Biotechnology Innovation Organization Comments on 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.

On behalf of the Biotechnology Innovation Organization (BIO) and its members, we would like to offer the below comments on 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.*

BIO is the world's largest advocacy association representing biotechnology companies, academic and research institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

Maine's bioscience industry employed 9,946 individuals in 2023 across 640 state business establishments. With 22.2 percent growth in bioscience industry employment since 2019, Maine has outpaced the strong job growth seen nationally, led by double-digit gains in four of the five industry subsectors. Maine has a highly specialized employment concentration in the pharmaceutical's subsector. The state's average bioscience industry wage was $95,859— 58 percent higher than the private sector average. State academic R&D expenditures in bioscience-related fields totaled $52.2 million in 2022, while NIH funding reached a new peak of $117.9 million in 2023 following steady growth since 2020.

If passed, LD 697 would make changes to the state's existing Prescription Drug Affordability Board (PDAB). The legislation would not only change the membership of the existing PDAB, but it would also change the scope of the duties of the board from determining prescription drug spending targets to focusing on an assessment of strategies to reduce prescription drug costs, reduce the rate of growth in prescription drug spending and reduce cost barriers for consumers. It would require the Board to review how other states that have the authority to establish "upper payment limits" have implemented that authority, how those states regulate pharmacy benefits managers, and to recommend whether the board should have comparable authority and to assess implementing reference-based pricing for the first 10 prescription drugs for which the Medicare program has negotiated maximum fair prices through the Medicare drug price negotiation program.

The premise that establishing upper limits does not impose price controls is a false narrative. Whether you call it establishing "Upper Limits" or a price control the effect is the

same. This policy still regulates free-market prices and creates a price ceiling based upon an arbitrary metric, often from the Canadian health system that establishes their prices at a much lower level than in the US or now the Medicare "Maximum Fair Price" (MFP). While the federal *Inflation Reduction Act* (IRA), which establishes the MFP process, speaks of government "negotiation" on the price of drugs in Medicare Part B and Part D, the "negotiation" is just a price control by another name. The government is directed to consider a number of factors about a given drug, and then **to set an MFP**. This acts as a ceiling price for the drug from which the government may try to move even lower. Just as other below-market government drug price setting schemes have done over the years, this one will likely lead to market distortions, cost-shifting, supply problems, and ultimately reduced access for patients. Furthermore, according to the IRA, states will have access to the MFP in Medicaid. If the Medicare MFP is lower than the Medicaid "Best Price," the MFP becomes the de facto "Best Price."

While the bill tasks the board with reviewing how other states have established upper payment limits for certain medications, this is typically and arbitrary measures for the selection of such medications, including "affordability," and prescribes no process for setting this "limit." The price control scheme is designed around the premise that prescription drug costs have ballooned out of control or are increasing at an unsustainable rate. Yet prescription drugs, including inpatient medicines, have and continue to make up about 14% of national health expenditures—both in the past and projected for the next decade.[1] And medicine spending on a per-patient-per-year basis, adjusted for inflation, grew by less than 1% between 2009 and 2018.[2]

Furthermore, it is premature for states to be looking at Medicare MFP to resolve any affordability concerns. The Centers for Medicare and Medicaid Services are still developing guidance for the establishment of the Medicare MFP, which won't be effective until 2026. States would be attempting to implement a policy that has not even been finalized by the federal agency, nor has its impact been tested.

Price controls in other countries have a chilling effect on innovation, as such more than 57% of all drugs come from the United States. Implementing price controls of any kind will stymie innovation in the U.S. Economists have estimated that a 50% drop in drug prices in the United States could see the number of drugs in the development pipeline reduced by 14-24 percent,[3]

Legislative proposals that target the most innovative medicines, disproportionately impacting patients with diseases where there is high unmet need and where low-cost treatment options are not available (e.g., rare diseases), running counter to the aims of personalized medicine, and availability of new treatments. Further troubling, the arbitrary nature of upper payment limits ignores the value that an innovative therapy can have to an individual patient—especially one who may have no other recourse—or the societal impact innovative technologies can have, including increased productivity and decreased overall healthcare costs (e.g., due to fewer hospitalizations, surgical interventions, and physicians'

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[1] Roehrig, Charles. *Projections of the Prescription Drug Share of National Health Expenditures Including Non-Retail*. June 2019.

[2] IVQIA Institute for Human Data Science. *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*. May 2019.

[3] Maloney, Michael and Civan, Abdulkadir, "The Effect of Price on Pharmaceutical R&D," The B.E. Journal of Economic Analysis and Policy, 2009.

office visits).

Price controls will dampen investment and would not allow companies to adequately establish prices that will provide a return on investment. The average biopharmaceutical costs $2.6 billion to bring from research and development to market.[4] Small and mid-sized innovative, therapeutic biotechnology companies which make up most of BIO's membership are responsible for more than 72% of all "late-stage" pipeline activity.[5] They sacrifice millions of dollars, often for decades before ever turning a profit, if at all. In fact, 92% of publicly traded therapeutic biotechnology companies, and 97% of private firms, operate with no profit.[6] The overall probability that a drug or compound that enters clinical testing will be approved is estimated to be less than 12%.[7] Only five out of 5,000 compounds become viable marketed products. Pricing must also account for the 4,995 failures before the company discovers that successful drug compound.

Modern biotechnology provides breakthrough products and technologies to combat debilitating diseases. Innovative medicines and cures help people lead longer, healthier lives. BIO is committed to working with the Maine legislature to ensure that patients have access to life saving medications and treatments.

[4] DiMasi, JA, et al., Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. February 12, 2016.

[5] "The Changing Landscape of Research and Development: Innovation, Drivers of Change, and Evolution of Clinical Trial Productivity," IQVIA Report, April 2019.

[6] Ibid.

[7] Biopharmaceutical Research and Development, The Process Behind New Medicines. PhRMA, 2015. http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf