STATEMENT

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In Opposition to Senate Bill 98

February 1, 2024

Position: PhRMA respectfully opposes Senate Bill 98 (S.98). 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 Vermont. S.98 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, S.98 directs the Green Mountain Care Board (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 Vermont residents. By disincentivizing the development of innovative treatments, this legislation could threaten the positive effect that the biopharmaceutical industry has on Vermont's economy.

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 $256 billion in 2022,[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 S.98 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

[1] Fein, A. "The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2023.

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 six years.[3] Specifically, brand medicine net prices for brand medicines averaged 0.0% growth in 2022.[4] Through the first three quarters of 2023, net prices declined by -3.0%.[5] 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]

In FY2021, only 4.5% of Vermont's Medicaid budget was spent on prescription drugs, including both brands and generics. Specifically, in FY2021, pharmaceutical manufacturers paid more than $122 million in brand and generic rebates on Vermont's Medicaid drug utilization alone, which represents 58% of Vermont's Medicaid drug spend.[7]

Price controls on brand medicines raise constitutional concerns.

Application of this price control to patented medicines as contemplated by S.98 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 Vermont 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 raises due process concerns as it provides broad authority to the PDAB, with very few standards or safeguards to ensure that authority is exercised in a

[2] BRG: Revisiting the Pharmaceutical Supply Chain 2013-2018. January 2022.

[3] IQVIA. "Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027." Published May 2023; Fein, A. "Tales of the Unsurprised: U.S. Brand-Name Drug Prices Fell for an Unprecedented Sixth Consecutive Year (And Will Fall Further in 2024)," Drug Channels. Access: https://www.drugchannels.net/2024/01/tales-of-unsurprised-us-brand-name-drug.html#:~:text=Net%20prices%20for%20brand%2Dname,%2D3.0%25%20minus%205.4%25). January 3, 2024.

[4] IQVIA. "Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027." Published May 2023.

[5] Fein, A. "Tales of the Unsurprised: U.S. Brand-Name Drug Prices Fell for an Unprecedented Sixth Consecutive Year (And Will Fall Further in 2024)," Drug Channels. Access: https://www.drugchannels.net/2024/01/tales-of-unsurprised-us-brand-name-drug.html#:~:text=Net%20prices%20for%20brand%2Dname,%2D3.0%25%20minus%205.4%25). January 3, 2024.

[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] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/50-State-Medicaid-Fact-Sheets/Medicaid-Fact-Sheets-2023/VT-One-Pager_22.pdf

consistent manner. The bill gives the PDAB the authority to determine which products will be subject to a cost review, and which products will ultimately have a UPL imposed on them, but provides no clear and consistent standard for how the PDAB will conduct price reviews or set UPLs. The bill also raises constitutional concerns about Vermont's ability to regulate commercial activity beyond its own borders. See Nat'l Pork Producers Council v. Ross, 143 S. Ct. 1142, 1157 n.1 (2023); Association for Affordable Medicines v. Frosh, 887 F.3d 664 (4th Cir. 2018).

This legislation could harm Vermont'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 Vermont 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 an important part of Vermont's economy and its economic competitiveness. The biopharmaceutical sector directly accounted for 1370 jobs in State in 2020 and supported another 4873 jobs in Vermont for a total of 6243 jobs.[8] These jobs generate over $81 million in state and federal tax revenue for Vermont in 2020. This bill could place these jobs, and tax revenue, in jeopardy.

PhRMA recognizes the access challenges faced by patients in Vermont with serious diseases. We stand ready to work with the Vermont legislature to develop solutions that help patients better afford their medicines at the pharmacy counter. For example, as suggested by Vermont's Department of Financial Regulation in its Act No. 131 (2022) Report, Vermont could consider requiring biopharmaceutical manufacturer rebates and discounts to be passed through to patients at the point of sale to reduce their out-of-pocket costs.[9] In contrast, we believe S.98 would not help patients better access breakthrough, innovative medicines and respectfully oppose its passage.

[8] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Economic-Impact-States-2022/Vermont_Eco-Impact-One-Pager-FINAL.pdf

[9] Vermont Department of Financial Regulation, "Act No. 131 (2022) Report: Pharmacy Benefit Management," January 15, 2023. Access: https://legislature.vermont.gov/assets/Legislative-Reports/DFR-Act-131-Report-on-PBMs.pdf. Page 40.