STATEMENT

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In Opposition to MN HF 801:
Prescription Drug Affordability Board

March 10, 2021

Position: PhRMA respectfully opposes HF 801. PhRMA believes that discussions about the affordability of drugs are important, but the intention of this bill is to cap drug prices through the establishment of a Prescription Drug Affordability Board, which could limit the availability of prescription options to Minnesotans and have harmful effects on innovation and the development of new therapies. HF 801 arbitrarily caps pharmaceutical prices, which raises constitutional concerns, and has the potential to result in unlawful disclosure of trade secret and sensitive commercial information. It 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 801 implements a Prescription Drug Affordability Board to review prescription drug costs with the goal of setting price controls when it is determined that the drug will create significant "affordability challenges" for the state health care system or for patients. In this case, the Board would establish an "upper payment limit," based on a number of factors, including cost of the drug, the price at which the drug is sold in the United States, and the range at which pharmacies are reimbursed in Canada, as well as other administrative cost information for the drug.

Legislating an ambiguous definition, "upper payment limit," is just another attempt at legislating a price control. Proposals such as this could have unintended impacts on future research and development of new drugs and new cures.[1] Price controls could come at a cost to innovation and long-term patient well-being. Price controls can limit access to needed medications, can undermine beneficial competitive forces, and ignore the ways in which medicine improves lives and saves the health system money. 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 and sharing negotiated savings on medicines with patients.

HF 801 jeopardizes patient access to needed medicines and innovative treatments.

This legislation could restrict patients' access to medicines and result in fewer new treatments for patients. Arbitrarily capping prices by imposing an "upper payment limit" is government price setting. Price setting means politicians, not a patient's health care provider, arbitrarily decides that some patients and some diseases are worth more than others. When the government determines the value of patients' medicine, they are also deciding the value of their lives and health. Often this discriminates against older people, those who suffer from a disability, those with a pre-existing condition or those affected by a rare disease.

[1] Kennedy, J. The Link Between Drug Prices and Research on the Next Generation of Cures, Information Technology & Innovation Foundation. Sept. 9, 2019, https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.

HF 801 provides no explanation or detail of how "upper payment limits" would be operationalized across the complex pharmaceutical supply chain. Payment limits that could cap providers' reimbursement at or below their acquisition cost could result in immediate and severe shortages within the distribution channel, denying patients' access to critically necessary prescription drugs.

This legislation does not account for insurance benefit designs that do not pass discounts on patients, and HF 801 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. The important role that these entities play in determining drug prices and drug coverage for patients 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. PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $175 billion in 2019,[2] do not make their way to offsetting patient costs at the pharmacy counter.

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 2018 manufacturers retained only 54% of brand medicine spending while members of the supply chain retained 46%.[3] Increased rebates and discounts have largely offset the modest increases in list prices noted and reflect the competitive market for brand medicines.

The growth rate of prescription drug costs has slowed in recent years.

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 1.7.% in 2019; and the Centers for Medicare and Medicaid Services (CMS) reported that growth in retail prescription drug spending was only 2.5% in 2018.[4] 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.

Medicines are the only part of the health care system where costs decrease over time. When brand name medicines face brand competition, or when they lose their patent protection and generic drugs become available, prices drop, often significantly. Today, nearly 90% of all medicines dispensed in the United States are generic and cost pennies on the dollar.[5]

In 2018, only 3.1% of Minnesota's Medicaid (i.e., "Medical Assistance") budget was spent on prescription drugs, including both brands and generics. Specifically, in 2018, pharmaceutical manufacturers paid rebates of $524

[2] Fein, A. "The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2020.
[3] BRG: Revisiting the Pharmaceutical Supply Chain 2013-2018. January 2020.
[4] IQVIA Institute, Medicine Spending and Affordability in the United States. August 2020. Centers for Medicare & Medicaid. "National Health Expenditure Data, Historical 2019." December 2019.
[5] Ass'n for Accessible Medicines. 2020 Report Generic Drug and Biosimilars Access and Savings in the U.S.

million back to Minnesota and the federal government as part of the Medicaid rebate program.[6] This is 56% of the total Medicaid spending on drugs in the state.

Price controls on brand medicines raise constitutional concerns.

This legislation seeks to implement a price control for certain medicines by way of an "upper payment limit" across all stakeholders in the supply chain. 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 brand 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.

This legislation also raises other constitutional concerns, such as under the Dormant Commerce Clause. In *AAM v. Frosh*, 887 F.3d 664 (2018), the U.S. Court of Appeals for the Fourth 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.

Potential disclosure of trade secret information raises concerns under federal and state law.

PhRMA also has legal and practical concerns with the HF 801 provisions that authorize the public disclosure of certain pricing information unless the information is "proprietary" based on standards established by the board.

The board's ability to publish sensitive commercial information—using standards the board itself will develop in its sole discretion after enactment of the law—threatens to authorize harmful and unlawful disclosures of trade secret information. Public disclosure would violate state and federal prohibitions against the "misappropriation" of trade secrets under both federal and state law.[7] Likewise, the Fifth Amendment's prohibition against taking private property without just compensation prohibits the uncompensated disclosure of trade secrets.[8] Indeed, courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality . . . can amount to an unconstitutional 'taking' of property."[9]

By giving the board the discretion to decide what information qualifies as "proprietary," HF 801 leaves open the possibility that the board will enact standards and procedures that unlawfully authorize misappropriation of trade secret information. To mitigate this problem, HF 801 should categorically prohibit disclosure of any information that qualifies as a trade secret under state or federal law. The legislature took this approach last year in the Prescription Drug Price Transparency Act, SF 1098, which exempts from its publication requirements any information that qualifies as a trade secret under Minnesota's public-records laws or under the federal

[6] The Facts About Medicaid in Minnesota, http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/MN-One-Pager_19.pdf.

[7] *See* 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act of 2016); Minn. Stat. 235C.01, subdivision 3 (defining "misappropriation' under Minnesota's Uniform Trade Secrets Act).

[8] *See, e.g.*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002–04 (1984).

[9] *St. Michael's Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981).

Defend Trade Secrets Act of 2016.[10] The Prescription Drug Price Transparency Act also allows manufacturers to identify information that qualifies as a trade secret and requires the State to provide 30 days' advance notice to the manufacturer in the event of a disagreement over a trade secret designation. At minimum, HF 801 should provide manufacturers these same protections.

Allowing public disclosure of sensitive commercial information could result in significant competitive harm and undermine the competitive market. The Federal Trade Commission (FTC) has repeatedly acknowledged that disclosure of competitively sensitive information could undermine beneficial market forces within the pharmaceutical industry.[11] 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 sensitive commercial information under HF 801 could jeopardize the competitive market by impacting incentives to provide discounts and additional rebates, which "…may increase pharmaceutical prices."[12]

This legislation could harm Minnesota's economy.

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 7,600 jobs in Minnesota and supported another 32,511 jobs in Minnesota for a total of 40,111 jobs. These jobs generate over $661 million in state and federal tax revenue for Minnesota. 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 HF 801.

[10] *See* Minn. Stat. 62J.84, subdivision 6(c).