July 13, 2026

VIA ELECTRONIC MAIL

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

Re: Comments Regarding SKYRIZI®'s Orphan Designation and the Statutory Limits on Oregon PDAB's Affordability Review Authority

Dear Members of the Oregon Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie") submits these comments to the Oregon Prescription Drug Affordability Board (the "Board") in advance of the Board's July 15 meeting to:

- Reiterate that SKYRIZI® (risankizumab-rzaa) ("SKYRIZI") should not be subject to, and must be removed from, the Board's affordability review process because the plain language of ORS § 646A.694(2) expressly excludes orphan-designated drugs from review;[1] and

- Highlight the significance of the July 1, 2026 decision issued by the United States District Court for the District of Colorado in *Amgen Inc. v. Mizner*, which reinforces the need for the Board to exercise restraint where the Oregon Legislature has expressly limited the scope of the Board's authority.

AbbVie is a research-based biopharmaceutical company whose medicines, including SKYRIZI, are relied upon by Oregon patients every day.

I. The Plain Language of the Oregon PDAB Statute is Clear that Orphan-Designated Drugs Like SKYRIZI are Not Subject to Affordability Review by the Board

ORS § 646A.694(2) unambiguously states that 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. SKYRIZI has an FDA orphan designation for the treatment of pediatric Crohn's disease.[2] Under the Oregon PDAB statute, this means SKYRIZI

[1] AbbVie urged the Board to remove SKYRIZI from the affordability review process in a May 4, 2026 comment letter. *See* AbbVie Inc. Comment Letter to Oregon Prescription Drug Affordability Board, "Oregon Prescription Drugs for Affordability Review – Orphan-Designated Drugs (May 4, 2026)," at https://dfr.oregon.gov/pdab/Documents/Letters/AbbVie-Skyrizi-20260504.pdf.
[2] U.S. Food and Drug Administration, Orphan Drug Designations and Approvals, at https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=544716.

is categorically ineligible for affordability review. This reading is further reinforced by Oregon rules of statutory construction.[3]

The distinction the Board has tried to draw between the "orphan indication" and the "non-orphan indications" of a single drug simply does not exist in the statutory text.[4] Had the Oregon Legislature intended to authorize any such distinction, it would have said so. Because it did not, the Oregon Legislature's use of categorical language—providing that an orphan-designated drug "is not subject to review"—provides no exception for non-orphan indications.

Indeed, this reading of the Oregon PDAB statute is consistent with the Board's longstanding interpretation prior to 2026. For years, the Board correctly applied ORS § 646A.694(2) to categorically exclude any drug with an orphan designation from affordability review. In May 2024, the Board voted to remove SKYRIZI from its list of drugs subject to affordability review due to its orphan designation.[5] In June 2025, the Board again correctly removed BOTOX® (onabotulinumtoxinA), DUPIXENT® (dupilumab), HUMIRA® (adalimumab), and RINVOQ® (upadacitinib) from its eligibility list, expressly citing each product's orphan designation and confirming, in the words of Board staff, that "[a]ccording to the language in our statute, it says the Board cannot [...] select a[n] orphan drug as unaffordable due to its designation."[6]

The Board's abrupt January 2026 reversal of this long-held, correct interpretation with no explanation, no rulemaking, and no accounting for manufacturers who relied on the prior position is arbitrary, capricious, and inconsistent with Oregon law, which requires that state agencies make rational, principled, and fair decisions.[7] The Board's unexplained departure from its consistent, prior interpretation also raises fundamental administrative law concerns under Oregon law,[8] especially when manufacturers, including AbbVie, have reasonably relied on that interpretation.

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[3] Under ORS § 174.010, statutes must be applied as written, and agencies may not "insert what has been omitted" or "omit what has been inserted." ORS § 646A.694(2) provides that an orphan-designated drug "is not subject to review," without qualification or limitation. The absence of limiting language confirms that the Oregon Legislature did not intend to authorize review of non-orphan indications for a drug that holds an orphan designation.

[4] The Oregon PDAB statute does not say that an orphan-designated drug is exempt only with respect to its orphan indication. It also does not say the Board can review the non-orphan indications of a drug that also has an orphan designation. Rather, the Oregon PDAB statute says that the drug is not subject to review. This reading is further reinforced by Oregon's well-established rules of statutory interpretation, which direct that statutory text be given its plain meaning and applied as written. *See, e.g.*, *Clark v. Eddie Bauer LLC*, 371 Or. 177, 185 (2023); *State ex rel. Rosenblum v. Nisley*, 367 Or. 78, 83 (2020); ORS § 174.010 (courts may not "insert what has been omitted" or "omit what has been inserted").

[5] Oregon Prescription Drug Affordability Board, Meeting Minutes (May 15, 2024), at 1, at https://dfr.oregon.gov/pdab/Documents/archive/20240515-PDAB-approved-minutes.pdf; Oregon Prescription Drug Affordability Board, May 15, 2024 Meeting, at https://youtu.be/s3gOiI3-lfo?si=uwAVteJO093EG0LN&t=1195 (beginning at minute 00:19:54).

[6] The Board Member who proposed those removals similarly confirmed: "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." Oregon Prescription Drug Affordability Board, June 18, 2025 Meeting, at https://www.youtube.com/watch?v=RP3A5s6hiwc.

[7] Oregon Prescription Drug Affordability Board, Agenda for January 1, 2026 Meeting at 14, at https://dfr.oregon.gov/pdab/Documents/20260121-PDAB-document-package.pdf.

[8] Oregon courts have made clear that agency decision-making must be rational, principled, and fair, and not the product of unexplained reversals in position. *See* ORS 183.482(8)(c) (authorizing reversal where agency action is "arbitrary or capricious"); *see, e.g.*, *Gordon v. Bd. of Parole & Post-Prison Supervision*, 343 Or. 618, 633 (2007) (explaining that agency decisions must be "rational, principled, and fair, rather than ad hoc and arbitrary").

These defects are not merely procedural—they go to the limits of the Board's statutory authority. The Board's authority is defined and limited by statute. ORS § 646A.694 establishes both the scope of review and explicit exclusions, including the categorical exemption for orphan-designated drugs. Any effort to subject exempted drugs to review exceeds the authority granted by the Oregon Legislature and conflicts with the governing statute.[9] For these reasons, the only interpretation consistent with ORS § 646A.694(2) and governing Oregon law is that SKYRIZI, as an orphan-designated drug, is categorically ineligible for affordability review. This conclusion is compelled by the statutory text and Oregon law, independent of any broader policy considerations.

Even if the Board were to look beyond the statute's clear command, related policy considerations further confirm that orphan-designated drugs should not be subject to affordability review. The orphan drug exclusion reflects Oregon Legislature's deliberate policy choice to preserve incentives for manufacturers to research and develop treatments for rare diseases. AbbVie has invested substantial resources in studying SKYRIZI for additional, and often rare, disease indications, including its ongoing Phase 3 clinical trial in pediatric Crohn's disease.[10] Subjecting an orphan-designated drug to an affordability review would chill exactly this kind of innovation, deterring manufacturers from pursuing rare disease research on drugs already approved for other indications. This would harm the very patients the orphan drug framework is designed to protect.

Consistent with the concerns set forth in our May 4, 2026 comment letter, AbbVie urges the Board to remove SKYRIZI from the affordability review process immediately.[11]

II. The District of Colorado's Decision in *Amgen Inc. v. Mizner* Cautions Against State Efforts to Expand Pharmaceutical Regulation Beyond Legislative Authorization

A failure to abide by the law may invalidate a prescription drug affordability review board's actions, as demonstrated by a recent court decision entered against another state board. On July 1, 2026, Judge Domenico of the United States District Court for the District of Colorado issued an order enjoining the Colorado Prescription Drug Affordability Review Board and the Colorado Attorney General from enforcing an upper payment limit on Enbrel®.[12] The court held that Amgen is "substantially likely to succeed on the merits" of its claim that Colorado's price-control regime, as applied to a patented pharmaceutical product, is preempted by federal patent law.

The significance of the decision extends beyond the specific issue of upper payment limits. The court emphasized that policy arguments regarding drug affordability, however important, cannot justify actions that violate the law. As the court observed, "those policy issues are not relevant to the legal decision."[13]

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[9] *See* ORS § 646A.694(1)-(2).
[10] *See, e.g.*, ClinicalTrials.gov, "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 (RISE)," at https://clinicaltrials.gov/study/NCT05995353?term=skyrizi&viewType=Card&rank=8.
[11] *See* AbbVie Inc. Comment Letter to Oregon Prescription Drug Affordability Board, "Oregon Prescription Drugs for Affordability Review – Orphan-Designated Drugs (May 4, 2026)," at https://dfr.oregon.gov/pdab/Documents/Letters/AbbVie-Skyrizi-20260504.pdf.
[12] *Amgen Inc. v. Mizner*, No. 1:25-cv-03452-DDD-STV, Order Granting Motion for Preliminary Injunction (D. Colo. July 1, 2026).
[13] *Amgen*, slip op. at 4.

That principle is directly relevant here. AbbVie recognizes that the Board is charged with addressing affordability concerns. But the Board's policy objectives cannot supplant statutory constraints imposed by the Oregon Legislature. As discussed above, ORS § 646A.694(2) expressly provides that a drug designated under the federal Orphan Drug Act "is not subject to review." The Board therefore lacks authority to subject SKYRIZI to an affordability review regardless of any policy arguments supporting review of the drug. Just as the federal court in Colorado rejected efforts to alter a balance struck by Congress, the Board should not alter the balance struck by the Oregon Legislature by narrowing a statutory exemption the Legislature made categorical.

III. Conclusion

AbbVie appreciates the Board's stated commitment to improving drug affordability for Oregonians, and we share that goal. At the same time, the Board's efforts must remain faithful to the limits imposed by the Oregon Legislature. ORS § 646A.694(2) expressly excludes orphan-designated drugs from affordability review, and recent judicial scrutiny of state prescription drug affordability programs further underscores the importance of adherence to statutory authority and legislative direction.

The Oregon Legislature has already resolved the question presented here. Through ORS § 646A.694(2), it determined that orphan-designated drugs are not subject to affordability review. The Board should apply that directive as written and avoid adopting an interpretation that narrows a categorical statutory exemption or expands the scope of the authority granted by the Legislature. Recent judicial scrutiny of state prescription drug affordability programs further underscores the importance of adherence to statutory authority and legislative direction.

In light of these considerations, AbbVie respectfully urges the Board to:

- Remove SKYRIZI from the affordability review process immediately because ORS § 646A.694(2) expressly excludes orphan-designated drugs from review.

- Repeal Oregon Administrative Rule (OAR) § 925-200-0030(2)(n), because it directly conflicts with ORS § 646A.694(2) and OAR § 925-200-0030(1)(m).

- Respect the Oregon Legislature's decision to exclude orphan-designated drugs from affordability review and refrain from adopting interpretations that effectively narrow that statutory exemption the Legislature elected to make categorical.

AbbVie remains committed to engaging constructively with the Board and looks forward to continuing dialogue. Please do not hesitate to contact me at hfitzpatrick@abbvie.com with any questions or to discuss these matters further.

Sincerely,

Helen Fitzpatrick

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