Bioscience Association of North Dakota
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January 13, 2023

Dear Chairman Lee, Respected Members of the Human Services Committee:

The Bioscience Association of North Dakota opposes North Dakota SB 2031– a Prescription Drug Reference Rate Pilot Program.

Position: BIO ND respectfully opposes SB 2031 a Prescription Drug Reference Rate Pilot Program which could have significant and detrimental effects on North Dakota patients. Imposing government price controls on manufacturers risks patient access to prescription drugs and would negatively impact the future of research and development of new drugs.

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 place price controls on prescription drugs. This is what SB 2031 is attempting to achieve.

Five 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 (the cost according to the Fiscal Note is $3.1 million dollars per year just for the Insurance Division, but ignores the Attorney General, who likely has to enforce it); (2). It is already being done by the Federal Government in the Inflation Reduction Act: (3) it violates the concept of a "Free Market System"; (4) it can cause life threatening shortages of essential drugs; and 5). would negatively impact the future of research and development of new drugs.

In the opinion of the Association, it would require the creation of a whole new bureaucracy to carry out this program. Such a program would ultimately assign new responsibilities to the Insurance Department of the State of North Dakota such as designing the program to comply with State and Federal Laws, hiring of an outside consulting firm, and law enforcement problems such as jurisdictional questions, litigation, and increased costs. It is the Association's belief that such a program will not provide significant savings, nor achieve appropriate levels of accessor availability. Further, it does not justify its annual cost of $3.1 million while increasing the regulatory burden on the pharmaceutical industry.

But a better argument for not passing this legislation is that the Federal Government is already doing it! A centerpiece of the **Inflation Reduction Act** as passed by Congress was drug pricing legislation, The prescription drug provisions included in the Inflation Reduction Act will:

1). Require the federal government to negotiate prices for some drugs covered under Medicare Part B and Part D with the highest total spending, beginning in 2026;

2). Require drug companies to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries, beginning in 2023;

3). Cap out-of-pocket spending for Medicare Part D enrollees and make other Part D benefit design changes, beginning in 2024;

4). Limit monthly cost sharing for insulin to $35 for people with Medicare, beginning in 2023;

5). Eliminate cost sharing for adult vaccines covered under Medicare Part D and improve access to adult vaccines in Medicaid and CHIP, beginning in 2023;

6). Expand eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program, beginning in 2024;

7). Further delay implementation of the Trump Administration's drug rebate rule, beginning in 2027.

It is true, that people 65 and older pay the most for prescription drug expenditures (Health Policy Institute, 2021). Medicare is the single largest customer in the pharmaceutical market. According to data from the Centers for Medicare & Medicaid Services (CMS), U.S. prescription drug expenditures totaled $370 billion in 2019.That is why the Inflation Reduction Act is so important. The Inflation Reduction Act will eventually reduce the amount that those people over 65 will pay for prescription drugs, thereby reducing costs to the government and consumers. So there is already Legislation in place to answer the needs of people 65 and older which will have the effect of on reducing prices of prescription drugs to other consumers.

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 2031, 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 investment, manufacture and distribution. If it is determined by the Insurance Commissioner that this constitutes for the "purpose of avoiding the impact of this pilot program as set forth in section 19 -25– 07", 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 - 25 - 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)

SB 2031 also would negatively impact the future of research and development of new drugs. For a new drug entering the market in 2022, the costs behind its approval averages US $2 billion. In addition, the drug development process takes around 14 years of research and regulatory procedures before it is approved for sale ("The Process and Costs of Drug Development (2022)", "Discovery To Market"; By Sean Lim, Published On: June 28, 2018 by "For the Love of Science", Last Updated: November 28, 2022, https://ftloscience.com/). Many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA (Congressional Budget Office, Apr 8, 2021; https://www.cbo.gov/publication/57126). That means the drug development business is very risky. It takes a lot of "capital investment" and a lot of time from time of discovery to entry into the marketplace. Then for each drug approved, there are about 9 failures. All of this is factored in when determining "price". By setting the price of medicine, North Dakota will be diminishing the incentive for biopharmaceutical companies to invest robustly in Research and development.

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 one of the reasons why price controls do not work.

We ask for an unfavorable vote on SB 2031.

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