STATEMENT

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In Opposition to Minnesota House File 3228 (HF 3228)

February 19, 2020

Position: PhRMA respectfully opposes HF 3228. PhRMA believes that discussions about the affordability of drugs are important but, the intention of this bill is to cap drug prices, which could limit the availability of prescription options to Minnesota. HF 3228 shortsightedly targets drug spending in ways that will likely have long-term, harmful effects on innovation and the development of new, life-saving therapies.

Specifically, HF 3228 implements a Commission to review prescription drug costs and value with the goal of setting price controls by way of a "maximum reimbursement level" for the entire drug supply system. Regulating drug prices in-state could lead to a shortage of or limit access to medicines for patients who may need a medicine. Further, the legislation also requires onerous disclosure of pricing information which will not benefit patients and could jeopardize the competitive market. In addition to limiting the development of innovative treatments, this legislation could threaten the positive effect that the biopharmaceutical industry has on Minnesota's economy.

This legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients and HF 3228 assumes incorrectly that the price of a drug is determined solely by drug manufacturers.

This legislation singles out the biopharmaceutical industry and ignores the variety of stakeholders involved in determining what consumers ultimately pay for a medicine, including insurers, pharmacy benefit managers (PBMs), wholesalers, and government agencies like Medicaid. The important role that these entities play in determining drug prices and drug coverage is overlooked by the requirements of this legislation. For example, PBMs and payers—which dictate the terms of coverage for medicines and the amount a patient ultimately pays—use their control over which medicines patients can access as leverage to negotiate substantial rebates and discounts. PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $166 billion in 2018,[1] do not make their way to offsetting patient costs at the pharmacy counter. In the state of Minnesota, manufacturers pay more than $524 million to the state and federal government, half of which goes to the state.

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

[1] Drug Channels Institute. "The Gross-to-Net Bubble Reached a Record $166 Billion in 2018." April 2019

spending while members of the supply chain retained 46%.[2] Increased rebates and discounts have largely offset the modest increases in list prices noted and reflect the competitive market for brand medicines.

Growth in prescription drug spending is at a historic low, and prescription drug costs are expected to remain a relatively small and stable share of total health care costs into the future. According to the IQVIA Institute (formerly the IMS Institute), net spending on medicines grew only 0.3% in 2018; and the Centers for Medicare and Medicaid Services reported that growth in retail prescription drug spending was only 2.5% in 2018. At the same time, overall prescription drug prices declined by 1%. This, of course, does not necessarily reconcile with what patients are feeling at the pharmacy counter, which is why looking at the whole system is so important.

In 2017, only 3.1% of Minnesota's Medicaid budget was spent on prescription drugs, including both brands and generics. The majority of Medicaid healthcare spend is on administrative fees and hospital care with prescription drugs accounting for a small portion. In addition, in 2017, pharmaceutical manufacturers paid more than $524 million in brand and generic rebates on Minnesota's Medicaid drug utilization alone.

Price controls on patented products are unconstitutional because they interfere with the goal of federal patent law.

This legislation seeks to implement a price control for certain medicines by way of establishing a "maximum reimbursement level" based on the cost of administering the drug, delivering the drug to consumers, and administrative costs related to the drug. The rate would apply to both public and private purchases, payments and reimbursements across all stakeholders in the supply chain. This does not solve the problem of rebates not flowing to the patient when paying for a medicine at a pharmacy. Additionally, this proposed policy raises constitutional concerns 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 the 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. The U.S. Court of Appeals for the Fourth Circuit recently overturned a Maryland drug pricing law on dormant Commerce Clause grounds because it regulated the price of transactions that occurred outside of the state.[3]

Requiring manufacturer reporting of price increases could harm consumers, interfere with market competition, and raises constitutional concerns.

HF 3228 would require manufacturers to provide notification of WAC price increases, which does not account for rebates, discounts, and other price concessions provided for prescription medicines and

[2] BRG: Revisiting the Pharmaceutical Supply Chain 2013-2018. January 2020.
[3] *Ass'n for Accessible Medicines v. Frosh* ("*AAM*"), 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).

thus do not accurately reflect the true cost to an insurer or pharmacy benefit manager. According to the IQVIA Institute, in 2018, brand prescription medicine invoice prices (~WAC prices) increased by 5.5 percent, but the associated net prices only increased by 0.3 percent once rebates and discounts paid to insurers by biopharmaceutical manufacturers were removed. Patient premiums are only impacted by the discounted price paid by the insurer. Thus, the vast majority of the increases, balanced against the significant manufacturer discounts, when taken together, will not have any impact on a plan's overall costs. Such notification could also result in voluminous reporting that will in no way assist in making thoughtful changes to formulary design or budgeting decisions.

Reporting of WAC price increases creates financial incentives for secondary distributors to enter the pharmaceutical supply chain thus creating a "gray" market. Gray market distribution networks consist of a number of different companies – some doing business as pharmacies and some as distributors – that buy and resell medicines to each other before one of them finally sells the drugs to a hospital or other health care facility. As the medicines are sold from one secondary distributor to another, the possibility of counterfeit medicines infiltrating the supply of legitimate medicines increases, thereby threatening patient safety. In the past, this type of purchasing has caused great difficulty for hospitals. For example, during medicine shortages, hospitals are sometimes unable to buy medicines from their normal trading partners, usually one of the three large national "primary" distributors, AmerisourceBergen, Cardinal Health, or McKesson. At the same time, hospitals are deluged by sales solicitations from gray market companies offering to sell the shortage medicines for prices that are often hundreds of times higher than the prices normally paid.

PhRMA has challenged the constitutionality of laws requiring advanced notification of price increases in California and Oregon on a number of grounds, including under the First Amendment and the dormant Commerce Clause. The litigation is pending. If the laws are invalidated, a similar analysis would apply to similar legislation in other states.

The biopharmaceutical industry is heavily regulated and discloses significant information to the public.

The biopharmaceutical industry is one of the most heavily regulated industries in the United States. Companies already report extensive information to the federal government about costs, sales, clinical trials, and total research and development (R&D) expenditures. HF 3228 goes further and focuses on the costs of approved medicines while ignoring a large portion of the drug discovery and development process—failure. Specifically, requiring information on production and distribution costs for individual products may not be feasible, as R&D is a long-term process and manufacturers pursue research efforts that include many failures before the development of one, FDA-approved drug. Accounting for these related discovery costs could be nearly impossible.

Much of the information that HF 3228 requires to be disclosed is considered proprietary and confidential trade secret information, which is protected by state and federal law. The Federal Trade Commission (FTC) has repeatedly acknowledged that disclosure of competitively sensitive information could undermine beneficial market forces within the pharmaceutical industry.[4] In a letter

[4] FTC Letter to Terry G. Kilgore, Member, Virginia House of Delegates, re: H.B. 945 (Oct. 2, 2006); FTC Letter to Representative Patrick McHenry, re: North Carolina Bill 1374 (July 15, 2005); FTC Letter to California Assembly Member Greg Aghazarian, re: AB 1960 (Sept. 7, 2004). FTC Letter to The Honorable Mark Formby, Mississippi House of Representatives, re: SB 2445 (March 22, 2011).

to the New York legislature in 2009, the FTC's Office of Policy and Planning, Bureau of Competition and Bureau of Economics cautioned that disclosure of information similar to what is requested in HF 3228 could jeopardize the competitive market by impacting incentives to provide discounts and additional rebates, which "…may increase pharmaceutical prices."

This legislation could harm Minnesota's economy.

On average, it takes more than 10 years and $2.6 billion to research and develop a new medicine. Just 12% of drug candidates that enter clinical testing are approved for use by patients. Efforts to impart price controls on innovative manufacturers could chill the research and development of new medicines by taking away the incentives that allow manufacturers to invent new medicines. Price controls also could severely reduce [insert state] patients' access to medicines, as is seen abroad.

The biopharmaceutical sector is committed to bringing new treatments and cures to patients. This commitment to innovation supports high-quality jobs and is a vital part of Minnesota's economy and its economic competitiveness. The biopharmaceutical sector directly accounted for 43,346 jobs in Minnesota in 2017. These jobs generate over $686.6 million in state tax revenue for Minnesota in 2017. This bill could place these jobs, and tax revenue, in jeopardy.

PhRMA recognizes the access challenges faced by patients in [state] with serious diseases. We stand ready to work with the Minnesota legislature to develop market-based solutions that help patients better afford their medicines at the pharmacy counter. We believe this bill would not help patients better access breakthrough innovative medicines and respectfully oppose the passage of HF 3228.