STATEMENT

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Opposition to Minnesota HF 294: Transparency and Price Controls

January 28, 2023

Position: PhRMA opposes House File (HF) 294 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 294, have a history of discouraging R&D, potentially harming the discovery of future treatments and cures.

Additionally, HF 294 requires additional transparency reporting from drug manufacturers even through the Minnesota Department of Health has yet to meet the requirements of the Minnesota Drug Price Transparency Act.

HF 294 prohibits a drug manufacturer with a drug whose wholesale acquisition cost (WAC) is $100 or more for a 30-day supply or course of treatment less than 30 days from increasing the WAC for the next calendar year. As written, this language could be interpreted from prohibiting a drug manufacturer from ever increasing the WAC of a prescription drug.

Implementing price controls in Minnesota could harm the R&D 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. In 2020, 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 294 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 294 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]

[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.

HF 294 raises legal concerns because price controls on patented products restrict the goals of federal patent law and are unconstitutional.

HF 294 seeks to implement a price control by prohibiting manufacturers of drugs that have a 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 294 fails to consider when suggesting a sweeping price control on patented prescription drugs.

HF 294 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, pharmacy benefit managers (PBMs), and others 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 and PBMs 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 2020, manufacturers retained only 49 ½ cents of every $1 spent on brand medicines while the other 50 ½ cents went to payers, middlemen, providers and other stakeholders.[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 $236 billion in 2021,[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] Brownlee, A. & Watson, J. (2022). The Pharmaceutical Supply Chain, 2013 – 2020. Berkley Research Group.
[6] Fein, A. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2022.

HF 294 could harm Minnesota's economy.

The biopharmaceutical industry is one of the most research-intensive industries in the United States. Since 2000, PhRMA member companies have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone. 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 294 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 11,700 jobs in Minnesota, supporting more than 50,000 positions and generates over $1.1 billion in state and federal tax revenue for the state. HF 294 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.

HF 294 is premature in requiring additional transparency information when the Minnesota Department of Health has yet to publish legislative reports or public information required by the 2020 Minnesota Drug Price Transparency Act.

In 2020, the Minnesota Legislature passed the Minnesota Prescription Drug Price Transparency Act. (Act), which required drug manufacturers to report specific information for new prescription drugs, newly acquired prescription drugs and prescription drug price increases that meet the criteria outlined in the Act. The Act required that specific information be reported publicly on the Minnesota Department of Health's website and required the Commissioner provide a report to the Chairs and Ranking Minority Members of legislative committees with jurisdiction over Commerce, Health and Human Services Policy, and Finance no later than May 15, 2022 and by January 15th each year after.

Drug manufacturers began reporting required information to the Minnesota Department of Health in February 2022, which means the Minnesota Department of Health has nearly 12 months of data. As of January 28, 2023, no information has been provided to the public on the Minnesota Department of Health's website and no public forum has been scheduled to discuss findings from drug manufacturer's reporting. It is unclear if the required reports have been delivered to the Minnesota Legislature. Adopting additional transparency requirements is premature without public discourse of the findings of what is currently being reported by drug manufacturers.

For these reasons, PhRMA urges a no vote on HF 294.