STATEMENT

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In Opposition to Vermont Senate Bill 98

April 11, 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 to establish a framework for the government to eventually set drug prices, which could limit the prescription options available to Vermont residents. 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.

S.98 directs the Green Mountain Care Board (Board), in consultation with its own technical advisory groups and other state agencies, to create a framework and methodology for implementing a program to regulate the cost of prescription drugs for Vermont consumers and Vermont's health care system. Several states have taken the "foot in the door" approach of setting up a Board and "studying" ways to reduce drug costs, and then aggressively push to set drug prices in subsequent legislative years. Specifically, by requiring the Board to consider options for regulating prescription drug costs that include the experiences of other states with Prescription Drug Affordability Boards (PDAB) and the federal Medicare Drug Price Negotiation Program, S.98 clearly indicates a goal of establishing price controls at some stage in the future.

This legislation takes an inexplicably narrow view of cost drivers and affordability, failing to account for insurance benefit design issues that prevent discounts from flowing to patients and assuming 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. The bill's references to other states' PDABs and the Medicare Drug Price Negotiation Program, which do not take a meaningful view of the supply chain, makes its true intent clear.

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%.[1] 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.[2] Specifically, average net prices for brand medicines stayed flat (0.0% growth) in 2022.[3] Through the first three quarters of 2023, net prices declined by -3.0%.[4] Looking ahead, average net price growth is projected to be -5 to -2% per year through 2027.[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]

Requiring the Board to consider the Medicare Drug Price Negotiation Program as a methodology for regulating the cost of prescription drugs is premature as the federal government is still in the stages of implementation.

S.98 requires the Board to consider options for regulating the price of prescription drugs, including the Centers for Medicare and Medicaid Services' development and operation of the Medicare Drug Price Negotiation Program. The Inflation Reduction Act ("IRA") directed the Department of Health and Human Services (HHS) to establish a "Drug Price Negotiation Program" for Medicare drug prices, forcing manufacturers into a "negotiation" process where HHS sets a "Maximum Fair Price" (MFP), which is a price-setting mechanism. Implementation of the IRA statute and the complex framework of its MFP provisions is at an early stage, and many operational and legal issues remain to be sorted out.[7] PhRMA believes it is premature to consider the Medicare Drug Price Negotiation Program as an option for regulating the price of prescription drugs because the MFP price is not effective until 2026 and important details remain unclear.

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 $334 billion in 2023,[8] do not make their way to offsetting patient costs at

[1] BRG: The Pharmaceutical Supply Chain, 2013–2020. January 2022.

[2] 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.

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

[4] 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.

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

[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] See Establishment of the Medicare Drug Rebate and Negotiations Group Within the Center for Medicare (CM), 87 Fed. Reg. 62433, 62433 (Oct. 14, 2022) ("The work required to implement and administer these new programs will be novel and differ significantly from the Medicare functions that CMS performs today ... Moreover, the scope and complexity of these new programs ... require that a new, dedicated organization be established to ensure that CMS is able to implement these programs successfully and on time.").

[8] Fein, A. "The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2024.

the pharmacy counter. Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as sharing negotiated savings on medicines with patients, making cost-sharing assistance count toward a plan's out-of-pocket spending requirements, and making monthly costs more predictable. These policies can be done without importing government price setting, which can reduce the options available to treat patients.

Price controls on brand medicines raise constitutional concerns.

Through references to other states' PDABs and the Medicare Drug Price Negotiation Program, this bill is clearly contemplating establishing a framework for price controls in Vermont. Application of a 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 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 consistent manner. A law that Colorado enacted, which would implement price controls similar to those contemplated by S.98, is currently the subject of litigation.

Efforts to impart price controls as S.98 intends 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 Vermont in 2020 and supported another 4873 jobs in Vermont for a total of 6243 jobs.[9] These jobs generated 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

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

out-of-pocket costs.[10] In contrast, we believe S.98 would not help patients better access breakthrough, innovative medicines and respectfully oppose its passage.

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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. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.

[10] 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.