



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

October 21, 2026

Re: October 2026 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 the Oregon Prescription Drug Affordability Board (PDAB)'s October 2026 meeting. Our comments below focus on the PDAB's policy memorandum titled "Orphan Drug Review Refinements."

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 Association (OLS) is the statewide trade association representing Oregon's life sciences industry, including biotechnology, medical devices, diagnostics, biomanufacturing, bio agriculture, and related research and supply-chain companies. Our members are on the front lines of discovering, developing and manufacturing cutting-edge therapies and devices to treat and cure a wide range of conditions. Our industry provides high-wage, long-term jobs that bolster our communities and tax revenues.

Orphan Drug Review Refinements Memo

At the September meeting, the Board released a memo that recommended an amendment to the orphan drug exemption, O.R.S. § 646A.694(2). The amendment would permit the Board to conduct affordability reviews for orphan drugs that have at least one non-orphan indication. BIO and OLS are extremely concerned by this proposed amendment and strongly oppose any changes to the statutory protection for orphan drugs in Oregon.

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. Legislators clearly recognize that orphan drugs require special consideration and included express language in the statute accordingly by prohibiting review of orphan drugs. The suggested revisions are not simply a "refinement" but would represent a substantial change to the intent and plain language of the statute.

As we have stated in previous comments, 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 would for the first time, grant orphan drugs seven years of 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's "problems" with the current framework do not reflect an ambiguity in the original legislative language or an inability to administer the existing exemption. Rather, the challenges listed in the memo arise from the complexity of drawing indication-specific distinctions between orphan and non-orphan indications. Implementing the statute as originally written would avoid these indication-specific complexities, resolve the Board's current administrative challenges, and protect the critical orphan protections as intended by the Legislature.

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

Sincerely,

Melody Calkins
Director, Health Policy
Biotechnology Innovation Organization

Sincerely,

Ndeye Makalou
Interim President & CEO
Oregon Life Sciences

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/doi/10.1377/forefront.20220128.987667/>

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