STATEMENT

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In Opposition to Minnesota Senate File 168
Prescription Drug Affordability Board and Upper Payment Limit

Updated February 6, 2023,

Position: PhRMA respectfully opposes Minnesota Senate File 168 (SF 168). PhRMA believes that discussions about the affordability of medicines are important, but the intention of this bill is for the government to decide drug prices, which could limit the prescription options available to Minnesotans. SF 168 shortsightedly targets drug spending in ways that likely will have long-term, harmful effects on innovation and the development of new, life-saving therapies.

Specifically, SF 168 implements a government-appointed Board to review prescription drug costs and value with the goal of setting price limits by way of an "upper payment limit" (UPL) for the entire drug supply system. Regulating drug prices in-state could lead to a shortage of or limit access to medicines for patients. Specifically, if a pharmacy or provider cannot obtain a medicine at the government price, the medicine will not be available to Minnesota residents. Further, the legislation also requires onerous disclosure of pricing information which will not benefit patients and could jeopardize the competitive market. By disincentivizing the development of innovative treatments, this legislation could threaten the positive effect that the biopharmaceutical industry has on Minnesota's economy.

Price controls on brand medicines raise constitutional concerns.

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 (2007)*, the U.S. Court of Appeals for the Federal Circuit overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the 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 bill also raises concerns under the Dormant Commerce Clause, which precludes the States from regulating commercial activity beyond their own borders. See Association for Affordable Medicines v. Frosh, 887 F.3d 664 (4th Cir. 2018). And, by allowing the board to take prices in Canada into account in setting the upper payment limit, the bill raises questions under the Foreign Commerce Clause.

Minnesota currently requires drug manufacturers to report information under the Minnesota Prescription Drug Price Transparency Act. To date, this information has not been made available for public review or discussion.

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. Additionally, the Act required that 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 21, 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 a Prescription Drug Affordability Board (PDAB) with the authority to establish upper payment limits for prescription drugs is premature without public discourse of the findings of what is currently being reported by drug manufacturers.

This legislation ignores that there are meaningful policies for addressing affordability without utilizing government price setting that could reduce treatment options.

PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $236 billion in 2021,[1] do not make their way to offsetting patient costs at the pharmacy counter. Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as making monthly costs more predictable, making cost-sharing assistance count toward a plan's out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients. These policies can be done without utilizing international price setting, which can reduce the options available to treat patients.

This legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients, and SF 168 assumes incorrectly that the price a patient pays 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 the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs 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—negotiate substantial rebates and discounts.

[1] Fein, A. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2022.

According to 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 49.5% of brand medicine spending while members of the supply chain retained 50.5%.[2] Increased rebates and discounts have largely offset the modest increases in list prices and reflect the competitive market for brand medicines.

The growth of net price prices, which reflects rebates and discounts, has been in line with or below inflation for the past five years. Specifically, brand medicine net prices increased 1.0% in 2021.[3] 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. For example, despite manufacturers' rebates and discounts negotiated by health plans, nearly half of commercially insured patients' out-of-pocket spending for brand medicines is based on the medicine's list price rather than the negotiated price that health plans receive.[4]

In FFY2020, only 3.6% of Minnesota's Medicaid budget was spent on prescription drugs, including both brands and generics. Specifically, in FFY2020, pharmaceutical manufacturers paid more than $632 million in brand and generic rebates, which is 55% of the total Medicaid spending on drugs, on Minnesota's Medicaid drug utilization alone.[5]

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. SF 168 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 SF 168 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

[2] BRG: The Pharmaceutical Supply Chain 2013-2020. January 2022.

[3] IQVIA Institute for Human Data Science. The Use of Medicines in the U.S. 2022. Published April 2022. Accessed January 2023. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022

[4] IQVIA Institute for Human Data Science. Medicine spending and affordability in the United States. Published August 2020. Accessed August 2020. https://www.iqvia.com/insights/theiqvia-institute/reports/medicine-spending-and-affordabilityin-the-us

[5] Menges Group analysis of FFY2020 CMS Financial Management Reports (FMR) and State Drug Utilization (SDU) data files. Brand/generic expenditure totals net of rebates. Data predominantly derived from CMS FMRs. Brand/generic prescription drug costs derived through tabulations performed by Menges. Pre-rebate expenditures tabulated using FFY2020 CMS SDU data files and CMS brand/generic indicators for each NDC. Statutory rebates and fee-for-service supplemental rebate information obtained from CMS FMRs. MCO supplemental rebates available in FMRs for several states and estimated in remaining states at similar percentages as the published FMR data indicate. Generic rebates assumed to always be at the statutory 13% level –no supplemental rebates assumed. Total brand rebates are therefore derived as the difference between total rebates and the generic statutory rebates. Post-rebate expenditures derived through Menges tabulations using above information.

undermine beneficial market forces within the pharmaceutical industry.[6] In a letter 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 SF 168 could jeopardize the competitive market by impacting incentives to provide discounts and additional rebates, which "…may increase pharmaceutical prices."[7]

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 Minnesota 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 11,733 jobs in Minnesota in 2020 and supported another 50,036 jobs in Minnesota for a total of 61,769 jobs. These jobs generated over $1.1 billion in state and federal tax revenue for in 2020. This bill could place these jobs, and tax revenue, in jeopardy.

PhRMA recognizes the access challenges faced by patients in Minnesota 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 SF 168.

We urge you to vote no for SF 168 for these reasons.

[6] 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).
[7] FTC Letter to Senator Seward, re: SB 58 (March 31, 2009).