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February 15, 2022

Senator Heather Sanborn, Chair
Committee on Health Coverage, Insurance and Financial Services
Cross Building, Room 220
100 State House Station Augusta, ME 04333

Representative Denise Tepler, Chair
Committee on Health Coverage, Insurance and Financial Services
Cross Building, Room 220
100 State House Station Augusta, ME 04333

RE: BIO Statement in Opposition to LD 1636

Dear Chair Sanborn, Chair Tepler, and Members of the Committee:

The Biotechnology Innovation Organization (BIO) respectfully **opposes LD 1636,** which would import Canadian price controls on medications in the United States. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. Government price controls like those proposed by this bill are an especially drastic action with unpredictable consequences. While the intent of this bill is to lower drug prices, we fear LD 1636 will fail to bring down costs for consumers or institutions and instead disincentivize development of new therapeutic breakthroughs.

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. 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

[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.

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 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 companies can 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 U.S. 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 U.S. 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

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[2] "The Effect of Price on Pharmaceutical R&D," *The B.E. Journal of Economic Analysis and Policy,* 2009.

[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

metric from Canadian health system that establishes their prices at a much lower level than in the United States.

For these reasons, we **oppose LD 1636** and respectfully request an unfavorable committee report. If you have any questions, please do not hesitate to contact me to discuss this further.

Sincerely,

/s/

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Biotechnology Innovation Organization
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