STATEMENT

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Opposition to Minnesota House File 4706 (A22-0419DE), Article 6:
Prescription Drug Affordability Board, Advance Price Notification, and Transparency

April 7, 2022

Position: PhRMA respectfully opposes transparency, advance price notification and the establishment of a prescription drug affordability board in House File 4706, Article 6. PhRMA believes that discussions about the affordability of medicines are important, but the intention of this bill focuses on drug pricing that is not related to what a patient pays for a medicine and prematurely makes changes to the 2020 Prescription Drug Price Transparency Act.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's 33 leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. We have concerns with House File 4706, Article 6 (HF 4706), which would implement price controls through a Prescription Drug Accountability Board with the ability to set an upper payment limit for prescription medicines and require manufacturers to provide 90 days' written notice prior to increasing the wholesale acquisition cost (WAC) of a prescription medicine in certain circumstances. The Act also prematurely amends the 2020 Prescription Drug Price Transparency Act (Act) by requiring drug manufacturers to report pricing information for up to 500 prescription medicines of "substantial public interest" and prescription medicines with a WAC of $100 or more for a 30-day supply annually.

Discussions about the cost and affordability of medicines are important. Patients should not need to worry about affording the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false - and ignores cost savings that medicines provide to the health care system overall. Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs. New medicines are making crucial contributions to medical advances, changing the direction of healthcare as we know it. This bill is likely to skew discussions of policy issues in ways that are systematically biased against innovation.

Below we outline our primary concerns with HF 4706, Article 6. We would welcome the opportunity to discuss further.

Prescription Drug Affordability Board (Article 6, Sections 29-39)

HF 4706 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" for the entire drug supply system in-state. Regulating drug prices in-state could lead to a shortage of or limit access to medicines for patients. Specifically, if a pharmacy or a 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.

This legislation ignores that there are meaningful policies for addressing affordability without importing 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 importing 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 HF 4706 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.

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 declined 2.9% in 2020.[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]

This legislation could limit patient access to life-saving therapies in the state.

Arbitrarily capping prices within the drug supply chain could restrict patients' access to medicines. If patients in the state if a payor cannot obtain a therapy at the state-prescribed price, and/or if a pharmacy or dispensing provider cannot stock the drug because it too cannot meet the state-prescribed price, the medicine may not be available to patients. Additionally, providers could be left with substantial costs if they acquired the drug before the price control is in place, but could not bill for reimbursement that covers their acquisition costs.

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

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

[3] IQVIA. "Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025." Published May 2021.

[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

Price controls on brand medicines raise constitutional concerns.

This bill 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.

Advance Price Notification (Article 6, Section 22)

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

HF 4706 would require manufacturers to provide 90 days advance notification of WAC price increases. In the United States, net prices for brand medicines declined 2.9 percent in 2020.[5] In fact, for the last five years, net price growth for brand medicines has been in line with or below inflation, even as many new treatments reached patients.[6] This is because biopharmaceutical manufacturers give substantial rebates and discounts to pharmacy benefit managers (PBMs) and insurers that significantly lower the list price, or WAC, of medicines. The magnitude of these rebates, discounts, and other reductions in price have more than doubled since 2012, totaling $187 billion in 2020.[7] Unfortunately, it doesn't feel that way for patients because insurers don't always share these savings with patients at the pharmacy counter.

Advance notification 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 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.[8]

[5] IQVIA. "Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025." Published May2021.
[6] IQVIA. "Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025." Published May 2021.
[7] Fein, A. "The 2021Economic Report on U.S. Pharmacies and Pharmacy BenefitManagers,"Drug Channels Institute. March 2021.
[8] *Ass'n for Accessible Medicines v. Frosh* ("*AAM*"), 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).

Additional Prescription Drug Transparency Reporting (Article 6, Sections 4, 6, 15, 16, 22)

By adding the definition of "drug product family," HF 4706 may result in manufacturers not identified as a "prescription drug of substantial public interest" to undertake cumbersome reporting requirements.

The new definition of "drug product family" would capture drug manufacturers not identified as a "prescription drug of substantial public interest," and dramatically expand the scope to manufacturers required to report far beyond 500 prescription drugs. While HF 4706 would require the Department of Health to "consider" certain criteria in selecting prescription drugs of substantial public interest, the Department of Health may rely on "any information the department deems relevant," and then apply reporting requirements to entire "drug product families." This provision unfairly burdens manufacturers with expanded reporting requirements based on another manufacturer's pricing decisions or the broad authority given to the Department of Health. Thus, HF 4706 creates a disconnect between pricing actions and the reasons to file substantial reporting requirements. This is fundamentally unfair given the significant reporting and penalties associated with these requirements.

Existing confidentiality protections under the Prescription Drug Price Transparency Act were not amended to cover the new reporting requirements.

Minn. Stat. Section 62J.84, subd. 6 currently provides confidentiality and trade secret protections for drug manufacturers under the Prescription Drug Price Transparency Act. The proposed language introduces the new term "reporting entity", which includes manufacturers and others required to report information to the Department of Health. However, Minn. Stat. Section 62J.84, subd. 6 was not amended to include "reporting entities" in the process to request the commissioner withhold not public or trade secret data. "Manufacturer" should be changed to "reporting entity" or all the reporting entities under 62J.84 (i.e., manufacturer, pharmacy, PBM, and wholesaler) should be listed in order for any reporting entity to use this process to request withholding of not public or trade section information under subd. 6.

HF 4706 prematurely makes changes to the 2020 Prescription Drug Price Transparency Act.

In 2020, the Minnesota Legislature passed the Prescription Drug Price Transparency Act, which requires drug manufacturers to report specific information when the price of a medicine increases by a certain percentage over a period of time. PhRMA has worked in good faith with the Minnesota Department of Health during the past year providing comments to the guidance drug manufacturers must follow for reporting. Initial drug manufacturer reports were not due until March 2022 and it is likely that information from these reports will not be available for review until later in 2022.

HF 4706 dramatically expands the number of prescription drugs and manufacturers impacted by transparency reporting requirements before the current reporting requirements have been evaluated and assessed. We would urge you to pause any additional reporting mandates on drug manufacturers until current reporting requirements have been fully implemented and assessed.

For these reasons, PhRMA opposes the above provisions in HF 4706, Article 6.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.