STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition Rhode Island House Bill 5620 (Potter)
March 5, 2025

Position: PhRMA respectfully opposes House Bill 5620 (HB 5620) because it will penalize the biopharmaceutical industry for certain price increases based on a third-party assessment. Proposals to arbitrarily cap pharmaceutical prices are irresponsible, can stifle innovation, and raise significant legal concerns.

This proposed legislation will not benefit patients and can jeopardize the competitive market that works to drive down drug prices. This proposal seeks to utilize a third party's prejudiced and distorted assessment of whether certain price increases are warranted and would effectively give the Institute for Clinical and Economic Review (ICER) the regulatory authority to penalize a private entity. If enacted, this would relinquish the state's legislative and regulatory authority to an outside organization.

We are in a new era of medicine that is bringing revolutionary, innovative treatments, therapies, and cures to patients. For example, we can now cure more than 95% of patients with hepatitis C, allowing patients to avoid liver failure and costly transplants.[i] Since peaking in 1991, the cancer death rate has declined by 33%, with experts agreeing that new medicines have contributed greatly to accelerating recent declines in cancer mortality.[ii, iii] Medicines and vaccines continue to play a central role in keeping patients healthy and reducing the need for more costly medical care. Unfortunately, this radical policy could freeze new, life-saving innovation and force patients to face the uncertainty of a health care system where the government sets prices for critical medicines, similar to what is done in other countries.

This legislation ignores that there are meaningful policies for addressing affordability without imposing government price controls that can jeopardize innovation.

This legislation does nothing to ensure affordability for patients when purchasing medicines and could limit patient access to needed medicines. Any funds generated from penalties are used primarily to run the program imposing such penalties and defend against appeals, with any remaining funds being deposited in the general fund.

PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $344 billion in 2023,[iv] do not make their way to offsetting patient costs at the pharmacy counter. Despite manufacturers' rebates and discounts negotiated by health plans that have kept price increases below inflation for the last five years, nearly half of commercially insured patients' out-of-pocket spending for brand medicines is based on the medicine's undiscounted list price.[v] 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, and sharing negotiated savings on medicines with patients.

Legislating an ambiguous definition for "unsupported price increase" (UPI) is just another attempt at legislating a price control. Proposals such as this could have unintended impacts on future research and development of new drugs and new cures.[vi] Price controls could come at a cost to innovation and long-term patient well-being. Price

controls can limit access to needed medications, can undermine competitive forces, and ignore the ways in which medicine improves lives and saves the health system money.

The use of ICER's UPI Report for the purposes of this legislation is inappropriate and inconsistent with the scope and purpose of the report and could negatively impact vulnerable populations.

This legislation relies on ICER's UPI Report as the sole determinant of which drugs have experienced a UPI. Sole reliance on the report means that this legislation takes an inappropriately narrow view of pricing factors and only considers new clinical evidence year over year, when many different factors impact pricing decisions. In addition, the processes behind the ICER report change year to year, creating a moving target.

There is growing recognition that ICER's methodologies lack transparency, fail to meet well-accepted standards for methodological rigor, and are biased against continued progress against serious diseases with unmet need.

In addition, the use of ICER's value assessments discriminate against the most vulnerable and disabled patients. The claim that ICER's UPI Report in no way implicates Quality Adjusted Life Years (QALYs) is not accurate. Although QALYs are not relevant in how the initial list of medicines that are selected for further review, ICER's own methodology document describes the use of cost-effectiveness analyses once the initial list is developed. Developed from population averages, QALYs ignore important variability in patients' individual needs and preferences and are acknowledged by experts to discriminate against people with disabilities by placing a lower value on their lives. Our health care system needs better approaches that do not put patient access at risk and that keep pace with rapidly changing science.

This legislation raises significant legal concerns.

Under the provisions in this bill, manufacturers are not provided due process before the determination and imposition of significant, excessive penalties because they will not know that a price increase was in violation of the law until they have been notified by the Tax Assessor. These due process concerns are exacerbated by the vague standards for imposing the significant and excessive penalties that are levied against manufacturers under the framework proposed by the legislation.

The proposed price control in this legislation, imposing a penalty on identified drugs that have an "unsupported price increase," 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 (20 07)*, 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 court's decision stated that "[t]he underlying determination about the proper balance between innovators' profits and consumer access to medication …is exclusively one for Congress."

In addition, this legislation relies on the ICER UPI Report, which is based on national sales and raises additional concerns under the Dormant Commerce Clause, among other issues.

This legislation could harm innovation and 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

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 2,424 jobs in Rhode Island in 2022 and supported another 9,234 jobs for a total of 11,658 jobs.[vii] These jobs generate over $253.6 million in state and federal tax revenue. 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. PhRMA stands ready to work with the legislature to develop market-based solutions that help patients better afford their medicines at the pharmacy counter. However, this legislation does nothing to ensure patient access to medicines and affordability and could create barriers to innovation. **PhRMA respectfully opposes HB 5620.**

***

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

---

[i] Kish T, Aziz A, Sorio M. Hepatitis C in a New Era: A Review of Current Therapies. P T. 2017 May; 42(5):316-329.

[ii] American Cancer Society, Cancer Facts & Figures 2023; American Cancer Society.

[iii] Howlader N, et al., "The Effect of Advances in Lung-Cancer Treatment on Population Mortality": N Engl J Med 2020; 383:640-649; J Berk-Kraus et al., "New Systemic Therapies and Trends in Cutaneous Melanoma Deaths Among US Whites, 1986-2016," American Journal of Public Health, May 2020.

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

[v] 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.

[vi] Kennedy, J. The Link Between Drug Prices and Research on the Next Generation of Cures. Information Technology & Innovation Foundation. Sept. 9, 2019. Available at https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures. https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.

[vii] TEConomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. February 2024. Prepared for PhRMA.