STATEMENT

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Statement Neither For nor Against LD 697
March 12, 2025

Position: PhRMA respectfully submits the below comments with respect to LD 697, An Act to Direct the Maine Prescription Drug Affordability Board to Assess Strategies to Reduce Prescription Drug Costs and to Take Steps to Implement Reference-based Pricing. While we recognize that LD 697 is ostensibly simply directing a study, the clear intent to ultimately impose price controls on prescription medicines raises serious concerns.

LD 697 overhauls the existing Prescription Drug Affordability Board, removing the initial, and yet to be accomplished, focus on spending targets for public payors and directing the Board to study and report on various "strategies to reduce costs of prescription drugs." 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 (PDABs), assessing the establishment of Upper Payment Limits and reference pricing based on the federal Medicare Drug Price Negotiation Program, LD 697 clearly indicates a goal of establishing price controls at some stage in the future. As such, PhRMA urges amendments to LD 697 to ensure the Advisory Council membership reflects the new charge of the Board and includes a range of stakeholders with critical expertise necessary to achieve a comprehensive and balanced study and legislative recommendations.

A variety of stakeholders are involved in determining what consumers ultimately pay for a medicine, including manufacturers, insurers, pharmacy benefit managers (PBMs), wholesalers, and the government. However, the Advisory Council membership remains focused on public payors related to the original charge of the Board that would be repealed by this legislation. We urge the Legislature to consider establishing an Advisory Council that reflects the new charge of the Board contemplated by LD 697, including a voice for providers and patients. This would aid in substantive, meaningful and balanced discussion of the study and recommendations contemplated by this legislation.

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.

LD 697 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.[1]

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 Maine. 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 Maine 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. A law that Colorado enacted, which would implement price controls similar to those contemplated by LD 697, is currently the subject of litigation.

Efforts to impart price controls could harm Maine's economy and inhibit patient access.

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 Maine 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 Maine's economy and its economic competitiveness. The biopharmaceutical sector directly accounted for 6689 jobs in Maine in 2022 and supported another 23,531 jobs in Maine for a total of over 30,000 jobs.[2] These jobs generated over $552 million in state and federal tax revenue for Maine in 2022. This bill could place these jobs, and tax revenue, in jeopardy.

PhRMA recognizes the access challenges faced by patients in Maine with serious diseases. We stand ready to work with the Maine legislature to develop solutions that help patients better afford their medicines at the pharmacy counter and be engaged in meaningful, solution-oriented discussions as the Board moves forward with the study contemplated by LD 697.

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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.

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[1] 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.").

[2] https://cdn.aglty.io/phrma/fact-sheets/economic-impact/Maine_Eco%20Impact%20One%20Pager%202022_2.pdf