***VIA ELECTRONIC DELIVERY***

February 18, 2020

The Honorable Laurie Halverson
Chair
Minnesota House Commerce Committee
Minnesota State Capitol
St. Paul, MN

**RE: Opposition of H.F. 3228**

Dear Chairwoman Halverson,

The Biotechnology Innovation Organization (BIO) thanks the committee for the opportunity to comment on our opposition to H.F. 3228. This legislation threatens to restrict patient access to innovative biopharmaceutical products.

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.

**BIO is opposed to any legislation that would restrict patient access to innovative biopharmaceutical products and disincentivize development of new therapeutic breakthroughs to treat and possibly cure disease.**

BIO has serious concerns with any legislation that would establish price controls or create a Prescription Drug Affordability Commission tasked with reviewing prescription drug costs and value, and setting prices for prescription drugs. These legislative proposals fail to provide any benefit to patients. They only serve to disincentivize biopharmaceutical companies from developing new more effective therapies and could disrupt the innovative market-based ecosystem having a detrimental impact on other markets. These types of proposals also add a significant regulatory burden onto the small innovative biotechnology companies.

This form of government-imposed price controls only serves to disincentivize innovation. Prescription drug price controls are shortsighted, sacrificing long-term gains from future innovation for perceived short-term budget benefits. In fact, one study found that U.S. price controls could cost more than $50,000 per person,[1] reducing American lives by an average of 2.8 percent. H.F. 3228 risks doing long-term damage to the innovative market-based ecosystem on which thousands of patients rely.

[1] Lakdawalla, D., et al. US Pharmaceutical Policy in a Global Marketplace. Health Affairs Vo. 28 No. 1. December 2008.

BIO's membership is by and large made up of small, emerging companies. Small and emerging companies are responsible for 70% of the global clinical pipeline, as well as account for 84% of all Orphan designated programs. Many of these companies work for years without products on the market but continue investing millions upon millions in research and development. In fact, 92% of publicly traded biotech companies in the US operate on a negative net income.[2] It is important to reflect on the impact any new regulatory requirements will have on small biopharmaceutical manufacturers.

Additionally, proposals like H.F. 3228 disproportionately impact patients with diseases where there is high unmet need and where low-cost treatment options are not available (e.g. rare diseases), running counter to the aims of personalized medicine, and availability of new treatments. In fact, the arbitrary nature of the proposed price caps ignores the value that an innovative therapy can have to an individual patient – especially one who may have no other recourse – or the societal impact innovative technologies can have – including increased productivity and decreased overall healthcare costs (e.g., due to fewer hospitalizations, surgical interventions, and physicians' office visits).

- A report by the Manhattan Institute found that advancing the Food and Drug Administration's (FDA's) approval of a single generation of drugs would be worth about $4 trillion in value to patients, from enhanced US life expectancy.[3]

Price controls offer a shortsighted suggestion that would sacrifice the long-term gains from future development of treatments and cures, and in turn, negatively impact future generations.

**BIO believes that any prescription drug transparency provisions should focus on what matters most for patients.**

Any transparency provisions should provide meaningful information to patients. More focus should be placed in areas that directly help consumers. This includes ensuring patients know what their cost-sharing obligations are, how health plans are using manufacturer rebates, and what prescription drugs are available on any given formulary. This type of information can assist beneficiaries in determining which health plan most appropriately meets their medical needs. By focusing on transparency of only one element of the pharmaceutical supply chain, legislation would not provide an accurate picture of the supply chain or an understanding of the overall innovative health care ecosystem or how that information can be used to help patients.

We oppose any effort for the state to set prices for biopharmaceutical products. This would fail to provide any benefit to patients. It would only serve to create a new state entity that will discourage biopharmaceutical companies from developing new more effective therapies.

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[2] Factset, BIO Industry Analysis, January 2016

[3] DiMasi, J., Milne, C., and Tabarrok, A. "An FDA Report Card: Wide Variance in Performance Found Among Agency's Drug Review Revisions." Manhattan Institute. https://www.manhattan-institute.org/pdf/fda_07.pdf. April 2014.

For these reasons, BIO would ask the committee to not move forward with H.F. 3228. On behalf of BIO and our member companies, thank you Madame Chair and Committee Members for allowing BIO an opportunity to express our concerns with this legislation.

Respectfully Submitted,

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