

STATEMENT



In Opposition to Rhode Island House Bill 7443 (Representative Tanzi)

February 28, 2024

Position: PhRMA respectfully opposes House Bill 7443 (HB 7443). PhRMA believes that discussions about the affordability of medicines are important, but the intention of this bill is for the government to set drug prices, which could limit the prescription options available to Rhode Islanders. HB 7443 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, HB 7443 automatically imposes a price control in the commercial insurance market based on the Medicare “maximum fair price.” 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 Rhode Island residents. Further, government price setting disincentivizes the development of innovative treatments, as has been seen in Europe. By disincentivizing the development of innovative treatments, this legislation could also threaten the positive effect that the biopharmaceutical industry has on Rhode Island’s economy.

This legislation ignores that there are meaningful policies for addressing affordability without utilizing 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. In a report issued by the Maine Bureau of Insurance in June of 2023, carriers reported that they, or their contracted PBMs, received directly or indirectly from pharmaceutical manufacturers, developers, or labelers a total of \$114,953,034.00 in the 2022 calendar year. Carriers minimally passed this remuneration on to patients at the point of sale: ranging from 0% to 11%.² Conservatively, that means that at least 89% of revenue derived from manufacturers does offset patient cost-sharing at 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 accomplished without price setting, which can reduce the options available to treat patients. For example, studies have shown that passing prescription drug rebates to patients will have minimal impact on health insurance premiums and can provide \$100s - \$1000s of savings for patients with high prescription drug out-of-pocket costs.³ In Arkansas, which requires insurers and PBMs to share 100% of the savings they negotiate on medicines directly with patients, a review of 2024 insurance rate filings indicates that plans are passing through drug rebates

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

² Maine Bureau of Insurance. “2022 Annual Report on Prescription Drug Compensation for the Benefit of Covered Persons.” June 2023.

³ Ding, Y. Miller, G.E. “[The Impact of Sharing Drug Rebates at the Point of Sale on Out-of-Pocket Payments for Enrollees in Employer-Sponsored Insurance.](#)” International Society for Pharmacoeconomics and Outcomes Research, Inc. September 13, 2022; Jonaitis, E., Klein, M., Petroske, J. “[Measuring the Impact of Point of Sales Rebates on the Commercial Health Insurance Market.](#)” Milliman. July 2021.

to patients at the pharmacy counter and that there has been no material impact on premium rate increases for Arkansas.⁴

This legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients, and HB 7443 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.

The growth of net prices, which reflects rebates and discounts, has been in line with or below inflation for the past six years and is projected to remain flat or decline by up to 5 percent annually through 2027.⁶ Specifically, average net prices for brand medicines stayed flat (0.0% growth) in 2022.⁷ Through the first three quarters of 2023, net prices declined by -3.0%.⁸ 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.⁹

PhRMA opposes price setting, including referencing the Maximum Fair Price (MFP).

These bills would automatically apply the MFP to the commercial market in Rhode Island. Medicare MFP is a price-setting mechanism recently enacted as part of the federal Inflation Reduction Act ("IRA"). It is premature to apply the MFP to the commercial market because the price is not effective until 2026. Implementation of the Inflation Reduction Act and the complex framework of its MFP provisions is at an early stage, and many operational and legal issues remain to be sorted out. Rhode Island would be locking itself into a price that has not been implemented. Further, the MFP would specifically be crafted for Medicare participants and not Rhode

⁴ Klein, Michelle; Holzer, Hanna. *Premium Impacts of POS Rebate Implementation in the ACA Market in the State of Arkansas*. Milliman. January 2024.

⁵ BRG: The Pharmaceutical Supply Chain 2013-2020. January 2022.

⁶ 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.

⁷ IQVIA Institute for Human Data Science. *The Use of Medicines in the U.S. 2023*. Published April 2023. Accessed May 2023. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2023>.

⁸ 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.

⁹ 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>.

Island's residents. Considering the work that still needs to be done at the federal level to shape the IRA's MFP provisions, MFP should not be applied to the commercial market in Rhode Island.

Price controls on brand medicines raise constitutional concerns.

Application of price controls 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 Rhode Island 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 also raises constitutional concerns about Rhode Island'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).

Price controls could severely reduce Rhode Island patients' access to medicines, as is seen abroad.

Enacting price controls could restrict patients' access to medicines and reduce the availability of life-saving therapies in Rhode Island. Specifically, if a pharmacy or provider cannot obtain a medicine at the government price, the medicine will not be available to Rhode Island residents. Additionally, providers could be left with substantial costs if they acquired the drug before the price control is in place yet could not bill for reimbursement that covers their acquisition costs.

Research shows that U.S. patients enjoy earlier and less restrictive access to new therapies.¹⁰ In countries with government price controls, patients have access to just half of medicines launched globally since 2012, compared to 85% in the United States.¹¹ In the United Kingdom, patients have access to 59% of new medicines launched globally since 2012, 50% in France, and 44% in Canada. Not only are patients in these countries unable to access as many medicines compared to patients in the United States, there is a significant delay in the availability of new medicines. In the United States, the average delay in availability after U.S. Food and Drug Administration (FDA) approval is 0-3 months compared to 13 months in the United Kingdom, 20 months in France, and 18 months in Canada.¹² When governments in other countries have implemented price setting policies, Research and Development (R&D) investment and innovation have significantly declined because governments choose via these policies which diseases are worth investing in and which are not.¹³ Until the 1970s, the majority of innovative medicines were developed in Europe. After adopting stringent price setting measures, Europe trails the United States in R&D investment by more than 40%.¹⁴

The legislation could harm Rhode Island'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

¹⁰ IQVIA Institute, *Global Oncology Trends 2017, Advances, Complexity and Cost*. May 2017.

¹¹ PhRMA analysis of IQVIA MIDAS and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Japan Pharmaceuticals and Medical Devices Agency (PMDA), Australia Therapeutic Goods Administration (TGA) and Health Canada data. July 2022.

¹² PhRMA analysis of IQVIA MIDAS and country regulatory data. October 2022.

¹³ *The Historical Impact of Price Controls on the Biopharma Industry*. Vital Transformation. 11 November 2021. <https://vitaltransformation.com/2021/11/the-historical-impact-of-price-controls-on-the-biopharma-industry/>.

¹⁴ Gunter Verheugen, Vice-President of the European Commission for Enterprise and Industry. 2005. "Biotechnology's contribution to an innovative and competitive Europe." Lyon. April 14, 2005.

incentives that allow manufacturers to invent new medicines. Price controls also could severely reduce Rhode Island 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 a vital part of Rhode Island's economy and its economic competitiveness.

The biopharmaceutical sector directly accounted for 2,005 jobs in Rhode Island in 2020 and supported another 9,183 jobs for a total of 11,188 jobs. These jobs generated over \$196.2 million in state and federal tax revenue for Rhode Island in 2020.¹⁵ This bill could place these jobs, and tax revenue, in jeopardy.

PhRMA recognizes the access challenges faced by patients in Rhode Island with serious diseases. We stand ready to work with the Rhode Island 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 HB 7443.

We urge you to vote no on HB 7443 for these reasons.

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.

¹⁵ TEconomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates. Report prepared for PhRMA.