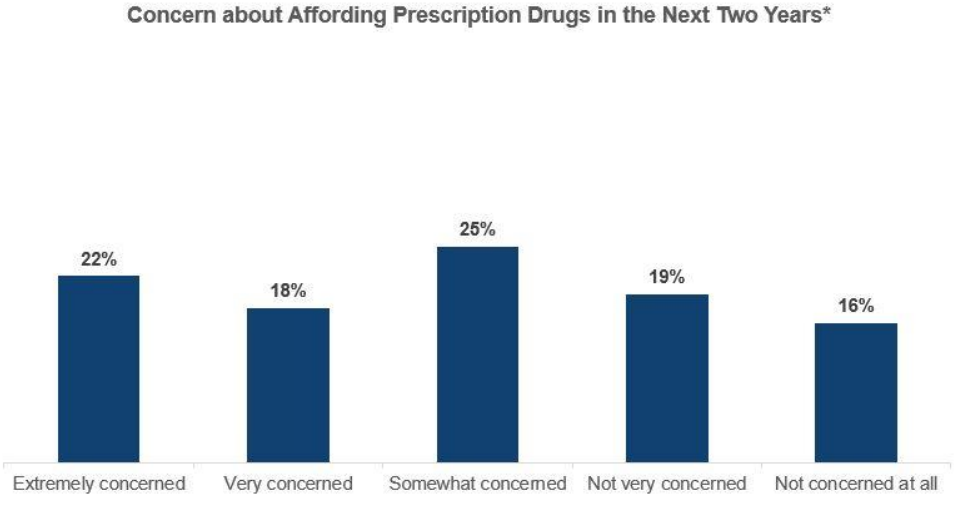
As Roger's story shows, the rising cost of prescription drugs hits our members, and frankly all North Dakotans. It's a high priority for us right now, not only at the state level, but at the federal level as well. Let me outline just a couple of the reasons why.

The average older American takes 4.5 prescription drugs on a chronic basis. As my handout that has the yellow background shows, 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.

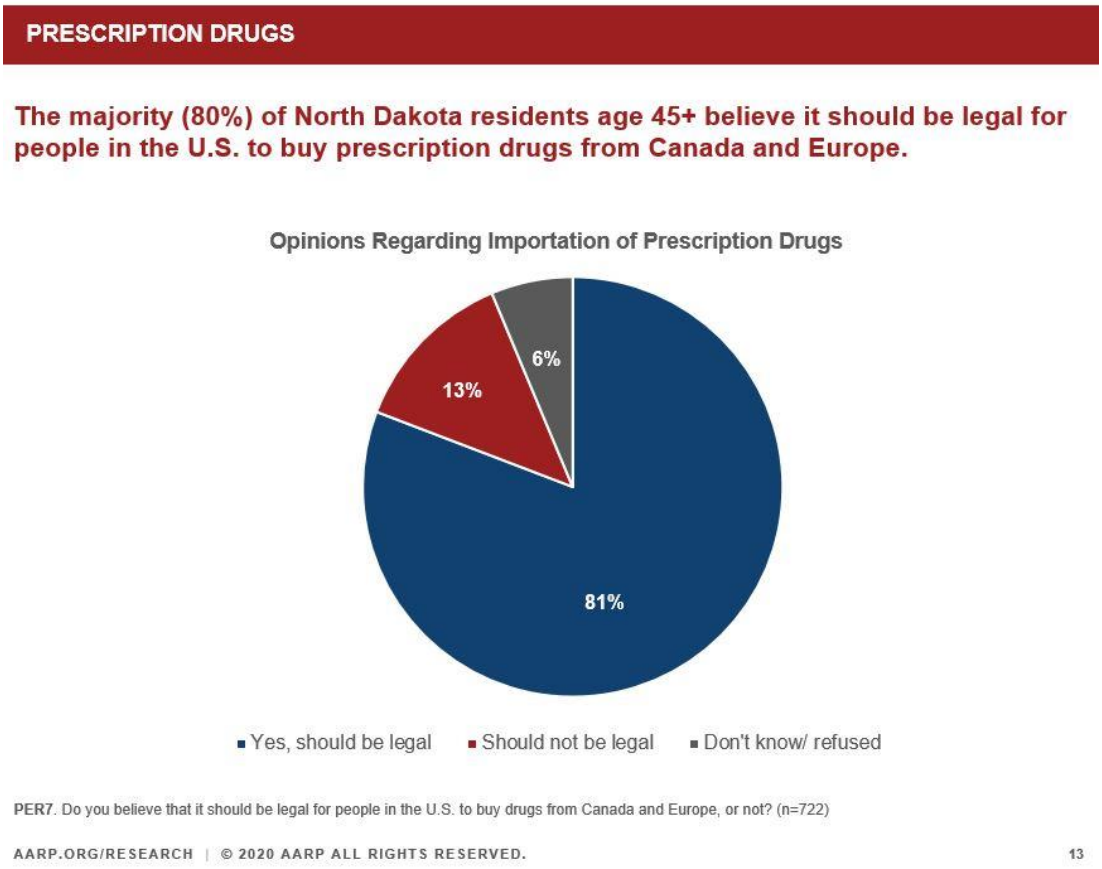
PRESCRIPTION DRUGS

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.



A second handout is attached along with my testimony. 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!** Reading this one 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.

Drug prices in other countries are often many times lower than in the United States. SB 2170 which was originally based on a model bill developed by the National Academy for State Health Policy or NASHP, determines referenced rates

for certain prescription drugs based on international prices, and establishes the referenced rate as the upper payment limit for payers within a state.

SB 2170 as it has been amended and appears before you would outline a process for having the Insurance Commissioner negotiate prices for PERS. The bill does not dictate what a manufacturer can charge for a drug – but after negotiation it does limit how much payers in a state pay. This is one approach that some states are considering to relieve consumer's financial burdens.

This bill proposes using price data from the four most populous Canadian provinces (Ontario, Quebec, British Columbia, and Alberta) to compare drug prices between the United States and Canada. If prices are not available for the provinces, the model act instead refers to the ceiling price set by Canada's Patented Medicine Prices Review Board (PMPRB) for referenced rates, which are posted online. After that comparison the bill outlines the process for the Insurance Commissioner to use these comparison prices to negotiate with manufacturers and distributors of the referenced drugs to set a referenced rate for each of the drugs.
Prices in Canada can be dramatically lower than in the United States. While a number of states have passed laws to import drugs from Canada in order to capture those savings, this model act allows a state to "import" the drugs' prices instead of the actual drugs.

For example, the drug Xeljanz is $76.07 for a 5-mg tablet in the United States, while the lowest price for the drug across Canada's four largest provinces is $16.96. The table below from NASHP provides additional comparisons, with savings ranging from 60 to 85 percent off US prices, for an average savings of 75 percent for these examples.

Drug*	US (NADAC)**	Quebec	Alberta	Ontario	British Columbia	Canadian PMPRB Maximum Price
Xeljanz [5 mg] *(rheumatoid arthritis)*	**$76.07**	$16.96	$ 17.49	$17.59	$ 18.47	$21.28
Eliquis [2.5 mg] *(anticoagulant)*	**$7.53**	$1.17	$1.19	$1.19	$1.29	$2.78
Eplcusa [400/100 mg] *(hepatitis C)*	**$869.05**	$521.43	$521.43	$521.43	$531.86	$722.86
Zytiga [250 mg] *(cancer)*	**$87.63**	$20.68	+	+	+	$36.96

* Prices, effective as of June 2020, represent unit cost (i.e., per tablet, pill, etc.) in US dollars, converted at an exchange rate of $1 CAN = 73 cents USD.

+ Price not available online.

Furthermore, federal law prohibits the importation of several major classes of drugs, such as controlled substances, biological products, infused and parenteral drugs, intravenously injected drugs, and drugs inhaled during surgery. A bill like SB 2170 can address those issues by using the international referenced rates for negotiations to reduce costs for drugs that are ineligible for importation – for example Humira, a medication for rheumatoid arthritis.

Rate setting is already in use. For example, determining maximum payment levels or payment rates for health care and other public goods is a practice that has existed for decades. States regulate insurers and other public goods and services in markets with little or no market competition and set payment rates for health

services through their public purchasing. This bill extends that precedent to prescription drugs by using Canadian prices as reference points to set fair payment rates.

Last, one question we hear frequently is how a bill like this will save consumers money. Under SB 2170, as outlined on page 3, lines 20-28, directs PERS to utilize savings to reduce costs for their members and submit a report to the Insurance Commissioner indicating how much they saved for each referenced drug by participating and how they passed those savings on to members.

Thank you again for your thoughtful work on this issue. We wholeheartedly appreciate the effort to make medicine more affordable. SB 2170 is a step in the right direction and we look forward to working with you to make it the best possible bill for North Dakotans.

10305

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.

How North Dakota Residents Are Impacted By High Rx Costs

10306

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

Why North Dakota Needs to Tackle Prescription Drug Prices

March 22, 2021

Chair Lefor and Members of the House Industry, Business, and Labor Committee,

My name is Roger Roehl and I'm testifying in support of SB 2170. 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.

Please vote yes on SB 2170.

Thank you.

10271

March 22, 2021
House Industry, Business, and Labor Committee
SB 2170
Rx Drug Importation
Kathi Schwan, Volunteer State President
AARP North Dakota

Chair Lefor and members of the House Industry, Business, and Labor Committee:

My name is Kathi Schwan. I serve as the Volunteer State President, for AARP North Dakota. I live in West Fargo and have been involved in AARP for several years after retirement, and before my current two terms as President. It has provided me a unique exposure to the health and financial challenges of the 50+, in nearly every corner of ND.

I appreciate your time today and look forward to talking with you about an issue that is crucial to our members. This is a topic you've already heard they are passionate about, during the first half of the Legislative Session. We support efforts to reduce the cost of prescription drugs.

Increasing drug prices hit older North Dakotans particularly hard. Most Medicare beneficiaries live on very modest incomes. A Kaiser Foundation study from 2016 shows the **median income for Medicare recipients is just over $26,000** – and a quarter of the population hover closer to $15,000. They also have very little savings. Half the Medicare population has less than $75,000 in savings. Their ability to absorb increasingly expensive prescription drugs is nearly impossible. Many people we have talked with recently tell us they have to make difficult decisions about how to live because of the price of those drugs. We hear from seniors who either cut back, or cannot fill a prescribed drug due to cost.

There is much discussion about the low cost of drugs in Canada. We are familiar with the Canadian reputation for safety standards. However, many ND snowbirds fly to Arizona in the winter, and while they're close to the border, search for the services or items Medicare covers poorly: such as dental care and medication. Most seniors know someone who makes that trip at least annually and can bring back for themselves or others what is needed. On any given day, you'll find many North Dakotans in the city of Los Algodones, just 5 miles south of Yuma. You can tell by the Bison t-shirts and the traditional high-fives you give when you see another North Dakotan. The discounted prices for pharmaceuticals in Los Algodones are incredible, and the many large pharmacies that sell this inventory is both professional and impressive. *You may ask, why would one risk taking a prescription drug sold in Mexico?* Is it far riskier to take it? Or to not take it at all? I can tell you from personal experience, there are many North Dakotans willing to take that risk because North Dakota offers few options. Those who go to Mexico, also bring along a shopping list to help friends and neighbors who need the drugs---but can't make the trip. *Mexican vendors are so familiar with North Dakotans, they sell NDSU and UND merchandise in their gift shops.*

I'm not just someone passing this story along. I've been there, and done this----many times.

- For example, why pay $168 for a tube of Retina-A for your skin cancer, when you can get two tubes for $2.50 in Mexico?
- Or $300 for a single, tiny 30-drop bottle of Restasis eye drops for dry eye disease, when you can pick up a 6-month supply for $25?
- How about 1 carton of 5 flex pens of Novolog insulin for $30 instead of $250? This item is among the most popular requests.

Most products in demand by snowbirds are manufactured in the US by Merck or Johnson & Johnson in these Mexican pharmacies. This isn't the only location, as I've been in the Costco store in Cabo San Lucas. They do a significant business in their pharmacy, where prescriptions aren't required. They readily point out the US manufacturers. One is allowed to bring back a 6-mo supply.

Now, we know States can't solve this problem alone. But there are some changes that can be made and we appreciate this committee's willingness to bring this issue to the forefront. This issue is relevant not only to the thousands of individual North Dakotans fighting disease, but it also affects those paying for health coverage and to the State. Spending increases which are driven by escalating drug prices, are passed along to everyone with health insurance coverage in the form of higher premiums, and deductibles. It increases costs for taxpayer-funded programs too – making this a relevant issue for every North Dakotan whether they are taking prescription medicine or not.

Thank you again for your thoughtful work on this issue. AARP wholeheartedly appreciates any effort to make medicine more affordable. SB 2170 is a step in the right direction and we look forward to working with you to make it the best possible bill for North Dakotans.

Thank you,

Kathi Schwan

Greater North Dakota Chamber
SB 2170
House Industry, Business, and Labor Committee
March 22, 2021

Mr. Chairman and members of the House Industry, Business, and Labor Committee, my name is Matt Gardner, Director of Government Affairs for the Greater North Dakota Chamber. GNDC is the largest statewide business advocacy organization in the state. We are affiliated with the US Chamber of Commerce and the National Association of Manufacturers, we stand in opposition to Senate Bill 2170.

The GNDC believes strongly in the free market system. This system gives strength to the consumer by enticing companies to compete among each other for thier business. This competion motivates companies to produce the products that meet the needs of the consumer at reasonable prices the market can support. This competition within the free market system has led our nation to innovate and develop world class products at reasonable prices, all at the demand of the consumer.

We oppose this bill because it is an infrindgment on the core of the free market system in North Dakota. Imagine if the prices of all goods and services in the State were negotiated by the government. This would remove all competition in the market leading to the development of what products the government feels are appropriate for its citizens.

GNDC asks you to resist the urge of what this bill is trying to accomplish and reject price control measures on drugs to promote not deminish innovation. It is critical that we foster a business climate in North Dakota and the nation that encourages private investment, research, innovation, product development, and the efficient delivery of products and services to meet the needs of the consumer.

Mr. Chairman, members of the House Industry, Business, and Labor Committee, thank you for the opportunity to comment. I respectfully urge you to reject SB 2170, and I would be happy to respond to any questions.

The Arc
North Dakota

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10298

SB 2170
IBL
March 22, 2021

Chairman Lefor and members of the House Industry, Business and Labor Committee. My name is Kirsten Dvorak, and I am the executive director of The Arc of North Dakota, which includes all six chapters of The Arc in North Dakota: Bismarck, Bowman, Dickinson, Fargo, Grand Forks, and Valley City. Our mission is to improve people's quality of life with intellectual and developmental disabilities and actively support their full inclusion and community participation.

The Arc of North Dakota supports the need for affordable health care. We encourage the state to manage health care that is person-centered on meeting our residents' needs with disabilities. We ask for a DO NOT PASS for SB 2170, as it is based on discriminatory metrics, the Quality-Adjusted Life Years (QALY). QALYs use measures based on the degree to which a drug or treatment extends life and improves the quality of life.

QALY-based assessments assign a financial value to health improvements provided by a treatment that does not account for outcomes that matter to people living with the relevant health condition and attribute a lower value to a life lived with a disability. When applied to health care decision-making, the results can mean that people with disabilities and chronic illnesses, including older adults, are deemed not worth the cost to treat. We encourage you to review the report from the National Council on Disability, an independent federal agency, recommending that policymakers avoid referencing or importing the QALY from other countries (such as Canada), clarifying that its use in public programs would be contrary to United States civil rights and disability policy.

SB 2170 would reference Canadian rates of prescription drugs. The bill directly references the process paid for drugs in five Canadian provinces. Before applying for coverage by the provinces, all medications must complete a Common Drug Review by Canadian Agency for Drugs and Technologies in Health (CADTH), which references QALYs. In Canada, the outcome is that many individuals living with disabilities are unable to receive the treatments and care they need.

The Arc
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The 2019 National Council on Disability report was direct in recommending that the United States should not reference prices established in other countries that rely on QALY use. The Affordable Care Act of 2010 (ACA) included a ban on the use of QALY and similar metrics in Medicare, and in 1992 it established Oregon's efforts to utilize a cost-effectiveness standard in Medicaid, which would violate the Americans with Disabilities Act. Most recently, the US Department of Health and Human Services (HHS) reiterated in a final rule that it is a violation of Section 504 of Rehabilitation the Act (ADA), the Age of Discrimination Act, and Section 1557 of the ACA for state Medicaid agencies to use measures that would unlawfully discriminate based on disability or age.

Thank you for taking the time today to understand why The Arc recommends a DO NOT PASS for SB 2170.

Kirsten Dvorak
K.dvorak@theacrofbismarck.org
701-222-1854

QUALITY –ADJUSTED LIFE YEAR (QALY) DEVALUE DISABLED LIVES.

SENATE 2170 BILL NO. – PRESCRIPTION DRUG COSTS

SB 2170 creates a new chapter, 19-03.7, of the North Dakota Century Code, relating to prescription drug costs.

SB 2170 would reference Canadian rates of prescription drugs. The bill directly references the process paid for drugs in five Canadian provinces. Before applying for coverage by the provinces, all medications must complete a Common Drug Review by Canadian Agency for Drugs and Technologies in Health (CADTH), which references QALYs. In Canada, the outcome is that many individuals living with disabilities are unable to receive the treatments and care they need.

MEDICARE QALY PROHIBITION:

The Affordable Care Act very clearly states that no one has the authority to deny coverage of items or services" solely based on comparative effectiveness research "nor to use such research" in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. "[1]

PRIOR PROHIBITIONS ON QALYS

- Section 504 of the Rehabilitation Act ensured that individuals with disabilities would not" be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination "under any program offered by any Executive Agency, including Medicare. Title II of the Americans with Disabilities Act (ADA) extended this protection to state and local governments' programs and services.
- And in 1992, the Administration, under President George H.W. Bush, established that Oregon's efforts to utilize a cost-effectiveness standard in Medicaid would violate the ADA.

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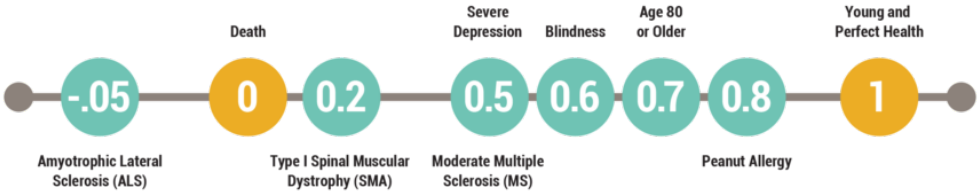
[1] https://secureservercdn.net/45.40.155.175/f2i.811.myftpupload.com/wp-content/uploads/2019/06/PIPC_ValueOurHealth_OnePager.pdf

QALYS- WHAT ARE YOU WORTH?

Quality-adjusted life years, or QALYs, is a metric commonly used to determine the value of a health care treatment. To calculate a QALY, we must assign a value to a person's life. Because the value assigned to seniors, the chronically ill, or people with disabilities is lower than that of a young, healthy person. [2]



NATIONAL COUNCIL ON DISABILITY:

The Nation Council On disability, an independent federal agency, recommends that policymakers avoid referencing or importing the QALY from other countries (such as Canada), clarifying that its use in public programs would be contrary to United States civil rights and disability policy. [3]

Thank you for taking the time today to understand why The Arc recommends a DO NOT PASS for SB 2170.

The Arc
North Dakota

The Arc of North Dakota
Contact: Kristen Dvorak | k.dvorak@thearcofbismarck.org

[2] https://valueourhealth.org/what-are-you-worth/

[3] https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

10147

March 19, 2021

Representative Mike Lefor
Chairman, House Industry, Business and Labor Committee
State Capitol
600 East Boulevard
Bismarck, ND 58505

Dear Representative Lefor,

The Association for Accessible Medicines (AAM) is opposed to Senate Bill 2170, which establishes price controls in the United States based on reference pricing from four Canadian provinces. AAM represents the manufacturers and distributors of generic and biosimilar medications and works to ensure these medicines are more accessible to the people who need them. Generic medications represent 90% of all prescriptions filled but only 20% of prescription drug spending in the United States. In 2019, the use of generic medicines saved $313 billion nationwide, while use of biosimilar medications saved U.S. patients $2.2 billion.

AAM is opposed to SB 2170 due to its effect on the competitive generic and biosimilar marketplace. AAM supports the goal of lowering prescription drug costs, however the use of reference pricing would not achieve this. Instead, reference pricing undermines savings already delivered through generic competition as well as future savings promised by biosimilar medicines. In fact, biosimilars are projected to save more than $100 billion over the next 4 years alone while savings from the use of generic medications also continues to increase.

The U.S. has the most competitive generic market in the world and saving the U.S. $2.2 trillion over the past ten years. Generic and biosimilar medicines are developed under a statutory and regulatory framework that provides, once approved by the FDA, they compete against brand products as well as other approved generics and biosimilars. This direct price competition benefits patients and payers, saving North Dakota nearly $915 million in 2019 alone. The use of reference pricing would undermine the competitive market and potentially stunt the developing market for biosimilars. These complex drugs offer competition for some of the most expensive drugs used to treat patients and manufacturers must balance the potential market post-launch before investing the significant research and development costs — which can range from an estimated $100 million to $300 million per drug.

For these reasons the AAM is opposed to Senate Bill 2170. Please feel free to contact me at brett.michelin@accessiblemeds.org if you have any questions regarding the AAM or its position on this bill.

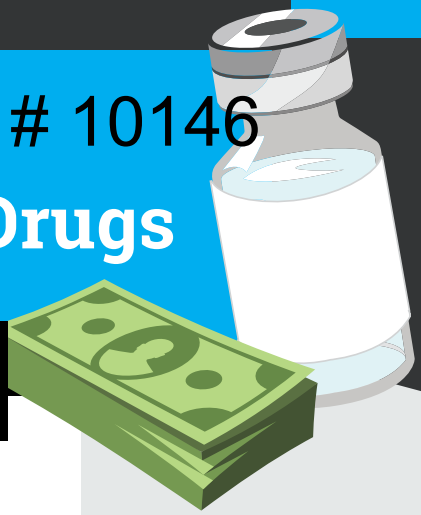
Sincerely,

Brett Michelin

Brett Michelin
Senior Director, State Government Affairs

North Dakota Secures Big Savings Through Generic Drugs

10146



Total Savings: $914.2 Million

In 2019, the use of safe, effective and affordable generic medicines saved the state's patients and taxpayers $417.2 million and $313 billion for the country. The COVID-19 global pandemic has highlighted the importance of affordable and accessible generics to help save lives and contain costs for America's patients.

These savings reach every patient in North Dakota. The average copay for a generic medicine is nearly $50 lower than the copay for a brand-name drug. In fact, 92% of generic prescriptions are filled for $20 or less. Through the pandemic and beyond, it's vital to make effective, affordable generic medicines more accessible to more people who need them.

"Abandonment" occurs when a patient does not collect the prescription called in or brought to the pharmacy. In North Dakota, reporting shows that in 2018 patients abandoned their brand-name prescriptions **17.7%** of the time, compared to only **6.3%** for generics.

Promise of Biosimilars

Only **2%** of prescriptions in the U.S. account for nearly **50%** of U.S. health care costs. These prescriptions are for biologics and other specialty medicines. Biosimilars, which meet the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines, are a growing area of savings for America's patients. They saved the health care system $2.2 billion in 2019 and $4.5 billion over the past 10 years. Biosimilars are projected to save America $80 billion or more over the next decade, but only if patients can access them.

Source: IQVIA 2019

Your State Savings

Medicaid
$82 Million

Medicare
$233.9 Million

Cash (non-insured)
$144.6 Million

Commercial Insured
$453.7 Million

TOTAL
$914.2 Million

Generic drug and biosimilars savings in the U.S.

Generics are 90% of Prescriptions Filled Yet Account for Only 20% of Prescription Drug Spending.

$313 Billion
Generics 2019 U.S. Savings

$2.2 Trillion
Generics 10-Year U.S. Savings

$4.5 Billion
Biosimilars 10-Year U.S. Savings

HDA
Healthcare Distribution Alliance
PATIENTS MOVE US.

10264

March 22, 2021

North Dakota State Legislature
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: Healthcare Distribution Alliance (HDA) Opposition to SB 2170

Chairman Lefor, Vice Chair Keiser, and Members of the Industry, Business and Labor Committee,

The Healthcare Distribution Alliance (HDA) offers this letter to indicate our opposition to Senate Bill (SB) 2170, relating to prescription drug costs. 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 HDA, I would like to express our opposition to SB 2170 and its failure to accurately reflect the complexity of the pharmaceutical supply chain.

Distributors are unlike any other supply chain participants – their core business **does not involve manufacturing, marketing, prescribing or dispensing medicines, nor do they set the list price of prescription drugs, influence prescribing patterns or determine patient-benefit design.** Their key role is to serve as a conduit for medicines to travel from manufacturer to the provider while making sure the supply chain is fully secure, fully functional, and as efficient as possible. Due to these efficiencies, HDA member companies generate between *$33 and $53 billion in estimated cost savings each year* to our nation's healthcare system.[1]

A wholesale distributor is responsible for fulfilling pharmacy customer orders. **Wholesale distributors have no insight into patient-level data, the price the patient pays, nor are they privy to how products are dispensed at the patient-level by the pharmacy.** At the time of the purchase from the wholesale distributor, a retail pharmacy is unaware of which patient would receive the medication and what coverage that individual would have, the wholesaler would not be able to differentiate when or how to sell the product at the proposed referenced rate upon the sale to the pharmacy. Simply put, a wholesale distributor has no insight into the patient and they have no impact on what that patient pays at the pharmacy counter.

Furthermore, a wholesale distributor would not be in a position to negotiate with the Insurance Commissioner the sale price of a prescription drug or the maximum reimbursement by a third-party payor for a prescription drug. Third-party payors and their pharmacy benefit manager agents set reimbursement for drugs dispensed to the health plan members. Such reimbursement formulas may be based on WAC or other metrics set by manufacturers; wholesale distributors are not privy to these reimbursement formulas. Similarly, a wholesale distributor would not be able to "negotiate in good faith" as they do not negotiate drug pricing with the Insurance Commissioner. These negotiations fall

[1] The Role of Distributors in the US Health Care Industry Report; https://www.hda.org/resources/the-role-of-distributors-in-the-us-health-care-industry

outside of the scope of a wholesale distributor. Likewise, the determination not to sell a product to a state would fall outside of the wholesale distributor's authority, this determination would occur at the direction of the manufacturer who could impose such conditions on the sale of the product to the wholesaler. Wholesale distributors should not be subject to a penalty if they are acting at the direction of the manufacturer.

The Centers for Medicare and Medicaid Services (CMS) recently proposed a similar model, Most Favored Nations (MFN). When CMS conducted their own impact analysis[1] they predicted that a transition to this type of model could disrupt care – the agency projected a nine percent increase in the rate at which patients at non-safety-net providers would have no access to Medicare covered medications in the first year of the demonstration – increasing to 19% in years 3 – 7. This projected loss of access could force beneficiaries to travel to seek care from an excluded provider or perhaps even postpone or forgo treatment altogether.[2] When addressing a similar policy proposal in Congress, HR 3, North Dakota Congressman Kelly stated "Speaker Pelosi's partisan drug bill will lead to fewer cures for patients. It suffocates innovation and development, and it could keep dozens of life-saving prescription drugs from entering the market in the next decade."

While HDA appreciates the importance of containing costs, SB 2170 is an uncontrolled experiment seeking to establish price controls on unspecified pharmaceutical products while inaccurately reflecting the supply chain. Due to these concerns, HDA opposes SB 2170 and we respectfully request an unfavorable vote.

Thank you,

Leah D. Lindahl

Leah Lindahl
Senior Director, State Government Affairs
Healthcare Distribution Alliance

[1] Federal Register, Vol. 85, No. 229, November 27, 2020 page 76237, "Table 11 – Assumptions Reflected in OACT Estimate"

[2] *See*, for e.g., *Id.* at 76237, 76248.

10185

BIO Opposes North Dakota SB 2170– Canadian Reference Pricing
February 17, 2021

Position: BIO respectfully opposes SB 2170 that would import Canadian price controls on medications in the United States. Price controls are discriminatory and would jeopardize patient access to innovative biopharmaceuticals.

Critics of the biopharmaceutical industry often condemn the industry for charging higher prices in the United States than abroad. The fact is that nearly all foreign countries operate on nationalized healthcare systems where prices are set and controlled by the government. When imposed on medicines, government price controls suppress innovation and access to new medicines. This deters the development and supply of new life saving and life improving medicines to the detriment of patients and doctors.

Pegging prescription drug prices in the United States to lower foreign prices will limit prescription drug prices and jeopardize patient access to innovative medicines here in the United States.
Lack of access to innovative medicines presents real dangers to patients. In a study conducted by the National Bureau of Economic Research estimated that cutting prescription drug prices in the United States will lead to between 30% to 60% fewer early-stage research and development project being undertaken.[1]

Another recent study highlighted these risks, comparing differences in health outcomes for patients being treated for locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC).

- The researchers found that, if the access conditions for five ex-U.S. comparator countries (Australia, Canada, France, South Korea, and the United Kingdom) were to replace the actual U.S. access conditions between 2006 and 2017, aggregate survival gains due to innovative medicines would have been cut in half for U.S. patients diagnosed with locally advanced and metastatic NSCLC.

- According to the authors, this reduction in health gains is due to the access delays experienced by patients in other countries compared to patients in the U.S.

- Across all cancers, the 5-year survival rate is 42% higher for men and 15% higher for women in the U.S. compared to Europe.

Importing Canadian prices controls to the United States will jeopardize the innovative health care ecosystem that produces life-saving therapies.
More than 57% of all drugs come from the United States. Implementing price controls of any kind will have a chilling effect on innovation. Economists have estimated that a 50% drop in drug prices in the United States could see the number of drugs in the development pipeline reduced by 14-24 percent,[2] decreasing the hopes of patients

[1] Abbott, Thomas and John Vernon, "The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions," NBER Working Paper Series, NBER, 2005.
[2] "The Effect of Price on Pharmaceutical R&D," *The B.E. Journal of Economic Analysis and Policy,* 2009.

seeking new cures and treatments. The impact would be felt far greater by patients with one of the more than 7,000 rare diseases only 5% of which have FDA-approved treatment options.[3]

The average biopharmaceutical costs $2.6 billion to bring from research and development to market.[4]
On average, prescription drug development takes more than a decade. Only one drug candidate out of thousands will receive regulatory approval. The overall probability is less than 12% for a drug or compound in clinical testing to reach final approval.[5] These research and development failures are part of pricing strategies so that companies have the ability to reinvest revenues into new research and development projects.

Canadian style prices controls discriminate against patients with chronic disease and disability.
Canadian prices are governed by price controls that are based on the use of quality-adjusted life years (QALYs). The federal government recognizes that QALYs are inherently discriminatory to patients with chronic disease and disability. In its November 2019 report on QALYs, the National Council on Disability (NCD) "found sufficient evidence of QALYs being discriminatory (or potentially discriminatory) to warrant concern." It called on Congress to pass legislation prohibiting the use of QALYs in Medicare and Medicaid. In addition, it encouraged CMS to use alternative measurements of value when "the exact cost and benefits of a drug or treatment are not known."

The NCD report also notes that basing prices in the US on foreign prices imports a discriminatory system and jeopardizes patient care. Studies have shown that countries that use QALYs have severe restrictions on patient access to innovative medicines in other countries. For example, one study has shown that between 2002 and 2014, 40% of medicines that treat rare diseases were rejected for coverage in the United Kingdom. Another study demonstrates that only 55% of new drugs approved globally for respiratory illnesses between 2011 and 2017 were available in Canada versus 100% in the United States.

The premise that establishing upper limits does not impose price controls is a false narrative.
Whether you call it establishing "Upper Limits" or a price control the effect is the same. This policy still regulates free-market prices and creates a price ceiling based upon a metric from Canadian health system that establishes their prices at a much lower level than in the US.

We ask for an unfavorable vote on SB 2170.

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[3] Kaufman, Petra, et al., From scientific discovery to treatments for rare diseases – the view from the National Center for Advancing Translational Sciences – Office of Rare Diseases Research, Orphanet Journal of Rare Diseases, 2018.
[4] DiMasi, JA, et al., Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. February 12, 2016.
[5] Biopharmaceutical Research and Development, The Process Behind New Medicines. PhRMA, 2015. http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf

10241

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to North Dakota
SB 2170 – Canadian Reference Pricing
March 22, 2021

Position: PhRMA respectfully opposes Senate Bill 2170 – Canadian Reference Pricing because it would place a price control on prescription drugs which could stifle innovation, limit patient access to medicines, and raises significant legal concerns.

This proposed legislation requires state-regulated commercial insurance plans to cap the amount they pay for prescription medicines at a reference price, essentially placing a price control on these medicines. This kind of legislation will not benefit patients and can jeopardize the competitive market that works to drive down drug prices. Proposals such as this that arbitrarily cap pharmaceutical prices fail to recognize the complexity of the pharmaceutical supply chain.

Implementing price controls, at a time when the industry has been tirelessly dedicated to finding treatments and vaccines for COVID-19, diverts industry resources elsewhere and risks current and future innovation. We are in a new era of medicine that is bringing revolutionary, innovative treatments, therapies, and cures to patients. Last year alone, the cancer death rate saw the biggest one-year drop in history.[1] Unfortunately, this radical policy would freeze new, life-saving innovation and force patients to face the uncertainty of a health care system where the government sets prices for critical medicines, similar to what is done in foreign countries.

International reference pricing could threaten drug development and replaces market competition with government price setting.

This legislation replaces market competition with government price setting or price controls, basing U.S. medicine prices on the policies of foreign governments that ration care in their own countries. The legislation threatens to drastically reduce development of new medicines at a time of remarkable scientific promise, undermining U.S. global leadership in biopharmaceutical innovation. Price controls diminish the incentive for biopharmaceutical manufacturers to invest in the research and development of new medicines. By requiring state-regulated commercial insurance plans to cap the amount they pay for the prescription medicines at a reference price, this creates a price control on these medicines that could have the long-term effect of decreasing access to medications.

On average, it takes more than 10 years and $2.6 billion to research and develop a new medicine. Just 12% of drug candidates that enter clinical testing are approved for use by patients. Efforts to impart price controls on innovative manufacturers could chill the research and development of new medicines by

[1] Facts and Figures 2019: US Cancer Death Rate has Dropped 27% in 25 Years, Cancer.org, https://www.cancer.org/latest-news/facts-and-figures-2019.html.

taking away the incentives that allow manufacturers to invent new medicines. Price controls also could severely reduce patients' access to medicines, as is seen abroad.

For years, Canada has imposed price controls and other measures that significantly undervalue innovative medicines developed in the United States. Research shows that U.S. patients enjoy earlier and less restrictive access to new therapies,[2] a finding that is reinforced by the United States Department of Health and Human Services' own analysis of Medicare Part B drugs which showed that only 11 of the 27 drugs examined (41 percent) were available in all 16 comparator countries, nearly all of which have single payer health care systems.[3]

In fact, American patients have faster access to more medicines than patients anywhere else in the world, and doctors and patients work together to decide which medicine is right for them. In countries that use international reference pricing and other government price controls, patients can access fewer new medicines and face long treatment delays. Nearly 90% of new medicines launched since 2011 are available in the United States compared to just 50% in France, **46% in Canada** and 41% in Ireland – countries that use some form of international reference pricing.[4] Even the medicines available in these countries take much longer to reach patients. On average, patients must wait at least 18 months longer in France, **15 months longer in Canada**, and 20 months longer in Ireland than in the U.S.

By importing prices set in other countries, this legislation also imports cost-effectiveness analyses that are known to be discriminatory.

Studies using cost-effectiveness analysis (CEA) relies on the use of discriminatory Quality Adjusted Life Years (QALYs) and cost-per-QALY thresholds. Developed from population averages, QALYs ignore important variability in patients' individual needs and preferences. Experts have identified that QALYs discriminate against people with disabilities by placing a lower value on their lives. A report issued by the National Council on Disability in 2019 "found sufficient evidence of the discriminatory effects of QALYs to warrant concern, including concerns raised by bioethicists, patient rights groups, and disability rights advocates about the limited access to lifesaving medications for chronic illnesses in countries where QALYs are frequently used."[5]

Value frameworks can be useful decision-support tools, but should not be viewed as providing a single, universally applicable answer to questions about a treatment's value. Value frameworks typically emphasize one of several perspectives (e.g., payer, patient, society, or innovator) and conclusions may not apply to individual patients. In addition, as with any economic model, value frameworks involve making choices about methods, assumptions and data that can yield important differences in results depending on the choices made. This is reflected in the disparate assessments produced by different frameworks. These factors, combined with lack of consensus on best practices and inconsistency in level of transparency, underscore the need to construct and use value frameworks appropriately. Experience in some countries outside the U.S. illustrates how value frameworks can be used in ways that deny access to care options that clinicians and patients recognize as highly valuable.

[2] IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost, May 2017.
[3] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018.
[4] https://catalyst.phrma.org/setting-the-record-straight-on-international-reference-pricing
[5] National Council on Disability, "Quality-Adjusted Live Years and the Devaluation of Life with Disability." November 6, 2019 (cite cover memo).

In countries that rely on CEA to determine coverage and payment, many patients face significant restrictions on access to treatments, including those diagnosed with cancer, diabetes, and rare diseases. A recent analysis noted that these types of cost-effectiveness assessments and recommendations, based on population-averages, fail to properly adjust to the demands of an evolving health care system and do not reflect the rapid pace of the science, or the needs and preferences of the patients.[6]

This legislation raises significant legal concerns.

This legislation raises a number of constitutional concerns.

The proposed legislation specifically caps prices payors and pharmacies may pay for a drug at an international benchmark (Canadian prices) which raises federal patent preemption concerns. Price controls have historically been found unconstitutional. Specifically, in the case of *BIO v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 1997), the court overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the D.C. law conflicted with the underlying objectives of the federal patent framework by undercutting a company's ability to set prices for its patented products. The court's decision stated, "The underlying determination about the proper balance between innovators' profits and consumer access to medication …is exclusively one for Congress."

This legislation gives the Superintendent of Insurance broad discretion to determine which products will be subject to a price control, and biopharmaceutical manufacturers are not provided due process at any stage of the Superintendent's determinations. In addition, there is no clear mechanism for a biopharmaceutical company to appeal a penalty from the Superintendent of Insurance and/or Attorney General.

Finally, this legislation regulates extraterritorial transactions and discriminates against manufacturers that sell patented products in foreign nations, raising Dormant Commerce Clause and Foreign Commerce Clause concerns respectively.

This legislation fails to recognize the role of the pharmaceutical supply chain in setting prices and fails to address patients' barriers to accessing care, particularly the costs patients pay at the pharmacy counter.

This legislation fails to recognize the role the pharmaceutical supply chain plays in the net price of a medicine. Biopharmaceutical companies that research, develop and manufacture medicines retain only 54% of total point-of-sale spending on brand medicines, with the remaining 46%, a staggering $166 billion in 2018, going to other members of the supply chain in the form of rebates and discounts.[7] This bill is affixing price controls without addressing actors within the supply chain who set the price a patient pays.

Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as making monthly costs more predictable, making cost sharing assistance count toward meeting plan out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients.

[6] Context Matters. NICE Limits Reimbursement for Oncology Products beyond EMA Product Labeling. May 2014.

[7] BRG: Revisiting the Pharmaceutical Supply Chain 2013-2018. January 2020

Discounts to plans and PBMs are growing while net prices remain under the rate of inflation, yet patients are being asked to shoulder a greater burden.

- Half (49%) of commercially insured patients' out-of-pocket spending for brand medicines in 2019 was based on the full list price.[8] This means that cost sharing did not consider any rebates or discounts in that scenario.
- The use of four or more cost-sharing tiers is becoming more common by rising from just 4% of all employer plans in 2005 to 45% by 2019.[9]

Sharing negotiated discounts could save patients a significant amount of money at the pharmacy counter. A recent report by Milliman estimates some patients would save over $1,000 per year on their prescription drug costs of rebates were shared with patients.[10] Any attempts at addressing drug affordability should start there.

The biopharmaceutical sector is committed to bringing new treatments and cures to patients. This commitment to innovation supports high-quality jobs and is a vital part of North Dakota's economy and its economic competitiveness. The biopharmaceutical sector directly accounted for more than 800 jobs in North Dakota through 2019. These jobs generate over $10 million in state and federal tax revenue. This bill could place these jobs, and tax revenue, in jeopardy.

PhRMA recognizes the access challenges faced by patients in North Dakota with serious diseases. **However, this legislation will stifle innovation and does nothing to address patient access and affordability.** In addition, this legislation raises a number of constitutional concerns including due process and patent preemption. PhRMA stands ready to work with the legislature to develop market-based solutions that help patients better afford their medicines at the pharmacy counter.

We respectfully oppose SB 2170 and ask for an unfavorable vote.

8 IQVIA. Medicine Spending and Affordability in the U.S. August 2020. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us

[9] Id.

[10] Point of Sale Rebate Analysis in the Commercial Market: Sharing Rebates May Lower Patient Costs and Likely has Minimal Impact on Premiums. Milliman, Inc. October 2017

The United States vs. Other Countries: # 10237

Availability of Cancer Medicines Varies

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The proposed International Pricing Index Model would set U.S. prices for medicines covered under Medicare Part B based on the pricing policies of 14 foreign governments – many of which set prices artificially low, resulting in severe access restrictions for patients.

	New Cancer Medicines Available	Average Delay in Availability of Cancer Medicines
Greece	16%	41 months
Ireland	53%	23 months
Belgium	55%	25 months
Czech Republic	55%	24 months
Italy	58%	21 months
Japan	58%	23 months
Canada	59%	14 months
Finland	61%	14 months
Netherlands	63%	9 months
Denmark	64%	11 months
France	67%	16 months
Austria	68%	11 months
United Kingdom	70%	12 months
Germany	73%	11 months
United States	96%	0-2 months

Source: PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data. June 2020. Note: New Active Substances (NASs) approved by the FDA, EMA and/or PMDA and first launched in any country between January 2011 and December 2019. Average delay represents the time in months since global first launch among NASs that have launched in a given country. IQVIA reports only the retail channel for Greece.

Updated July 2020

IQVIA: Medicine Spending and Affordability in the U.S. # 10238

August 2020

Key Findings:

Overall Prescription Medicine Findings, 2019:

- Brand medicine net prices increased 1.7% on average, below the rate of inflation for the third year in a row.
- Net spending (net manufacturer revenue) on all medicines increased 5.2%.
- Manufacturers received less than half (46%) of total WAC (list price) spending on prescription medicines.

Patient Spending Findings, 2019:

- Just 1.1% of all prescriptions have final out-of-pocket costs above $125.
- Overall, 90% of all patients pay less than $500 out of pocket per year on their prescription medicines.
- Patients saved a total of $12 B in out-of-pocket costs due to the use of copay coupons
- Spending in the deductible and through coinsurance, which often exposes patients to the undiscounted price of the medicine, now accounts for half (49%) of total patient out-of-pocket spending on all medicines but just 9.5% of all prescriptions filled
- 60% of new prescriptions with final OOP costs above $500 are abandoned at the pharmacy, compared to just 5-6% of new prescriptions with cost sharing less than $10.

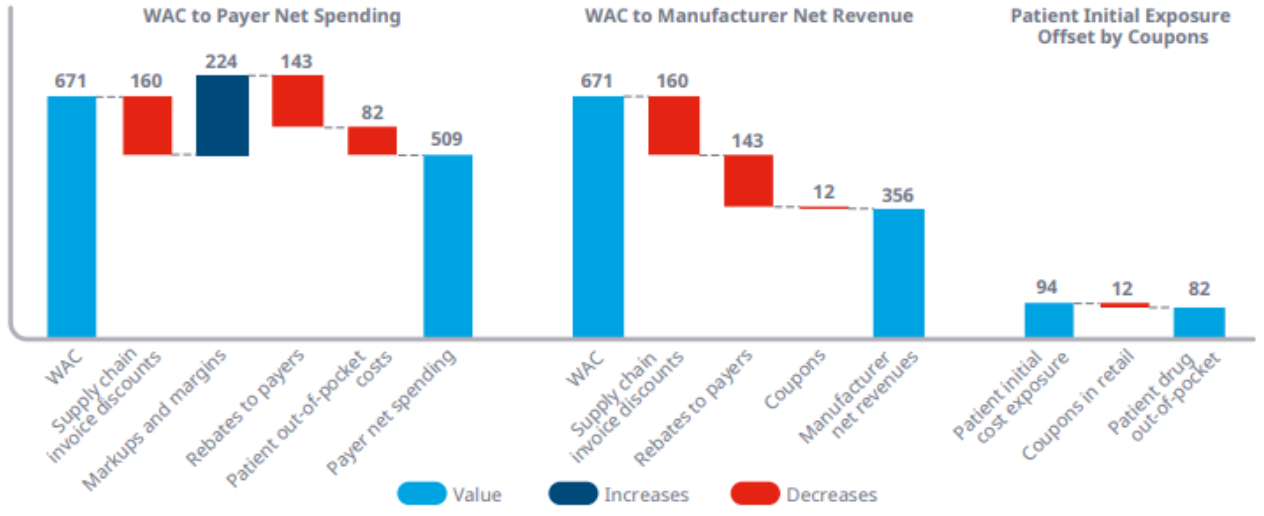
Full Summary:

Drug Prices and Spending Trends:

2019 Total Spending:

- Net spending (net manufacturer revenue) on all medicines increased 5.2%
- Total WAC (list price) spending on prescription medicines was $671 B, total net payer spending on medicines was $509 B, and total manufacturer net sales was $356 B (less than half, 46%, of total WAC spending)
- Payers received $143 B in rebates from manufacturers and supply chain and other entities retained $224 B in mark-ups and margins on prescription drugs

Exhibit 2: Differences Between Various Spending Levels for U.S. Prescription Medicines in 2019, US$Bn



Source: IQVIA Institute, Jun 2020; CMS National Health Expenditures (NHE), Dec 2019

- In 2019 alone, loss of exclusivity lowed medicine spending by $21.1 B

Meet MAT

10239

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.

Lessons Learned from Europe:

Price Setting Policies Erode Biopharmaceutical Leadership

10240

Before adopting price setting policies, Europe led the world in biopharmaceutical innovation.

Until the 1970's the majority of innovative medicines were developed in Europe.

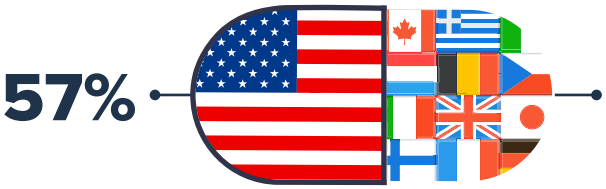
As European governments adopted stringent price setting measures, output fell and this leadership slipped away.

After adopting these measures, Europe trails the United States in R&D investment by more than 40%.*

Now biopharmaceutical innovation in the United States delivers more new medicines than the rest of the world combined.

America leads the world in medical innovation because of the unique research ecosystem. The coronavirus only highlights how important it is to have American companies and scientists finding new treatments and cures to protect our citizens.

American innovation is responsible for 57% of all new medicines that treat patients around the world **



International reference pricing would threaten American leadership in biopharmaceutical innovation.

International reference pricing is a form of government price setting in which U.S. bureaucrats would determine the value of our medicines based on how foreign governments and politicians value these treatments and cures.

If the United States adopted European-style price setting policies, it would have resulted in an estimated **117 fewer new medicine compounds** being developed between 1986 and 2004.***

We need U.S. innovation in new treatments and vaccines.
Tell policymakers to protect American biopharmaceutical innovation.

*Günter Verheugen, Vice-President of the European Commission for Enterprise and Industry. 2005. "Biotechnology's contribution to an innovative and competitive Europe." Lyon. April 14, 2005.
**The Milken Institute (http://assets1c.milkeninstitute.org/assets/Publication/ResearchReport/PDF/CASMIFullReport.pdf)
***Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms, Pharmacoeconomics (http://pubmed.ncbi.nlm.nih.gov/20617857/)

Learn more at PhRMA.org

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	2021 - 2022			2022-2023		
Position	**Salary**	**Fringe**	**Total**	**Salary**	**Fringe**	**Total**
Attorney	79,175.16	33,102.93	112,278.09	79,175.16	33,102.93	112,278.09
Investigator	58,507.20	28,942.48	87,449.68	58,507.20	28,942.48	87,449.68
Director	96,156.72	36,483.97	132,640.69	96,156.72	36,483.97	132,640.69
Analyst	73,440.00	31,915.58	105,355.58	73,440.00	31,915.58	105,355.58
Total	**307,279.08**	**130,444.96**	**437,724.04**	**307,279.08**	**130,444.96**	**437,724.04**
4 FTEs Total for the Biennium $875,448.08						

10138

March 22, 2021

The Honorable Mike Lefor, Chairman
The Honorable George Keiser, Vice Chairman
House Committee on Industry, Business and Labor

Dear Chairman Lefor, Vice Chairman Keiser, and Members of the North Dakota House Committee on Industry, Business and Labor:

On behalf of National Taxpayers Union (NTU), the nation's oldest taxpayer advocacy organization, we are here to testify against SB 2170, an act which establishes prescription drug price controls for patented pharmaceuticals. Despite well-meaning legislative intent and the importance of prescription drug affordability, North Dakota patients and taxpayers will not be well-served should the provisions of this bill become law.

The objective of SB 2170 is to reduce drug prices by granting authority to effectively cap the amount that state-regulated insurance plans pay for prescription drugs that have been subjectively deemed to be too costly. Unfortunately, regardless of its intent this legislation creates adverse consequences which could limit the availability and development of prescription options to North Dakota consumers during a time in which biopharmaceutical innovation is needed more than ever.

SB 2170 will likely have a longstanding, detrimental effect on the development of groundbreaking, life-saving medications. Explicitly, the legislation establishes government price setting, basing the cost of prescription drugs on the policies and prices of the Canadian government. It is rather notable that the legislation does not account for systemic flaws that prevent discounts from directly flowing to patients and erroneously assumes that the price of a drug is determined solely by one piece of the supply chain puzzle.

This legislation blatantly ignores the multiple stakeholders involved in determining what consumers ultimately pay for medications and overlooks the role of consumer drug coverage. For example, pharmacy benefit managers determine the terms of drug coverage for medications and then exert influence over which prescription drugs are included on formularies based upon rebates and discounts. NTU has previously expressed concern that negotiated rebates are not always passed along to the consumer, effectively failing to offset patient costs at the point of

sale. This legislation would implement price controls while failing to address policies regarding other actors within the supply chain who set the price a patient pays.

Imparting price controls will invariably diminish research and development and will remove incentives that encourage manufacturers to pursue innovative prescription drug solutions. SB 2170 fails to consider that manipulating the economic structure through regulatory provisions or legislative decree often generates negative results. Research has consistently shown that patients in the United States are afforded earlier, less restrictive access to new drug therapies -- analysis confirmed by the U.S. Department of Health and Human Services. If lawmakers elect to artificially and arbitrarily reduce the price paid for prescription drugs, North Dakota will eventually have less access to innovative medications. Over the long run, that means taxpayers will face heavier burdens from government health programs forced to pay for more expensive treatments than drugs, such as surgeries and longer hospital stays.

The stated purpose of this legislation is to lower prescription drug prices and reduce out-of-pocket costs for North Dakota patients. NTU shares these goals with lawmakers and recognizes the challenges faced by patients and taxpayers. In consideration of our mutual goals, we strongly believe that imposing government-dictated price controls on prescription drugs will not lower drug prices and will ultimately decrease patient access and limit the innovation of new life saving medications.

We hope you stand with the patients and taxpayers of North Dakota and oppose this legislation. Thank you for your time and consideration of NTU's comments. Please reach out should you have any questions.

Sincerely,

Jess Ward
Director of State Affairs

10141

Complaining about a problem without proposing a solution is called whining.
-Teddy Roosevelt

Roughrider POLICY CENTER

Bette B. Grande
President & CEO

Chairman Lefor and members of the House Industry and Business committee,

My name is Bette Grande, and I am the CEO of the Roughrider Policy Center (RPC). Thank you for this opportunity to submit testimony regarding SB 2170.

As a research and education organization, RPC has a goal to support policies that expand access, increase choice, improve quality, and reduce cost for all North Dakotans seeking healthcare. We are all fighting for more affordable medications for patients in need. However, this Bill is not the way to reach our goal. This proposal will cause more harm than good, and we urge lawmakers to reject SB 2170.

This bill would impose price controls on prescription drugs, referencing prices from Canada with significant unintended consequences. The history and experience of price controls, in whatever form, has been harmful for consumers. Imposing a cap on prescription drugs based on an entirely different healthcare system with different policies in another country would simply not work in our American free market system.

Additionally, this price cap policy will risk future innovation in the field of medicine and innovation has led to many of the breakthroughs we benefit from today. The United States is a leader in this regard, and it has allowed Americans to get the quickest and best access to new, life-saving medications. Especially during COVID-19, when we need innovative ways to combat a new virus, we cannot begin to limit our research opportunities.

For Liberty,

Bette Grande

Bette Grande

Bette Grande is the CEO of the Roughrider Policy Center, North Dakotas Think Tank

10184

March 22, 2020

Chair Lefor and Members of the House Industry, Business and Labor Committee,

We are Dr. 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 submitting written testimony in support of Senate Bill 2170 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. We are requesting your support on Senate Bill 2170, related to containing/reducing prescription drug costs.

Our family needs your assistance passing this bill so that prescription drugs can be obtained at a more reasonable cost. Personally, we claimed $22,000.00 in medical costs when filing our income tax this year - - about 30% of our income. It is necessary for my husband to use prescription eyedrops that cost approximately $1,700.00 for a three-month supply ($6,800.00 annually). Because of the high cost of this medication he has reduced his eye drop usage to one half of the prescribed dosage. The medication has no generic or over the counter alternative. Recently he was able to obtain his prescription drug from a visitor who was from a South American country at a cost of $60.00 for a three-month supply. Interestingly, BOTH of the medications were manufactured in the United States by the same company- - one in Waco, TX and one in Irvine, CA. This is not right!

We are extremely concerned about the future when our doctors prescribe another costly medication that we will be unable to afford. 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?

Your positive work on Senate Bill 2170 will demonstrate the importance of this issue on a state and national basis. We would appreciate a YES vote on this bill so that it gets a fair discussion and debate in the House.

Thank you for your service to the citizens of our great state. We appreciate your hard work and commitment.

Sincerely,

Dr. Michael and Mrs. Marilyn Worner
District 44
Fargo, ND 58102

Chairman Lefor and Members of the House IB&L:

Please vote "no" on SB 2170 which requires the State Insurance Commissioner to negotiate and **set prescription drug prices** with manufacturers, using reference rates imported from Canada. This is a well-intentioned bill trying to offer a solution to a real problem. *But it is the wrong solution to lower drug costs.*

Some important factors to consider:

- The **fiscal note** on SB 2170 determined this is a **price control, and it will require more state FTEs to administer.**
- North Dakotans don't like federal – or state - **government price fixing.** Price fixing sounds good, but does not work.
- **Price Controls** distort markets and have shown to never solve the problem they were created to fix.
- Government price controls mean **less funding, less incentives for innovation, less R&D,** as well as **less patient access** for groundbreaking, life-saving drugs. If there are no incentives to profit, there are no results. That is how entrepreneurship and free enterprise works.
- American patients have **faster access to more new medicines** than patients anywhere else in the world today, including 90% of new medicines. That is not true in Canada. This is because of U.S. *incentives that work* and the ability to make profits.
- Ultimately, **government price controls** lead to **less patient access** to critical drugs. Manufacturers will simply not provide their drugs to North Dakota, leaving doctors and patients with **fewer prescription options –** or forcing our citizens **to go out of state for healthcare.**
- A **better solution** to lowering drug costs is to put pressure on the federal government, esp. FDA for **faster generic drugs approvals**, and create a **competitive environment** for more "**me too" drugs** among pharma companies; as well as renegotiate **trade policies** to require Canada, Europe, and other allies to pay their fair share of U.S. Biopharmaceutical R&D. Those policies would create competition, and lower prices by sharing development costs.
- **Generic drugs** represent 90% of all prescriptions, but only 20% of prescription drug spending, saving over $300 B nationwide in 2019. **Biosimilar prescriptions** saved another $2.2B. The U.S. has the most competitive generic and biosimilar markets in the world, and this direct price competition benefits patients and payers. Canadian price fixing would undermine the American competitive market ecosystem… that works better than any other for patient access and affordability.

The ND Senate wisely passed a study bill (SB 2212) to discern the possibilities of a Canadian drug importation and reference pricing.

I encourage the House to secure the results of the study, but also avoid government price controls.

Bruce Gjovig
Chair, Bioscience Association of North Dakota (BioND)
CEO Emeritus, Center for Innovation Foundation
Bruce@Gjovig.net
701-739-3132

Bioscience Association of North Dakota
4200 James Ray Drive Suite 500 #503
Grand Forks ND
Ph: 701-738-2431
richard@ndbio.com

March 21, 2021

Dear Chairman Lefor, Respected Members of the House of Representatives committee on Industry, Business and Labor,

The Bioscience Association of North Dakota opposes
North Dakota SB 2170– Canadian Reference Pricing

Position: BIO ND respectfully opposes SB 2170 that would import Canadian price controls on medications in the United States. Price controls are discriminatory and would jeopardize patient access to innovative biopharmaceuticals, and violate the concept of a "Free Market System," thereby causing shortages.

It is no secret that both the State and Federal Governments are trying to find ways to reduce the cost of prescription medications. One of the ways that the Government is trying to reduce the cost of prescription medications is 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. But three of the biggest reasons not to implement this program is (1) the fact that it will require extensive state resources for the implementation and administration of such a program; (2) it violates the concept of a "Free Market System"; and (3) it can cause life threatening shortages of essential drugs.

In the opinion of the Association, it would require the creation of a whole new bureaucracy to carry out a drug importation program. Such a program would ultimately assign new responsibilities to the State of North Dakota such as designing the program to comply with State and Federal Laws; development of a drug importation list; law enforcement problems such as jurisdictional questions, litigation, and increased costs. It is the Associations belief that such a program will not provide significant savings, achieve appropriate levels of accessor operate efficiently.

North Dakotans are believers in the "Free Market System". They believe in an economic system based on supply and demand with little or no government control. It contributes to economic growth and transparency. It ensures competitive markets and adequate supply to meet demand. Consumers' voices are heard in that their decisions determine what products or

services are in demand. Supply and demand create competition, which helps ensure that the best goods or services are provided to consumers at a lower price.

The “system” being proposed in SB 2170, is not a “Free Market System”, rather it is the opposite of a market economy — i.e, a "non-market" or "planned" economy — one that is heavily regulated or controlled by the government. The sale of Prescriptions Drugs in this State is going to be controlled by the Insurance Commissioner and enforced by the Insurance Commissioner in collaboration with the Attorney General. Violate the provisions of this act and in specific instances a company can be fined up to $500,000.00.

The way I interpret this law, let us say, I am the manufacturer of a specific referenced drug, as defined in the act. I determine that I no longer wish to “sell” that drug in our State because the price I am allowed to charge does not cover the cost of my manufacture and distribution costs. If it is determined by the Insurance Commissioner that this constitutes a “. . . purpose of avoiding the impact of the rate limitations set forth in section 19 - 03.7 – 02”, I can be “fined” five hundred thousand dollars or the amount of annual savings determined by the insurance commissioner as described in subsection 4 of section 19 - 03.7 - 04, whichever is greater.

Hardly a “free market system”. I wonder how this would go over if this was “beef cattle” and a law is passed saying beef producers must sell their cattle at a price determined to be fair by the Commissioner of Agriculture? Or they can be fined out of existence.

But one of the greatest drawbacks to this type of system is that it causes “shortages”. As the Canadians themselves found out.

> “In 2018 alone, Canadian patients faced shortages for hundreds of medications, including EpiPens, opioid drugs, and treatments for Parkinson's disease, schizophrenia, and depression. In many cases, these shortages can have severe and life-threatening consequences. One of the reasons behind this finding could be related to the lower reimbursement price for generic drugs based on the pan-Canadian tiered pricing framework and provincial price-cap policies. The team also found that markets with a larger proportion of their drugs covered under provincial formularies were more likely to be in shortage.” **(“One quarter of prescription drugs in Canada may be in short supply”;** Published in “Science Daily” Dated, September 1, 2020; Source: University of British Columbia; https://www.sciencedaily.com/releases/2020/09/200901085306.htm)

In the Association’s opinion, history has shown that people are going to sell their goods and services in markets where they can get the highest prices. If a manufacturer or distributer can get a higher price for his goods in, say New York rather than North Dakota, he is going to

service that market first and that is going to lead to shortages in other markets. That is why price controls do not work.

We ask for an unfavorable vote on SB 2170.

Richard Glynn
Executive Director
Bioscience Association

10221

March 22, 2021

Chair Lefor and Members of the House Industry, Business, and Labor 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 2170.

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. SB 2170 is a step in the right direction and I hope you give the bill a favorable recommendation.

Thank you.

SB 2170 – Testimony by Dustin Gawrylow (Lobbyist #266) North Dakota Watchdog Network

The COVID-19 pandemic has shown us how much Americans and North Dakotans rely on our robust healthcare system. The many different stakeholders, from the manufacturers to the patients themselves, work in the free market to determine prices and pushes for innovation on all fronts. This system has been imperative in our fight against COVID-19, especially in developing multiple vaccines in record time.

So, with all these good things, why would the North Dakotan state government want to replace our system with restrictive socialist policies?

Unfortunately, our legislature is considering a bill, SB 2170, that would limit the free market and pin medicine prices to those in Canada, a foreign, socialist market. The goal of this legislation is to reduce drug prices. Instead, it will raise prices of medicines and limit our state's access to medical innovations. This bill, an a few others like it have already passed the State Senate. So this debate is not just about an idol threat from bills that have no chance of passing.

America's free market encourages competition to create the most effective medications at the cheapest price. Setting the price of our medicines will take away any drive for innovation. And unfortunately, it could result in North Dakotans going without potentially life-saving options. Our innovators worked to create three vaccines in less than a year since this pandemic reached a critical mass. With socialist price fixing, we would have zero.

SB 2170 has the good intentions of lowering healthcare prices, but it will have the complete opposite effect. The American way is all about using the free market to find solutions. We should continue with, rather than give up on, the free market.

10259

In Opposition to North Dakota SB 2170
Canadian Reference Pricing
March, 22, 2021 2:30pm.

Chairman Lefor and members of the House Industry, Business, and Labor committee,

With the North Dakota Americans for Prosperity organization behind me, I am asking you to reject SB 2170, or the introduction of prescription price controls. The adoption of this act will not result in its expected outcome and will instead cause additional red tape and bureaucracy that will limit the ability for North Dakotans to get the care they need and deserve.

It is important that we find fiscally responsible ways to decrease drug prices to make them readily available to those who need them. Price controls are not the way to do it. We believe using the American free market and the strengthen of competition and innovation will lower healthcare price and open accessibility—not socialist policies tied to socialized governments.

The COVID-19 pandemic showed us that unnecessary red tape and bureaucracy limit medical professionals from providing the care patients deserve. Even now as the vaccine rollouts out, we see states with more limitations on who can be vaccinated have been significantly slower than those without. Simply put, red tape and bureaucracy stop doctors and nurses from saving lives.

SB 2170 will do the same to North Dakota's prescription drug marketplace. By introducing anti-free market methods, you will be limiting access to the United States' most innovative drug therapies that we have to

offer. Consider the long-term results of this as less innovation is promoted and North Dakotans are unable to get care for new viruses or conditions that may arise.

Reject SB 2170 and embrace American values in your legislation. Think of the long-lasting effects SB 2170 would have on the North Dakotan market and citizens when making your decision. I along with everyone at Americans for Prosperity hope that you see the problems with your legislation and reject this un-American policy.

Regards,

Abigail Christiansen

Americans for Prosperity North Dakota
Grassroots Engagement Director
abchristiansen@afphq.org

PIPC Partnership to Improve Patient Care

10296

March 22, 2021

Dear Members of the Committee:

My name is Thayer Roberts, registered lobbyist for Partnership to Improve Patient Care (PIPC), and I would like to present PIPC's chairman, The Honorable Tony Coelho, to provide written testimony:

Dear Members of the Committee:

We understand that the rising cost of healthcare is a concerning issue that requires real solutions. While we agree health care affordability is a significant priority, we oppose policies, like SB 2170, that rely on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that are known to devalue disabled lives and lead to restricted access to needed care and treatment in countries like Canada.

As background, the American Association of People with Disabilities (AAPD) is a national cross-disability rights organization, advocating for full civil rights for the over 61 million Americans with disabilities by promoting equal opportunity, economic power, independent living, and political participation. The Association of University Centers on Disabilities (AUCD) is a membership organization that supports and promotes a national network of university-based interdisciplinary programs. The Partnership to Improve Patient Care (PIPC) is a coalition effort to apply principles of patient-centeredness to the nation's health care system. We encourage policymakers to manage health costs in a manner centered on meeting the health care needs of people with disabilities and chronic conditions. We are all joined in opposition to the use of the QALY, including the importation of the QALY through SB 2170.

Experts agree that referencing discriminatory metrics such as QALYs, whether in reference to QALY-based decisions from foreign governments or to value assessments conducted by the Institute for Clinical and Economic Review (ICER), is discriminatory and risks depriving North Dakotans of needed medical treatments.[1] QALY-based assessments assign a financial value to health improvements provided by a treatment that do not account for outcomes that matter to people living with the relevant health condition and that attribute a lower value to life lived with a disability. When applied to health care decision-making, the results can mean that people with disabilities and chronic illnesses, including older adults, are deemed not worth the cost to treat. In 2019, experts at the National Council on Disability (NCD), an independent federal agency advising Congress and the administration on disability issues, published a report finding that use of the QALY would be contrary to United States civil rights and disability law and recommended that the United States avoid referencing prices from other countries that rely on the QALY in order to avoid the access challenges experienced in those countries.[2]

[1] https://f2i.811.myftpupload.com/wp-content/uploads/2019/12/IPI-One-pager-.pdf
[2] https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

SB 2170 would reference rates of prescriptions drugs from a third party, the Canadian government, which relies on the QALY for coverage and reimbursement decisions.[3] The bill directly references the prices paid for drugs in five Canadian provinces. Before applying for coverage by the provinces, all drugs must complete a Common Drug Review by CADTH, which references QALYs. In Canada, the outcome is that many individuals living with disabilities are unable to receive the treatments and care they need.[4]

Yet, the United States has a thirty-year, bipartisan track record of opposing the use of the QALY and similar discriminatory metrics and has established legal safeguards to mitigate their use:

- Section 504 of the Rehabilitation Act ensures that people with disabilities will not be "excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency, including Medicare.[5]
- Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.[6] Based on the ADA's passage in 1990, in 1992 the George H.W. Bush Administration established that it would be a violation of the ADA for state Medicaid programs to rely on cost-effectiveness standards, as this could lead to discrimination against people with disabilities.[7]
- The Affordable Care Act (ACA) passed under President Barack Obama directly states that the Secretary of Health and Human Services has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research "in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."[8] Additionally, the ACA specifically prohibits the development or use of a "dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended." The ACA also states, "The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII" (Medicare)."[9]
- Most recently, the U.S. Department of Health and Human Services (HHS) reiterated in a final rule that it is a violation of section 504 of the Rehabilitation Act, the ADA, the Age Discrimination Act, and section 1557 of the ACA for state Medicaid agencies to use measures that would unlawfully discriminate on the basis of disability or age.[10]

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[3] https://cadth.ca/sites/default/files/pdf/guidelines_for_the_economic_evaluation_of_health_technologies_canada_4th_ed.pdf

[4] https://valueourhealth.org/wp-content/uploads/2020/04/Canada.pdf

[5] 29 USC Sec 794, 2017. Accessed November 30, 2020.

[6] 42 USC Sec 12131, 2017. Accessed November 30, 2020.

[7] Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. *The New York Times*.

[8] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.

[9] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.

[10] https://www.federalregister.gov/d/2020-12970

PIPC Partnership to Improve Patient Care

We hope that you will consider these legal protections under existing health and civil rights laws as you work on policies to reduce the cost of care for beneficiaries. We urge you to reject SB 2170 and stand ready to work with you on appropriate policies that do not devalue disabled lives.

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

NASHP NATIONAL ACADEMY FOR STATE HEALTH POLICY Center for State Rx Drug Pricing

Testimony of the National Academy for State Health Policy on SB 2170 - Relating to Prescription Drug Costs and to Provide a Penalty

Representative LeFor and Members of the Committee,

My name is Drew Gattine and I am a Senior Policy Fellow at the National Academy for State Health Policy (NASHP). NASHP is a non-partisan forum of state policy makers that works to develop and implement innovative health care policy solutions at the state level. At NASHP we believe that when it comes to health care, the states are a tremendous source of innovative ideas and solutions. We approach our work by engaging and convening state leaders to solve problems. We conduct policy analysis and research and we provide technical assistance to states.

In 2017 NASHP created its Center for Drug Pricing to focus attention on steps that states can take to tackle the spiraling costs of prescription drugs and the impact it has on consumers, the overall cost of health care and state budgets. NASHP's Center for Drug Pricing develops model legislation for states and provides technical assistance and support to legislators and executive branch leaders who wish to move them forward. When these bills pass, NASHP continues to support states as they are implemented.

The original version of bill before the Committee today, SB 2170, is based on one of NASHP's model bills. Because NASHP is not an advocacy organization we do not take a position "for" or "against" a bill but we do stand by to answer questions and provide technical support for sponsors and legislative committees.

I think we are all aware that when compared to citizens of other countries, Americans pay a lot more for prescription drugs and that the rising cost of prescription drugs is a huge driver in the overall annual increase in health care costs that Americans experience routinely. Other countries spend less for the same drugs because they set rates for prescription drugs. In the United States, rate setting is the norm for many health care services. Public programs like Medicaid or Medicare, and commercial payers routinely negotiate rates. But when it comes to prescription drugs, the United States has a very complicated payment and distribution system that begins with prices set by drug manufacturers.

States could undertake to do this rate-setting themselves but the process is complicated and requires up-front investment. Most states don't have the infrastructure to do this analytical work. The good news is that other countries are already doing it and the results of that work are readily and publicly available for states to use.

NASHP Center for State Rx Drug Pricing

This bill directs North Dakota Insurance Commissioner to determine the most expensive drugs dispensed in the state, using a list from the public employee retirement system as the benchmark. This list is then compared to publicly available information from the four most populous Canadian provinces (Ontario, Quebec, British Columbia, and Alberta) and directs that this price becomes the basis of negotiation between the Insurance Commissioner and manufacturers. The bill applies to state entities other than Medicaid, commercial payers and ERISA plans that chose to participate. (Medicaid was excluded in acknowledgement of the unique design of the Medicaid pharmacy benefit that requires states to cover all drugs in exchange for substantial rebates. Including Medicaid would require up-front agreement by the federal government through either a waiver of state plan amendment.)

Referencing North Dakota rates to Canadian rates should lead to significant savings to the state and to commercial payers. Based on Information that NASHP received from ND PERS, using 2020 utilization numbers, referencing the top 25 drugs in terms of spending to the Canadian price as would have resulted in savings of over $22 million to the state. (This does not include the savings that would accrue in the commercial market.) Below are the differences between Canadian prices and prices paid in North Dakota for the top 10 products in terms of total cost utilization in 2020:

Drug Name & Dosage	Condition	Plan Net Package Price	Canadian Reference Rate*	Price Difference	Approximate Savings Off US Prices
Humira (40 mg/0.4 ml)** Package of 2 syringes	Autoimmune Diseases	$7,621.13	$1,193.88	$6,427.24	84%
Stelara (90 mg/ml) Package of 1 syringe	Autoimmune Diseases	$23,091.57	$3,276.91	$19,814.67	86%
Humira Pen (4 mg/0.8 ml) Package of 2 syringes	Autoimmune Diseases	$8,528.45	$1,193.88	$7,334.56	86%
Novolog Flexpen/Novolog FlexTouch (100 u/ml) Package of 5 syringes	Diabetes	$749.24	$31.65	$717.59	96%
Gilenya (0.5 mg) 30 capsules	Multiple Sclerosis	$11,793.41	$535.28	$11,258.13	95%
Enbrel SureClick (50 mg/ml) Package of 1 syringe	Autoimmune Diseases	$7,659.31	$273.05	$7,386.25	96%
Novolog/Novorapid (100 u/ml) 10 ml vial	Diabetes	$864.19	$19.31	$844.88	98%
Victoza (18 mg/3 ml) Package of 3 syringes	Type 2 Diabetes	$898.84	$156.42	$742.42	83%
Cosentyx Pen (150 mg/ml) Package with 2 ml	Autoimmune Diseases	$5,978.13	$1,174.20	$4,803.93	80%
Ozempic (2/1.5 ml) Package of 1 syringe	Type 2 Diabetes	$841.64	$148.25	$693.40	82%

*Currency conversions were done at .76 USD = 1 Canadian Dollar. Canadian prices were found on the Ontario, Quebec, British Columbia, and Alberta formularies.

**Canadian price listed on formularies was not an exact match - price listed is for a 40 mg/0.8 ml pen.

In another state where this bill was also introduced this session, the legislature's fiscal office estimated that referencing to the Canadian rate could generate upwards of $50 million in annual savings for the state employee plan alone for just 20 drugs alone.

http://webserver1.lsb.state.ok.us/cf_pdf/2021-22%20SUPPORT%20DOCUMENTS/impact%20statements/fiscal/senate/SB734%20INT%20FI.PDF

The potential value to North Dakota residents would be the reduction of the cost of prescription drugs and the requirement that any savings, achieved either by health plans or by state payers, be used to benefit consumers. The bill requires that any savings generated by implementing the reference rates, whether generated by state entities or commercial health plans, be used to reduce the health care costs of the people of North Dakota. Lowering the cost of life-saving drugs should increase the ability of people who rely on those drugs to have better access. Pharmacy manufacturers, who continue to make profits in Canada and in other countries with lower prices than the US, will still be left with the necessary revenue to invest in research and development and bring new, innovative, drugs to market. The profits that pharmaceutical manufacurers make in the US by charging more to Americans than they do to the citizens of other countries far exceeds their entire global R&D budget. (This does not even account for the billions of direct government support that pharmacy R&D receives from the National Institute of Health.)

As the Committee continues its work on this bill NASHP is available to support your work as necessary. Prior to drafting its latest round of model legislation, NASHP engaged with a team of legal experts to design legally sound approaches that can withstand the inevitable challenges from manufacturers and their allies. NASHP has made our legal analysis available on our website. (https://www.nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/). The NASHP website also contains other materials (Written Q&A, Blog Articles, etc.) that may be useful material for the Committee. Thank you.

Drew Gattine
NASHP Senior Policy Fellow
Email: dgattine@nashp.org
Phone: (207) 409-3477