STATEMENT

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In Opposition to Maine L.D. 1829 and L.D. 1816

May 15, 2023

Position: PhRMA respectfully opposes Senate Bill L.D. 1829 and House Bill L.D. 1816. PhRMA believes that discussions about the affordability of medicines are important, but the intention of these bills is for the government to set drug prices, which could limit the prescription options available to Mainers. L.D. 1829 and L.D. 1816 shortsightedly target drug spending in ways that likely will have long-term, harmful effects on innovation and the development of new, life-saving therapies.

Specifically, L.D. 1829 and L.D. 1816 automatically impose 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 Maine residents. Further, government price setting disincentivizes the development of innovative treatments, as has been seen in Europe.

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 March of 2022, carriers reported that they, or their contracted PBMs, received directly or indirectly from pharmaceutical manufacturers, developers, or labelers a total of $97,381379.84 in the 2021 calendar year. Carriers minimally passed this remuneration on to patients at the point of sale: ranging from 0% to 5%.[2] Conservatively, that means that at least 95% 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. For example, there is legislation pending in Maine that would require 100% of these negotiated savings to pass through to patients at the pharmacy counter (L.D. 1165). 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] One study demonstrated that, even if health insurance companies were required to share all the negotiated rebates with patients, premiums would increase at most 0.6%, while patients could save up to $1,000 each year on their medicine costs.[4]

[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. "2021 Annual Report on Prescription Drug Compensation for the Benefit of Covered Persons." March 2022.
[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.
[4] https://www.milliman.com/en/insight/measuring-impact-point-of-sale-rebates-commercial-health-insurance-market-january-2022.

This legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients, and L.D. 1829 and L.D. 1816 assume 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 five years. Specifically, average net prices for brand medicines stayed flat (0.0% growth) in 2022.[6] 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.[7]

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

These bills would automatically apply the MFP to the commercial market in Maine. Implementation of the Inflation Redution 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. Maine would be locking itself into a price that has not been implemented. Further, the MFP would specifically be crafted for Medicare participants and not Maine's residents. Implementing a price control, even if referencing Medicare's MFP, could have devastating consequences for Mainers, including those waiting for new, innovative treatments.

Price controls on brand medicines raise constitutional concerns.

Among other constitutional concerns, application of price controls to patented medicines raises concerns under the Supremacy Clause of the U.S. Constitution 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.

[5] BRG: The Pharmaceutical Supply Chain 2013-2020. January 2022.
[6] 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.
[7] 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 Accessed May 2023. https://www.maine.gov/pfr/sites/maine.gov.pfr/files/inline-files/2021_pbm_report.pdf.

Price controls could severely reduce Maine 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 Maine. Specifically, if a pharmacy or provider cannot obtain a medicine at the government price, the medicine will not be available to Maine 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.[8] 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.[9] 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.[10] 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.[11] 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%.[12]

We urge you to vote no on L.D. 1829 and L.D. 1816 for these reasons.

[8] IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost. May 2017.
[9] 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.
[10] PhRMA analysis of IQVIA MIDAS and country regulatory data. October 2022.
[11] 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/.
[12] 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.