VIA Electronic Delivery
Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

February 18, 2025

Re: October 2025 Oregon Prescription Drug Affordability Board Meeting

Dear Prescription Drug Affordability Board Members and Staff:

The Biotechnology Innovation Organization (BIO) and Oregon Life Sciences appreciate the opportunity to provide comments for consideration at the Oregon Prescription Drug Affordability Board (PDAB)'s February 2026 meeting. Our comments below focus on the PDAB's policy recommendations for inclusion in the 2025 drug review report and the 2026 drug review of the updated prescription drugs and insulin products preliminary lists.

The Biotechnology Innovation Organization (BIO) is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector.

Oregon Life Sciences is the statewide trade association representing Oregon's life sciences ecosystem, including biotechnology, biopharmaceuticals, medical devices, diagnostics, research institutions, contract research and manufacturing organizations, suppliers, and workforce and economic development partners. Our members range from early-stage startups and academic research centers to established manufacturers and global companies with operations in Oregon. Oregon Life Sciences works to advance scientific innovation, support a skilled workforce, and promote policies that enable patient access to safe, effective, and affordable medical products while sustaining a strong and competitive life sciences ecosystem across the state.

Policy recommendations for inclusion in the 2025 drug review report

As we have previously commented, BIO and Oregon Life Sciences appreciate that the Board has included certain policy alternatives for the 2025 drug review report that would meaningfully address issues in the broader pharmaceutical supply chain.

In particular we support the following policy alternatives and areas for further study & investigation that were included in the February PDAB meeting materials for the 2025 drug review report. These policies would improve patient access and reduce patient out-of-pocket expenses.

- Exploring enactment of state law that delinks PBM payment with list prices;
- Further study and investigation of PBM conduct and rebate dynamics;
- Further studying and investigation of copay accumulators/maximizers.

2026 drug review: Discussion and review of the updated prescription drugs and insulin products preliminary lists

At the January meeting, the Board presented on its perceived authority to review drugs with orphan-drug designations. In this discussion, several Board members made remarks claiming that it would be "time consuming" and "difficult" to remove orphan indication data. Members went on to deliberate whether drugs with multiple orphan indications should be removed from the preliminary lists, or whether the Board should only remove drugs with a single orphan indication.

BIO and Oregon Life Sciences strongly believes that orphan drugs, including those with multiple orphan indications, should not be subject to the drug review process, given the importance of the orphan drug exception and the need to maximize protection for rare disease drugs.

Orphan drugs treating multiple orphan conditions have become an important part of meeting unmet patient need. IQVIA data from 2020 show that since Congress passed the ODA in 1983, the FDA has granted 838 orphan drug indications to 564 distinct drugs, meaning hundreds of drugs carry multiple orphan indications.[1] There are over 7,000 known rare diseases, and approximately thirty new ones are identified each year.[2] While each rare disease affects only a relatively small number of patients, collectively, over thirty million Americans are affected by a rare disease.[3] The federal government has an extensive existing policy structure intended to support innovation and investment in orphan drugs and conditions for which patients are desperately waiting for cures and treatments. The OR PDAB cannot risk undermining the important incentives provided at the federal level to support rare-disease innovation. Preserving incentives to develop orphan drugs is also critical for the United States to maintain its leadership in biomedical innovation. Recently, China has announced that it will, for the first time, grant orphan drugs seven years of

[1] "Orphan Drugs in the United States" IQVIA Institute. December 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/orphan-drugs-in-the-united-states-rare-disease-innovation-and-cost-trends-through-2019

[2] "Rare Diseases at FDA." https://www.fda.gov/patients/rare-diseases-fda.

[3] S. Garrison, et al., *The Economic Burden of Rare Diseases: Quantifying the Sizeable Collective Burden and Offering Solutions*, Health Affairs Forefront, https://www.healthaffairs.org/do/10.1377/forefront.20220128.987667/

market exclusivity.[4] Given this development, it is critical to preserve American competitiveness by ensuring that the incentives for developing orphan drugs remain robust. The PDAB must implement the orphan drug exclusion to be maximally protective of orphan drugs, in recognition of the unique need to maintain incentives for developing new therapies targeting rare diseases.

Further, the Board does not have the capacity and experience to accurately remove orphan indication data. The Board does not even specify any methodology for removing orphan indications from the preliminary lists or how that removal would be validated. The Board also has not mentioned how or if the Board will need to access data sourced from medical records to determine diagnoses and the reason(s) for which a drug was prescribed for a particular patient, which would evidently require privacy assurances if the data is individualized. Without the data and expertise to filter out orphan indications from non-orphan indications, this is likely to lead to discrepancies between drug reviews.

It is evident that the Board is already facing challenges with this process, given the discrepancies and variations that have been documented in the data sets used for the Board's price trend analysis. For instance, in the Drug Review Preliminary List, many of the WAC prices listed for a specific drug are lower than the listed "average cost net of rebate per prescription," and other WAC prices are listed as one dollar and even as low as zero dollars. Evidently, it is clear that data errors continue to persist with no acknowledgement from the Board. BIO and Oregon Life Sciences are deeply concerned by this misleading and inaccurate data and a continued lack of clear definitions and standards from the Board.

Before the PDAB continues with its affordability review process, it is evident that the Board must establish a more transparent process that allows stakeholders to review and validate the data sets and staff analysis. Manufacturers should also be able to submit evidence or validate that an indication falls within an orphan drug designation to account for situations where the PDAB does not have the capacity or experience to identify orphan indications for all drugs eligible for review. We also reiterate that the Board's current process provides insufficient time for public comment; for a truly transparent process, it is essential that the Board release all agenda materials well ahead of the meeting date.

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BIO and Oregon Life Sciences appreciate the opportunity to provide feedback to the Board through these February meeting materials. We look forward to continuing to work with the Board to ensure Oregon residents can access medicines in an efficient, affordable, and timely manner.

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[4] Steve Usdin, China's orphan drug exclusivity could bolster market, incentivize development, Biocentury (Jan. 28, 2026).

Sincerely,

Melody Calkins
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Biotechnology Innovation Organization

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