May 4, 2026

VIA ELECTRONIC MAIL
Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drugs for Affordability Review – Orphan-Designated Drugs

Dear Members of the Oregon Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie") is writing in response to the Oregon Prescription Drug Affordability Board ("Board") January 21, 2026 board meeting presentation titled "Oregon PDAB Authority to Review Drugs with Orphan-Drug Designations" and April 15, 2026 board meeting presentation titled "2026 Drug Methodology."[1] AbbVie Inc. is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, and neuroscience. AbbVie is using advanced technologies and data science to gain unprecedented insights that help us to target medicines more precisely, identify opportunities for combinations and provide patients and their physicians with actionable diagnostic tools. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and to respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives.

At the January 21 and April 15, 2026 meetings, the Board indicated that drugs with FDA orphan designations that are also approved for non-orphan indications are deemed eligible for affordability reviews. As explained below, the Board's interpretation is directly contrary to the Board's recent prior interpretation and wholly inconsistent with the plain language of Oregon Revised Statutes (ORS) § 646A.694(2), which excludes drugs with orphan designations from affordability review. Further, including drugs with orphan designations in affordability reviews would have significant negative consequences for rare disease drug innovation and patient access.

I. The Oregon PDAB Statute States that Orphan-Designated Drugs are Ineligible for Affordability Review

ORS § 646A.694(1) provides that each calendar year the Board will identify nine drugs and at least one insulin product that may create affordability challenges for healthcare systems or

[1] Oregon Prescription Drug Affordability Board, January 21, 2026 PDAB Document Package, at https://dfr.oregon.gov/pdab/Documents/20260121-PDAB-document-package.pdf; Oregon Prescription Drug Affordability Board, April 15, 2026 PDAB Document Package, at https://dfr.oregon.gov/pdab/Documents/20260415-PDAB-document-package.pdf.

patients in Oregon. However, under ORS § 646A.694(2), a "drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review" by the Board.[2] The statute explicitly exempts orphan-designated drugs from the Board's affordability review.

On July 19, 2023, the Oregon PDAB approved a rule that would impermissibly narrow the statute's orphan drug exclusion. Oregon Administrative Rule (OAR) § 925-200-0020(2)(n) provides that "[a] prescription drug approved by the FDA for other indications, in addition to a rare disease or condition, is not exempt from an affordability review for those other indications." This rule became effective August 1, 2023.

The statute, however, does not distinguish between orphan drugs that also have non-orphan indications and those that do not. Under the statute, if a "drug" has an orphan designation, then that "drug" is ineligible for an affordability review. Thus, the statute categorically excludes any drug with an orphan designation from affordability review, regardless of whether that drug also has non-orphan indications. Had the Oregon legislature intended to distinguish between indications of an orphan drug, it would have made that clear in the statutory language of ORS § 646A.694(2). It did not.

Under Oregon case law, when a statute uses plain and unambiguous language, it should be presumed that the legislature intends exactly what the words state.[3] Moreover, ORS § 174.010 provides that "[i]n the construction of a statute, the office of the judge is simply to ascertain and declare what is, in terms or in substance, contained therein, not to insert what has been omitted, or to omit what has been inserted." Therefore, both case law and Oregon law on statutory interpretation direct that the application of a statute should follow the plain language of the statute.

OAR § 925-200-0020(2)(n) violates the plain language of the statute, which unambiguously excludes orphan-designated drugs from being eligible for affordability review. AbbVie urges the Board to follow the plain language of the statute and exempt all orphan-designated drugs from affordability reviews, notwithstanding the conflicting regulation. For these reasons, the Board should repeal OAR § 925-200-0020(2)(n), because it directly conflicts with ORS § 646A.694(2).

II. The Board Understood and Complied with the Plain and Correct Reading of the Oregon PDAB Statute Until 2026

For years, even after the finalization of OAR § 925-200-0020(2)(n), the Board consistently interpreted Oregon law correctly as excluding orphan-designated drugs from affordability reviews:

---

[2] Oregon Administrative Code ("OAC") § 925-200-0020 codifies this statutory exemption in Oregon regulations, providing that a "prescription drug that is designated by the [FDA] under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to an affordability review."

[3] *See, e.g.*, *Clark v. Eddie Bauer LLC*, 371 Or. 177, 185 (Or. 2023) ("Because the words of a statute are the best evidence of the legislature's intent, we give 'primary weight to the [statute's] text and context.' *State ex rel. Rosenblum v. Nisley*, 367 Or. 78, 83, 473 P.3d 46 (2020). In considering that statutory text, we give words of common usage their ordinary meaning. *Gaines*, 346 Or. at 175, 206 P.3d 1042."); *see also State v. Buck*, 200 Or. 87 (Or. 1953) ("It is well recognized that when the language of an act is unambiguous the intent of the legislature must be gained from the language used.").

- In November 2023, the Board confirmed that drugs with any orphan indication are exempt from affordability review selection by removing drugs that have both orphan-designated indications and non-orphan indications from the list of drugs eligible to be selected for affordability review.[4]

- In December 2023, the Board selected the AbbVie drug Skyrizi[5] for an affordability review – seemingly unaware that the product had an orphan designation.[6] Skyrizi serves as an example of a drug that holds at least one orphan designation.[7] Following AbbVie's

---

[4] Oregon Prescription Drug Affordability Board, November 15, 2023 Meeting Recording, at 1:37:50, at https://www.youtube.com/watch?v=6Gk2182MFZw&t=6385s.

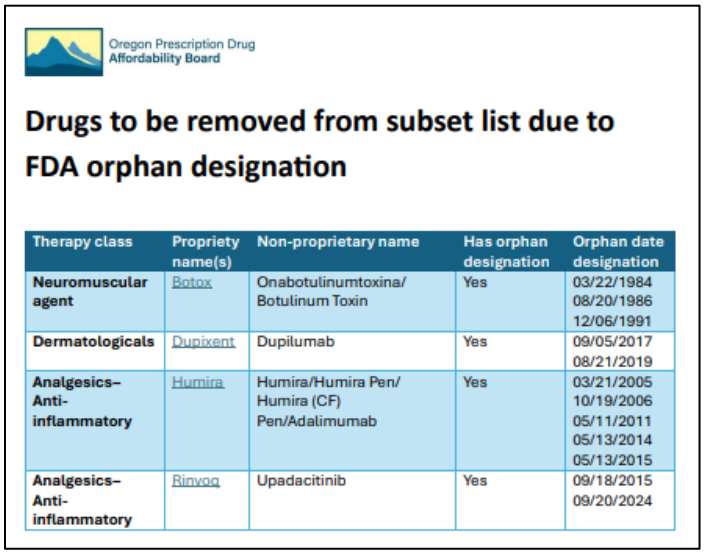
[5] Skyrizi (Risankizumab-rzaa) is a prescription interleukin-23 antagonist that, in certain circumstances, is indicated to treat adults with moderate to severe plaque psoriasis, active psoriatic arthritis, and moderate to severe Crohn's disease. *See Skyrizi*, https://www.skyrizi.com/. Skyrizi was first approved by the U.S. Food and Drug Administration (FDA) for the treatment of moderate-to-severe plaque psoriasis in adults in April 2019. ABBVIE, Press Release: AbbVie Expands Immunology Portfolio in the U.S. with FDA Approval of SKYRIZI™ (risankizumab-rzaa) for Moderate to Severe Plaque Psoriasis (Apr. 23, 2019), https://news.abbvie.com/2019-04-23-AbbVie-Expands-Immunology-Portfolio-in-the-U-S-with-FDA-Approval-of-SKYRIZI-TM-risankizumab-rzaa-for-Moderate-to-Severe-Plaque-Psoriasis. Since the initial approval, AbbVie has continued to sponsor research on the use of Skyrizi to meet unmet patient needs, including for rare diseases. In 2016, the FDA granted an orphan designation to AbbVie for risankizumab (the active ingredient in Skyrizi) for the "[t]reatment of pediatric Crohn's disease." FDA, *Search Orphan Drug Designations and Approvals: Risankizumab*, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=544716. We acknowledge that the active ingredient as identified in the Skyrizi label differs from the way the generic name appears in FDA's orphan database (Risankizumab-rzaa vs. Risankizumab). However, "Risankizumab" (orphan designation) and "Risankizumab-rzaa" (generic name) are the same drug. The difference is due to a biologics naming convention change that post-dates when AbbVie first obtained the orphan designation. In 2017, FDA modified its naming conventions for biological products to add a "distinguishing suffix that is devoid of meaning and composed of four lowercase letters" to the nonproprietary name for biological products licensed under the Public Health Service Act. *See* FDA, *Nonproprietary Naming of Biological Products*, *Guidance for Industry* (Jan. 2017), https://www.fda.gov/files/drugs/published/Nonproprietary-Naming-of-Biological-Products-Guidance-for-Industry.pdf. FDA's naming convention change happened after AbbVie received an orphan designation for risankizumab (November 29, 2016), but before it was first approved for marketing (April 23, 2019) (under the brand name Skyrizi). This explains why the "rzaa" suffix is appended to the "risankizumab" approved generic name for Skyrizi, as appears in the Prescribing Information and other labeling materials.

[6] Oregon Prescription Drug Affordability Board, "Prescription Drugs for Affordability Review Approved by the Board on December 13, 2023," at https://web.archive.org/web/20240219115852/https://dfr.oregon.gov/pdab/Documents/OR-PDAB-RX-insulin-list.pdf.

[7] Pediatric Crohn's disease is a "rare, inflammatory bowel disease characterized by severe, chronic inflammation of the intestinal wall or any portion of the gastrointestinal tract." RARE DISEASES, *Pediatric Crohn's Disease*, https://rarediseases.org/rare-diseases/pediatric-crohns-disease/. At the time that AbbVie obtained this orphan designation, risankizumab had not yet been approved for marketing for any indication and thus had not been assigned a proprietary name. Upon approval of the biologics license application (BLA) in 2019, AbbVie launched risankizumab with the brand name Skyrizi. Although FDA's orphan database does not identify risankizumab with a brand name, the designation does in fact apply to Skyrizi. This is made clear in FDA's decision to exempt Skyrizi from certain Pediatric Research Equity Act (PREA) requirements because of its orphan designation. In the Skyrizi approval letter, FDA explicitly states "[b]ecause this drug product for this indication has an orphan drug designation, you are exempt from this requirement." Letter from FDA to AbbVie, Inc. Re: Supplement Approval (June 16, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/761105Orig1s016ltr.pdf ("Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement."). Moreover, although Skyrizi is not yet approved for pediatric Crohn's disease, consistent with post-marketing commitments for Skyrizi, AbbVie currently is sponsoring a Phase 3, multi-center study to assess the pharmacokinetics, efficacy, and safety of Skyrizi in pediatric participants with moderately to severely active Crohn's disease. The study began in

submission of a letter to the Board in March 2024 explaining why Skyrizi is not eligible for an affordability review, the Board voted in May 2024 to remove Skyrizi from its list of drugs that would undergo an affordability review, citing Skyrizi's orphan designation for pediatric Crohn's disease.[8]

- In June 2025, the Board reaffirmed that drugs with any orphan indication are exempt from affordability review selection, even if they have non-orphan indications. At its meeting, the Board removed Botox, Dupixent, Humira, and Rinvoq from its list of drugs eligible for affordability review due to those products' orphan designations.[9]


Oregon Prescription Drug Affordability Board

Drugs to be removed from subset list due to FDA orphan designation

Therapy class	Propriety name(s)	Non-proprietary name	Has orphan designation	Orphan date designation
Neuromuscular agent	Botox	Onabotulinumtoxina/ Botulinum Toxin	Yes	03/22/1984 08/20/1986 12/06/1991
Dermatologicals	Dupixent	Dupilumab	Yes	09/05/2017 08/21/2019
Analgesics–Anti-inflammatory	Humira	Humira/Humira Pen/ Humira (CF) Pen/Adalimumab	Yes	03/21/2005 10/19/2006 05/11/2011 05/13/2014 05/13/2015
Analgesics–Anti-inflammatory	Rinvoq	Upadacitinib	Yes	09/18/2015 09/20/2024

Botox, for example, has several FDA-approved non-orphan indications, such as chronic migraine and overactive bladder; yet, the Board still removed it from affordability review eligibility due to the product's orphan designations. As noted by staff, "According to the language in our statute, it says the Board cannot [. . .] select a [sic] orphan drug as unaffordable due to its designation."[10] Additionally, Board Member Daniel Hartung also

December 2023, and is estimated to be completed in April 2029. *See* Letter from FDA to AbbVie, Inc. Re: Supplement Approval (June 16, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/761105Orig1s016ltr.pdf; *see also* CLINICAL TRIALS, *A Study to Assess Adverse Events, Change in Disease Activity, and How Intravenous and Subcutaneous Risankizumab Moves Through the Body of Pediatric Participants With Moderately to Severely Active Crohn's Disease*, https://clinicaltrials.gov/study/NCT05995353?term=m16-194&rank=1.

[8] Oregon Prescription Drug Affordability Board, May 15, 2024 Meeting Recording, at 00:26:40, at https://www.youtube.com/watch?v=s3gOiI3-lfo&t=1195s.

[9] Oregon Prescription Drug Affordability Board, June 18, 2025 Meeting Agenda, at https://web.archive.org/web/20251127001901/https://dfr.oregon.gov/pdab/Documents/20250618-PDAB-document-package.pdf.

[10] Oregon Prescription Drug Affordability Board, June 18, 2025 Meeting Recording, at 01:04:32, at https://www.youtube.com/watch?v=s3gOiI3-lfo&t=1195s (Board Staff Cortnee Whitlock responding to Board Member Robert Judge's question); *see id.* at 01:08:17 (confirming the removal of Botox, Dupixent, Humira, and Rinvoq from the Board's list of drugs eligible for affordability review "due to our current language in our statute").

noted that, "This is what it is. We have to take [orphan-designated drugs] out because it's in the rules that if it has a[n orphan] designation, [the Board] can't review it."[11]

This extensive history demonstrates that the Board, until January 2026, repeatedly understood and applied the Oregon PDAB statute consistent with its plain language: that an orphan-designated drug *cannot* be selected for an affordability review. Put another way, ORS § 646A.694 does not permit the Board to select non-rare indications of an orphan-designated drug.

III. The Board's 2023 Rule is Contrary to Law and The Board's 2026 Change in Position is Arbitrary and Capricious

In January 2026, the Board reversed its position and stated that ORS § 646A.694(2) did not prohibit review of a drug's non-orphan indications.[12] The Board has now taken the position that ORS § 646A.694(2) "[e]xempts only the orphan indication" and that OAR § 925-200-0020 "[c]larifies that non-orphan indications remain reviewable."[13] In April 2026, the Board erroneously proceeded to take steps towards an affordability review of Skyrizi and another orphan-designated drug by discussing approaches to distinguishing the drugs' "orphan vs. non-orphan utilization" in claims data.[14]

The Board's 2026 position is a complete reversal of the Board's prior stance, and it is particularly difficult to reconcile with the Board's actions in May 2024 and June 2025, set forth above. Further, the Board has not provided any rationale for its change in statutory interpretation, despite the impact this policy reversal will have on manufacturers who have relied upon the Board's preexisting interpretation for several years. The Board's shifting viewpoint on orphan drug eligibility makes it difficult for manufacturers to effectively prepare for and participate in the affordability review process. The Board's 2026 about-face is contrary to the statute, textbook arbitrary and capricious, and inconsistent with Oregon law, which requires that state agencies make rational, principled, and fair decisions.[15]

IV. By Allowing Affordability Reviews of Orphan-Designated Drugs, the Board Would Disincentivize Orphan Drug Innovation and Negatively Impact Oregon Patients Diagnosed with Rare Diseases

If the Board ignores the statute and follows OAR § 925-200-0020(2)(n) by selecting orphan-designated drugs for affordability reviews, this would disincentivize innovators from conducting further research on drugs that treat rare diseases. This outcome would undermine the

---

[11] Oregon Prescription Drug Affordability Board, June 18, 2025 Meeting Recording, at 01:07:10, at https://www.youtube.com/watch?v=s3gOiI3-lfo&t=1195s (Board Member Daniel Hartung proposing that the Board make recommendation to the state legislature to revise the Oregon PDAB statute so that the Board may conduct affordability reviews on orphan drugs for their non-rare indications).

[12] Oregon Prescription Drug Affordability Board, January 21, 2026 PDAB Document Package, at 19, at https://dfr.oregon.gov/pdab/Documents/20260121-PDAB-document-package.pdf.

[13] *Id.* at 20.

[14] Oregon Prescription Drug Affordability Board, April 15, 2026 PDAB Document Package, at 12-17, at https://dfr.oregon.gov/pdab/Documents/20260415-PDAB-document-package.pdf.

[15] *See, e.g.*, *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007) (explaining the Oregon Administrative Procedure Act policy that decisions by administrative agencies be rational, principled, and fair, rather than ad hoc and arbitrary.").

clear intent of the statute to encourage innovation by allowing manufacturers to explore different indications for drugs that treat rare diseases, including new indications for drugs that treat non-rare diseases as well. Subjecting orphan-designated drugs to a burdensome affordability review would deter innovation of such drugs for smaller patient populations[16] – the very patients these treatments are designed to help.

Oregon has recognized the unique nature of orphan drugs and the legislature set its own incentives to encourage the development of new indications to treat rare diseases by excluding drugs with any orphan designation from affordability reviews. The Board should act in accordance with the plain meaning of that law, as it has done for the past several years.

In no small part due to legal protections of orphan drug development, AbbVie has been able to dedicate significant resources to the further research and development of drugs like Skyrizi, with the intent of identifying additional – often rare – diseases that can be successfully treated by AbbVie products that are already approved for other indications. AbbVie urges the Board to strongly consider the unique nature of drugs that hold any orphan indication and exempt these drugs from affordability reviews.

V. Conclusion

Thank you for considering AbbVie's significant concerns with the Board's stated view that orphan-designated drugs with approved non-orphan indications are eligible for affordability reviews. The Board should revert to its prior position that drugs with any orphan indication are exempt from affordability reviews. This interpretation is consistent with the PDAB statute and consistent with the Oregon legislature's intent to promote continued innovation of these life-saving treatments for vulnerable Oregon patients. Please contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Kim Fitpatrick
Vice President, State Government Affairs
Government Affairs
On behalf of AbbVie Inc.

[16] *See* CHARLES RIVER ASSOCIATES, *The Impact of Price Controls on Rare Disease Medicines Access and Lessons for the U.S.* (Sept. 2025), at ii, 14, at https://media.crai.com/wp-content/uploads/2025/09/25124214/CRA-RDCC-Price-Referencing-Report-September2025.pdf; *see also* ADVI, *The Unintended Consequences of Drug Pricing Policies on Orphan Drug Development* (June 2025), at 4-7, at https://advi.com/wp-content/uploads/2025/06/Report-IRA_Impact_Orphan_Drug_Innovation.pdf.