Biotechnology Innovation Organization
1201 New York Avenue NW
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Washington, DC, 20005
202-962-9200

Bill: SB 357 / HB 424- Prescription Drug Affordability Board - Authority for Upper Payment Limits

Position: OPPOSE

Dear Chair, Vice-Chair, and Members of the Committee:

The Biotechnology Innovation Organization (BIO) is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO respectfully opposes HB 424/SB 357 as it does not address the root cause of the problems affecting patients, including lowering out-of-pocket costs. Prescription Drug Affordability Boards (PDAB) across the country have failed to determine whether patients will see any savings to out-of-pocket expenses. In fact, Maryland's own PDAB has said patients will not see savings at the counter. Imposing government price controls like those proposed in this legislation will jeopardize patient access to life saving and life-altering biopharmaceuticals and stymie innovation.

This bill does not address the root cause affecting patients' out-of-pocket costs.

Nearly 90% of patients[1] pay a given price based on what their health insurer determines. Out-of-pocket costs have been rising for patients because of decisions made by health insurers. Net of rebates and other price concessions, medicine spending grew by only 0.8% in 2020.[2] Despite this fact, many insurers require more and more patients to pay for their drug costs through deductibles and cost-sharing rather than an established copayment, increasing their out-of-pocket costs. A May 2021 Congressional Research Service report found that insurers are imposing higher levels of cost sharing and forcing some patients, i.e., the chronically ill, to pay a greater financial burden than others.[3] In fact, insurers require patients to pay proportionately almost 5 times more out of pocket for prescription drugs than for hospital care.[4]

Legislative proposals such as these 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.

The arbitrary nature of the PDAB process ignores the value that an innovative therapy can have

[1] Kaiser Family Foundation. https://www.kff.org/uninsured/state-indicator/nonelderly-uninsured-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
[2] "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025, IQVIA, June 2021.
[3] "Frequently Asked Questions About Prescription Drug Pricing and Policy," Congressional Research Service Report, Updated May 6, 2021.
[4] "BIO Analysis of Historical National Health Expenditure Data, Centers for Medicare & Medicaid Services. December 2020.

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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 health provider office visits). "Affordability reviews" also create discriminatory effects on patients with rare diseases by prioritizing cost containment over patient value. Patients with rare and chronic diseases have complex treatment plans that must be tailored to individual needs, making access to treatments without interruptions absolutely critical. The affordability review's biased focus on cost containment could lead to restrictions on patient access to treatments for rare diseases, which would be especially devastating on these populations.

Price controls will dampen investment and will not allow companies to adequately establish prices that will provide a return on investment.

The cost to bring an average biopharmaceutical from research and development to market is $2.6 billion.[5] 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.[6] 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.[7] The overall probability that a drug or compound that enters clinical testing will be approved is estimated to be less than 12%.[8] 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.

PDABs fail to consider the significant and devastating unintended consequences of its policies on patient access.

Drugs deemed to be "unaffordable" may shift market-based access incentives and lead payers to reform their benefit designs with greater utilization management or adverse formulary adjustments.[9] This in turn may reduce patient access to those medications. Under PDAB laws, insurers can deny coverage on products with a UPL.[10] Since insurers already have wide discretion to deny coverage on drugs that are deemed to not be "medically necessary", it is problematic that UPLs may provide yet another incentive for insurers to deny coverage for critical drugs.

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[5] DiMasi, JA, et al., Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. February 12, 2016.
[6] "The Changing Landscape of Research and Development: Innovation, Drivers of Change, and Evolution of Clinical Trial Productivity," IQVIA Report, April 2019.
[7] Ibid.
[8] Biopharmaceutical Research and Development, The Process Behind New Medicines. PhRMA, 2015. http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf
[9] Upper Payment Limits on Drugs Could Alter Patient Access. Avalere. April 8, 2024. Retrieved: https://avalere.com/insights/upper-payment-limits-on-drugs-could-alter-patient-access
[10] "Stop the Minnesota Prescription Drug Affordability Board." Patients Rising Now. Retrieved: https://patientsrisingnow.org/stop-the-mn-pdab/

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In addition, patient access could be harmed as providers change prescribing patterns for drugs subject to price setting. Patients who visit small provider practices and specialty providers may be disproportionately harmed if those providers cannot, or will not, access these drugs anymore because reimbursement for associated services is limited. To circumvent drug shortages and limitations on patient access, patients may be forced to travel outside the state to access drugs not available under the UPL. This may exacerbate growing health inequities between those high-income patients with the means to travel outside the state, and low-income patients who have a more difficult time to take leave and travel across state lines.

For these reasons, BIO opposes HB 424/SB 357 requests an unfavorable report. Please do not hesitate to contact us for any further information.

Sincerely,

Russell Palk