STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to Oregon SB 404-1 amendment

February 17, 2023

Position: PhRMA respectfully opposes SB 404-1 amendment – a premature bill that significantly expands the authority of the Prescription Drug Affordability Board despite the fact that the Board is only just beginning to exercise its existing authority. Specifically, this proposal broadens the Board's authority by permitting the Board to establish price controls by way of an upper payment limit (UPLs). Price controls do not address underlying barriers to accessing healthcare and could result in greater costs to the state, the federal government, and consumers. SB 404-1 also requires manufacturers to report additional data on all patient assistance programs, which exacerbates our existing concerns around adequate protection of manufacturers' confidential and proprietary information**.**

Price controls fail to address most patients' barriers to accessing care, particularly the costs patients pay at the pharmacy counter.

Proposals to arbitrarily cap pharmaceutical prices ignore other cost drivers in the supply chain and do not help patients. The ambiguous definition in the underlying law, "affordability challenges," is just another attempt at a price control. This legislation does not address benefit designs that continue to push more cost-sharing onto patients and which determine how much patients pay out-of-pocket for their drugs. Patients that currently have deductibles will still be required to meet those deductibles if no changes are made to health benefit designs. PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers to plans and PBMs, approximately $236 billion in 2021,[1] do not make their way to offsetting patient costs at the pharmacy counter. Yet, despite manufacturers' rebates and discounts negotiated by health plans that have kept net 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.[2]

Implementing price controls diminishes the incentives for biopharmaceutical manufacturers to invest in and introduce new medicines and could limit the prescription drug options available to Oregon residents.

Research shows that "[i]t is simply not true that government can impose significant price controls without damaging the chances for future cures."[3] Experts estimate a 50% decrease in the price of medicines would result in a 25% to 60% decrease in the number of new drugs in the pipeline.[4] U.S. patients enjoy earlier and less restrictive access to new therapies,[5] a finding that is reinforced by HHS's own analysis of Medicare Part B drugs which showed that only 11 of the 27 drugs examined (41%) were available in all 16 comparator countries, nearly all of which have

[1] Fein, A. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2022.
[2] 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/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us.
[3] 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.
[4] Abbot, T. and Vernon, J. The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions. National Bureau of Economic Research. Available at https://www.nber.org/papers/w11114; Civan, A. & Maloney, M. (2009). The Effect of Price on Pharmaceutical R&D. The B.E. Journal of Economic Analysis & Policy, 9(1).
[5] IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost. May 2017.

single-payer healthcare systems.[6] In countries where governments set medicine prices, patients have access to fewer treatment options. For example, the U.S. has access to nearly 85% of all medicines launched between 2012 and 2021, while just 61% are available in Germany, 59% in the U.K., 51% in Japan, 52% in France, 45% in Canada, and 34% in Australia.[7]

Additional supply chain entities should bear the cost of paying for the Prescription Drug Price Transparency Program and Prescription Drug Affordability Board.

Under SB 404-1 amendment, the scope of reporting on prescription drug spending to the Prescription Drug Price Transparency Program and Prescription Drug Affordability Board would be expanded to require additional reporting from other supply chain entities like pharmacy benefit managers (PBMs) and health plans. PhRMA supports this effort, as those entities significantly influence the ultimate price that a patient pays for a medicine. In fact, non-manufacturer stakeholders—including PBMs, health plans, hospitals, the government, pharmacies, and others—realize the majority of total spending on brand medicines. In 2020, manufacturers retained just 49.5% of brand medicine spending, while members of the supply chain retained 50.5%.[8] Since the bill recognizes the role these entities play in the ability for patients to afford their prescription drugs by extending transparency reporting to those entities, those entities should also be responsible for paying fees to run these programs.

SB 404-1 lacks necessary protections for manufacturers' trade secret, confidential, and proprietary information.

The bill suggests a number of technical changes to Oregon's Drug Price Transparency program and the Prescription Drug Affordability Board statutes, some of which may implicate manufacturers' trade secret, confidential, or proprietary information, including requiring manufacturers to submit data on all patient assistance programs that a manufacturer has offered or funded for any drug. PhRMA is concerned that, without adequate safeguards to protect against the disclosure of this and other such information, these changes would create a serious and unjustified risk of disclosure, which would cause irreparable harm to manufacturers and violate their rights both under state and federal law.

We are also concerned that Section 5 does not amend provisions in ORS section 646A.689 that could be construed to require the disclosure of confidential, proprietary, or trade secret information in violation of state and federal rights. Most notably, subsections (9) and (10)(a) purport to require the Department to post manufacturers' trade secret information to its website unless "[t]he public interest does not require disclosure of the information." In addition, subsection (10)(c) provides that a person may petition the Attorney General to review a decision to withhold a manufacturer's trade secret information, but it does not provide any express mechanism for a manufacturer to challenge a decision to disclose such information, including in instances where disclosure is deemed to be "in the public interest."

Disclosing manufacturers' trade secret information whenever Department of Consumer and Business Services deems disclosure to be in "the public interest" would violate both state and federal law. Both Oregon and federal law protect manufacturers' trade secret, confidential, and proprietary information from disclosure; such information cannot be publicly disclosed without violating state and federal prohibitions against the "misappropriation" of trade secrets.[9] The Fifth Amendment's prohibition against taking private property without just compensation similarly prohibits the uncompensated disclosure of trade secrets.[10] Courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality . . . can amount to an unconstitutional 'taking' of property."[11]

[6] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018.
[7] PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration, European Medicines Agency, Japan Pharmaceuticals and Medical Devices Administration, Health Canada and Australia Therapeutic Goods Administration data. Note: Sample includes new active substances launched globally from January 1, 2012 to December 31, 2021. Updated June 2022.
[8] BRG: The Pharmaceutical Supply Chain, 2013-2020. January 2022.
[9] See 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act); ORS 646.461(4) (defining "misappropriation" under Oregon's Uniform Trade Secrets Act).
[10] See, e.g., Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1002–04 (1984).
[11] St. Michael's Convalescent Hosp. v. California, 643 F.3d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted).

SB 404-1 raises significant legal concerns.

As with the underlying statute, we continue to have legal concerns with this bill. This bill gives the Prescription Drug Affordability Board the authority to set a price control, which raises constitutional concerns under the Supremacy Clause, among other concerns, 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 an appropriate incentive for invention, and Oregon 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 brand drugs, reasoning that the D.C. law 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 states that "[t]he underlying determination about the proper balance between innovators' profits and consumer access to medication …is exclusively one for Congress."

PhRMA recognizes the serious access challenges faced by patients in Oregon. Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as making monthly costs more predictable and sharing negotiated savings on medicines with patients. However, **this legislation fails to address patient access and affordability and will only serve to create barriers to innovation.** PhRMA stands ready to work with the legislature to develop solutions that help patients better afford their medicines at the pharmacy counter.

PhRMA opposes SB 404-1 for the above stated reasons.
Please vote "NO" on SB 404-1 amendments.

About PhRMA
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.