STATEMENT

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Opposition to Minnesota HF 58: Transparency

February 3, 2021

Position: PhRMA opposes House File (HF) 58 because this bill imposes a price control on biopharmaceutical manufacturers, which could discourage research and development (R&D) of new treatments and cures, raises legal concerns, fails to consider the real problem of health plan benefit design, and may harm Minnesota's economy.

Price controls, like those contained in HF 58, have a history of discouraging R&D, potentially harming the discovery of future treatments and cures.

Implementing price controls in Minnesota could harm the research and development of new treatments and cures for patients, especially at a time when medical innovation is needed to fight COVID-19 and other diseases. The biopharmaceutical industry is bringing revolutionary, innovative treatments to patients and families, changing and improving their lives. Last year alone, the rate of cancer-related deaths had the biggest one-year drop in history due to earlier detection and treatment with new approved therapies.[1] However, research has shown that price controls similar to HF 58 may negatively impact the R&D on future cures.

In countries with government price controls on prescription drugs, there can be a delay of over a year from the time a drug is approved to the time it is available to patients. For example, in some countries there may be a delay for cancer drugs of over three years. Proposals like HF 58 would be no different and may jeopardize the development of life-saving drugs. Research shows that "[i]t is simply not true that government can impose significant price controls without damaging the chances for future cures."[2] Experts estimate a 50% decrease in the price of medicines would result in a 25% to 60% decrease in the number of new drugs in the pipeline.[3]

HF 58 raises legal concerns because price controls on patented products restrict the goals of federal patent law and are unconstitutional.

HF 58 seeks to implement a price control by prohibiting manufacturers of drugs that have

[1] Cancer Statistics, 2020. American Cancer Society, January/February 2020, available at: http://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21590.
[2]Kennedy, J. The Link Between Drug Prices and Research on the Next Generation of Cures. Information Technology & Innovation Foundation, Sept. 9, 2019, available at http://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.
[3] Civan, A. & Maloney, M. (2009). The Effect of Price on Pharmaceutical R&D. The B.E. Journal of Economic Analysis & Policy, 9(1), available at https://www.nber.org/papers/w11114.

a wholesale acquisition cost (WAC) of $100 or more for a 30-day supply or less than a 30-day course of treatment from increasing the prices of those drugs if they are on an approved health plan formulary. Application of this price control to patented medicines 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 Minnesota 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 (Fed. Cir. 1997), the court overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the D.C. 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.

This legislation also raises other constitutional concerns, including under the Dormant Commerce Clause. In 2018, the 4th Circuit overturned a law in Maryland on Dormant Commerce Clause grounds because it directly regulated the price of transactions that occurred outside of the state.

The real problem is health plan benefit design, something that HF 58 fails to consider when suggesting a sweeping price control on patented prescription drugs.

HF 58 does not address health benefit design even though health insurers determine how much consumers ultimately pay for a medicine, not biopharmaceutical companies. Recent data show that insurers are increasingly requiring patients to pay exorbitant out-of-pocket costs to access the medicines they need, far more than for other covered health care services under a patient's health plan.[4] This is contrary to the purpose of health insurance—to spread the costs of health care utilization so that patients can access affordable needed care including medicines. Additionally, insurers are increasing the use of utilization management techniques to aggressively restrict a patient's use of medicine.

In addition, biopharmaceutical companies are giving larger discounts to insurance companies, middlemen, and hospitals each year, but those savings are not being passed on to consumers at the pharmacy counter. When patients are facing their deductible or paying coinsurance, the amount they must pay is often based on the full list price of the medicine – even if their insurance company and pharmacy benefit manager are only paying the discounted amount they negotiated with the manufacturer. Insurance companies, middlemen, and hospitals should be required to pass along more of the discounts they get from biopharmaceutical companies directly to patients.

According to new research from the Berkeley Research Group (BRG), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year while the share received by manufacturers has decreased over time. In 2018, manufacturers retained only 54% of brand medicine spending while members of the supply chain retained 46%.[5] As noted in the BRG report, increased rebates and discounts have largely offset the modest increases in list prices noted and reflect the competitive market for brand medicines. PhRMA is concerned that the substantial rebates and discounts paid by biopharmaceutical manufacturers, approximately $175 billion in 2019,[6] do not make their way to patients at the pharmacy counter.

[4] IQVIA. Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines. August 2020.
[5] BRG: Revisiting the Pharmaceutical Supply Chain 2013-2018. January 2020.
[6] Drug Channels Institute. The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. March 2019.

HF 58 could harm Minnesota's economy.

The biopharmaceutical industry is one of the most research-intensive industries in the United States. In 2019, the biopharmaceutical sector invested about $83 billion in R&D, more than any other industry in the U.S. Clearly, R&D is an expensive and risky undertaking with millions of patients benefiting from new cures and treatments. On average, it takes more than 10-12 years and $2.6 billion to bring a new medicine to market. Yet only 12% of drug candidates that enter clinical testing are eventually approved, meaning 88% will fail throughout the lengthy clinical trial process. Companies must continue to re-invest and attempt to recoup investments of failed clinical trials. However, policies such as HF 58 may further strain and disincentivize biopharmaceutical companies to continue to push through the R&D process.

Efforts to impose price controls on innovative manufacturers may reduce their incentives to invest in Minnesota with research and jobs. The biopharmaceutical industry currently provides more than 7,600 jobs in Minnesota, supporting more than 32,500 positions and generates over $661 million in state and federal tax revenue for the state. HF 58 could place these jobs and tax revenue in jeopardy.

In summary, PhRMA stands ready to participate in the important discussions around cost and affordability of medicines. No patient should have to worry about whether they can afford their medicine or healthcare that they need. However, the notion that price controls will help access and affordability is false and ignores the immense efforts around research and development that the industry is currently conducting, not to mention the cost savings that medicines provide to the health care system overall.

For these reasons, PhRMA urges a no vote on HF 58.