STATEMENT

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In Opposition to North Dakota SB 2031
– Prescription Drug Reference Rate Pilot Program
January 16, 2023

Position: PhRMA respectfully opposes SB 2031 – Prescription Drug Reference Rate Pilot Program - because it allows the government to set the price of prescription drugs, which could limit the prescription options available to patients in North Dakota, discriminate against patients, stifle innovation, and raises significant legal concerns.

This proposed legislation requires state-regulated commercial insurance plans and pharmacies to cap the amount paid for prescription medicines at a Canadian reference price. This legislation could harm patient health outcomes because if a medicine cannot be purchased at the reference price, it will not be available to patients—inserting the government between health care provider and patient decision making. This legislation also could jeopardize the competitive market that works to drive down drug prices if the number of medicines available on the market is reduced.

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 could 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 other countries.

This proposed legislation ignores that there are meaningful policies for addressing affordability without importing government price setting that could reduce treatment options.

PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $236 billion in 2021,[2] do not make their way to offsetting patient costs at the pharmacy counter. 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 a plan's out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients. These policies can be done without importing international price setting, which can reduce the options available to treat patients.

[1] Facts and Figures 2019: US Cancer Death Rate has Dropped 27% in 25 Years, Cancer.org. Available at https://www.cancer.org/latest-news/facts-and-figures-2019.html.
[2] Fein, A. "The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 202. https://www.drugchannels.net/2021/04/gross-to-net-bubble-update-net-prices.html

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 other 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. Government price setting diminishes the incentive for biopharmaceutical manufacturers to invest in the research and development of new medicines. By requiring state-regulated commercial insurance plans and pharmacies to cap the amount paid for 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 taking away the incentives that allow manufacturers to invent new medicines.

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.[3] This 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%) were available in all 16 comparator countries, nearly all of which have single payer health care systems.[4]

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 U.S. compared to just 50% in France, **46% in Canada** and 41% in Ireland – countries that use some form of international reference pricing.[5] 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) rely 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

[3] IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost. May 2017.
[4] 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.
[5] The Catalyst, Setting the record straight on international reference pricing. July 19, 2019. Available at https://catalyst.phrma.org/setting-the-record-straight-on-international-reference-pricing.

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."[6]

In countries that rely on CEA to determine coverage and payment, like Canada, many patients face significant restrictions on access to treatments, including those diagnosed with cancer, diabetes, and rare diseases. An 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.[7]

This legislation raises significant legal concerns.

The proposed legislation raises constitutional concerns under the Supremacy Clause because it would restrict the goal of federal patent law, which is to provide pharmaceutical patent holders with the economic value of exclusivity during the life of a patent. Congress determined that this economic reward provides appropriate incentive for invention, and [State] is not free to diminish the value of that economic reward. Specifically, in the case of *BIO v. District of Columbia, 496 F.3d 1362 (2007)*, the U.S. Court of Appeals for the Federal Circuit overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the law at issue 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 that "[t]he underlying determination about the proper balance between innovators' profits and consumer access to medication …is exclusively one for Congress."

This legislation gives the insurance commissioner 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 commissioner's determinations. In addition, there is no clear mechanism for a biopharmaceutical company to appeal a penalty from the insurance commissioner and/or Attorney General.

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

PhRMA recognizes the access challenges faced by patients in North Dakota with serious diseases. **However, this legislation could limit the treatments available to patients and stifle innovation.** PhRMA stands ready to work with the legislature to develop market-based solutions that help patients better afford their medicines at the pharmacy counter.

For these reasons, we respectfully oppose SB 2031.

[6] National Council on Disability, "Quality-Adjusted Life Years and the Devaluation of Life with Disability (letter of transmittal)." November 6, 2019.
[7] Context Matters. NICE Limits Reimbursement for Oncology Products beyond EMA Product Labeling. May 2014.