

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