Rare Disease Company Coalition

BY ELECTRONIC DELIVERY

October 19, 2026

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
State of Oregon

RE: Rare Disease Company Coalition Urges Preservation of the Oregon Prescription Drug Affordability Board Orphan Drug Exemption

Dear Members of the Oregon Prescription Drug Affordability Board:

On behalf of the Rare Disease Company Coalition (RDCC), we appreciate the opportunity to provide feedback on the Board's consideration of changes to Oregon's orphan drug exemption under ORS 646A.694(2). We strongly urge the Board to preserve the existing orphan drug exemption as written and oppose any effort to repeal or narrow this critical protection.

RDCC represents companies dedicated to discovering, developing, and delivering treatments to patients living with rare diseases. RDCC members have spent a collective 900 years dedicated to rare disease innovation. Our members invest, on average, nearly 60 percent of their annual expenditures in research and development (R&D)—more than $25 billion annually—to advance treatments for patients with rare diseases. RDCC members have brought more than 100 rare disease treatments to market and have more than 230 programs in their development pipelines, many of which could become the first FDA-approved therapies for their respective diseases.

The need for continued innovation is urgent. Approximately 30 million Americans live with a rare disease, and 95 percent of the approximately 10,000 known rare diseases still lack an FDA-approved treatment. Patients and families facing these conditions often have few or no treatment options, making continued investment in rare disease research essential.

Oregon policymakers recognized the significant unmet need faced by the rare disease community through enactment of the critical orphan drug exemption from Oregon's affordability review process. However, narrowing or eliminating the existing orphan drug exemption risks exposing rare disease therapies to an affordability review framework that may not adequately account for the unique challenges of rare disease drug development, the value of treatments for small patient populations, or the consequences of restricting access to therapies for serious and often life-threatening conditions.

Rare disease drug development carries unique challenges. Small patient populations, limited natural history data, difficulties recruiting clinical trial participants, and a lack of established treatment options make development complex, lengthy, and costly. Policies that introduce additional uncertainty around the value and affordability of these therapies risk discouraging investment in treatments for these conditions.

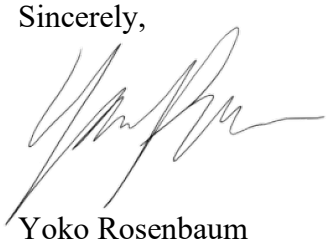
The existing exemption provides an important safeguard for patients who frequently have few or no alternative treatments. Unlike patients with common conditions, those living with rare diseases may not be able to switch to another medication if access to their treatment is disrupted. Affordability reviews can influence subsequent policy decisions, coverage practices, and reimbursement considerations, even when a board does not directly impose price limits.

Furthermore, in its September 8 memorandum, the Board identifies challenges distinguishing orphan and non-orphan utilization in claims data as a rationale for allowing review of drugs with both orphan and non-orphan indications. However, the memorandum acknowledges that pharmacy and medical claims do not consistently contain sufficient diagnostic information to identify the condition for which a drug was prescribed or administered. Under the proposed approach, a product could become eligible for review whenever it has at least one FDA-approved indication outside the scope of an orphan designation—even when the Board cannot reliably distinguish spending associated with rare disease treatment from spending for other indications. This could lead to affordability findings and recommendations based on aggregate product spending without adequately accounting for the circumstances of rare disease patients.

While we recognize the Board's interest in improving its review process and share the Board's goals of improving prescription drug affordability and preserving patient access, narrowing or eliminating this vital protection will have significant consequences for Oregonians living with a rare disease. We respectfully urge the Board to retain the existing exemption.

We appreciate the Board's consideration of these comments and stand ready to work with Oregon policymakers to promote prescription drug affordability while sustaining the development and availability of innovative treatments for patients living with rare diseases.

Sincerely,



Yoko Rosenbaum
Senior Director
Rare Disease Company Coalition