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Novato, CA 94949
Phone: 415-483-8800

July 2, 2024

Karen Winkel
Rules Coordinator
Office of the Secretary of State for the State of Oregon
800 Summer Street NE
Salem, OR 97310

Sent via email to karen.j.winkel@dcbs.oregon.gov

Re: Notice of Proposed Rulemaking regarding Drug Manufacturers Annual Fee Assessment

Dear Ms. Winkel,

On behalf of Ultragenyx Pharmaceutical Inc., we are writing in response to the Notice of Proposed Rulemaking regarding Drug Manufacturers Annual Fee Assessment. We appreciate the opportunity to provide comments on this important topic.

Ultragenyx is a biopharmaceutical company committed to bringing novel products to patients for the treatment of serious rare and ultrarare genetic diseases. The company has built a diverse portfolio of approved therapies and product candidates aimed at addressing issues with high unmet medical need and clear biology for treatment, for which there are typically no approved therapies treating the underlying disease. Ultragenyx's strategy is predicated upon time- and cost-efficient drug development, with the goal of delivering safe and effective therapies to patients with the utmost urgency.

We understand that current law requires the Department of Consumer and Business Services to adopt by rule, in consultation with the Prescription Drug Affordability Board (PDAB), annual fees to be paid by manufacturers of prescription drugs that are sold in Oregon. These fees cover the expenses incurred by the Division of Financial Regulation (DFR) for administering the Drug Price Transparency program and the PDAB.

We also understand that, as currently required by Oregon Administrative Rules (OAR) Section 836-200-0555, all reporting manufacturers pay an annual assessment of $400 and that any reporting manufacturers who have filed one or more reports pursuant to OAR Sections 836-200-0515 (Threshold for Reporting Drug Price Increase) and/or 836-200-0520 (Threshold for Reporting New Specialty Drug) will pay an additional assessment for each report filed.

Under the proposed rule, the method for calculating the annual assessment will change to instead be based on the number of National Drug Codes (NDCs) for prescription drugs approved by the U.S. Food and Drug Administration in a manufacturer's portfolio; a manufacturer will be categorized as a small, medium or large manufacturer based on the number of NDCs in its portfolio.

We have two main concerns with the approach taken in the proposed rule.

- The fees assessed are designed to cover the expenses incurred by the DFR for administering the Drug Price Transparency program, but the number of NDCs alone that a manufacturer has in its portfolio does not necessarily increase the expenses incurred by the DFR in the administration of the program.
- A manufacturer may very well have multiple NDCs for a given product to enable better dosing options for patients. Manufacturers should be encouraged to provide optimal dosing options for patients and we believe that an unintended consequence of the proposed rule is that it will encourage manufacturers to do the exact opposite.

Accordingly, we recommend that the proposed rule consider retaining the concept that manufacturers be assessed additional fees based on the expenses they create in terms of filing reports under OAR Sections 836-200-0515 (Threshold for Reporting Drug Price Increase) and/or 836-200-0520 (Threshold for Reporting New Specialty Drug). For those manufacturers who file such reports, they could still be categorized as a small, medium or large manufacturer, but that categorization would be based on some other metric besides number of NDCs in the manufacturer's portfolio. An alternate metric could be Medicaid spend on the manufacturer's drug(s) in the State of Oregon.

We thank you for your consideration as you finalize the proposed rule.

Sincerely,

Julie Haeber Boyd
Senior Director, State Government Affairs
jhaeber@ultragenyx.com

cc: Cortnee Whitlock, Dept. of Consumer and Business Services (cortnee.whitlock@dcbs.oregon.gov)
Erik Harris, Chief Commercial Officer at Ultragenyx
Dave Libby, Commercial Head of North America