

**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