STATEMENT

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In Opposition to Advance Price Notification language (SF 328) in the Senate position in Senate File 2995

May 2, 2023

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes the advance price notification provisions (SF 328), that would require reporting of confidential trade secret information by biopharmaceutical manufacturers. This language could be harmful to the market and to future innovation and raise constitutional concerns.

SF 328 amends the Prescription Drug Price Transparency Act to require drug manufacturers to report pricing information for prescription medicines with a wholesale acquisition cost (WAC) of $100 or more for a 30-day supply annually and give the insurance commissioner 90 days' written notice prior to increasing the WAC of a prescription medicine.

Specifically, the concerning language is:

> *If a drug subject to price reporting under subdivision 2 is included in the formulary of a health plan submitted to and approved by the commissioner of commerce for the next calendar year under section 62A.02, subdivision 1, the manufacturer may increase the wholesale acquisition cost of the drug for the next calendar year only after providing the commissioner with at least 90 days' written notice.*

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

SF 328 **would require manufacturers to provide 90 days advance notification of WAC price increases. The WAC price does not account for rebates, discounts, and other price concessions provided for prescription medicines and therefore, does not accurately reflect the true cost to an insurer or pharmacy benefit manager.** According to the IQVIA Institute, in 2021, net prices for brand medicines were, on average, 49% lower than WAC prices.[1] Such notification could also result in voluminous reporting that will in no way assist in making thoughtful changes to formulary design or budgeting decisions.

The Federal Trade Commission has acknowledged that disclosure of competitively sensitive information could undermine beneficial market forces within the industry,[2] so advance notice and other disclosure requirements could have the opposite of their intended effect and undermine competitive bidding in the

[1] IQVIA. "Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2026." May 2022

[2] FTC's comment to the Honorable James L. Seward concerning the competitive effects of the pharmacy benefit manager provisions of NY SB 58, March 31, 2009, available at: https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.

market.[3] In addition, 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.

PhRMA has challenged the constitutionality of a law requiring advance notification of price increases in Oregon on a number of grounds, including under the First Amendment and the Dormant Commerce Clause. The litigation is pending. If the law is invalidated, a similar analysis would apply to similar legislation in other states. The U.S. Court of Appeals for the Fourth Circuit overturned a Maryland drug pricing law in 2019 on Dormant Commerce Clause grounds because it regulated the price of transactions that occurred outside of the state.[4]

This legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients and 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%.[5]Increased rebates and discounts have largely offset the modest increases in list prices and reflect the competitive market for brand medicines.

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.[6]

PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $236 billion in 2021,[7] 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.

[3] 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).
[4] *Ass'n for Accessible Medicines v. Frosh* ("*AAM*"), 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).
[5] BRG: The Pharmaceutical Supply Chain 2013-2020. January 2022.

Innovative therapies provide unique value in the health care system.

It is important to remember that advances in medicine help control health care spending. Greater patient access to prescription medicines means fewer doctor visits and hospital stays and a decrease in costly medical procedures, all of which translate into lower health care costs overall. For example, in 2014, a new drug came to the market that provided a cure for more than 90% of patients with hepatitis C, eliminating a lifetime of hospitalizations, debilitating symptoms, and treatments with harsh side effects and replacing it with a complete cure in just 12 weeks. Often, patients with hepatitis C needed liver transplants, which could cost almost $500,000. Since 2014, several new treatments have come to the market, further driving down the price of the medicine and recent research indicates that these medications have saved Medicaid $15 billion, with the cost of a cure now lower than a single year of disease burden.[8] Innovation and progress in the pharmaceutical industry means better outcomes and quality of life for patients and their families as well as reduced health care costs to patients and the system.

PhRMA opposes the Senate position (SF 328) for the above stated reasons.

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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 $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone.

In Minnesota the biopharmaceutical industry employs over 11,000 individuals and the industry generates a total economic output of over $16.9 billion per year while contributing over $1.1 billion in state and federal taxes annually. Additionally, according to the Minnesota State Medicaid Program, the industry rebates more than $632 million back to the federal and State governments through Medicaid prescription drug rebates, which is 55% of the total Medicaid drug spend in the State.

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[6] 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

[7] Drug Channels Institute. The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. March 2022

[8] Roebuck, M. Christopher "Impact of Direct-Acting antiviral use for chronic Hepatitis C on health care costs in Medicaid: Economic Model Update." The American Journal of Managed Care December 2022, Vol. 28 Issue 12.