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February 9, 2026

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

Re: Oregon Prescription Drug Affordability Board: January 21, 2026, Meeting Materials

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's (the "PDAB's" or "Board's") January 21, 2026, meeting ("January Board Meeting"), including the affordability review materials and the presentation titled "Oregon PDAB authority to review drugs with orphan-drug designations" (collectively, the "Meeting Materials").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

We provide below select comments and concerns with respect to the Meeting Materials and the decisions rendered during the January Board Meeting.

I. Decision on "Unaffordable" Insulin Product

PhRMA has serious concerns about the process underlying the Board's decision to find an insulin product unaffordable. In its initial vote, Board members did not conclude that *any* of the insulin products under review could create affordability challenges.[2] But, because the PDAB Statute requires the Board to identify "at least one insulin product . . . that the board determines may create affordability challenges" each year, the Board revisited its determination for a single insulin product and reversed its finding. The Board selected this insulin product without engaging in a systematic process to identify which insulin products warranted further consideration and re-voting. This is a prime example of the "ad hoc" agency decision-making that the Oregon Administrative Procedures Act ("APA") forbids.[3]

[1] January Meeting Materials (Jan. 21, 2026), *available at* https://dfr.oregon.gov/pdab/Documents/20260121-PDAB-document-package.pdf. In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) and Oregon Senate Bill 289 (2025) (codified at Or. Rev. Stat. § 646A.693 *et seq*.) (collectively, the "PDAB Statute"), and the Board's implementation of the PDAB Statute. PhRMA also incorporates by reference all prior comment letters to the extent applicable. *See, e.g.*, Letter from PhRMA to Board (Jan. 9, 2026); Letter from PhRMA to Board (Nov. 16, 2025); Letter from PhRMA to Board (Nov. 5, 2025); Letter from PhRMA to Board (Oct. 3, 2025); Letter from PhRMA to Board (January 7, 2025).

[2] *See* Board, Meeting Recording at 39:30–46:00 (Jan. 21, 2026), *available at* https://www.youtube.com/watch?v=cbykiLL17YE.

[3] *See, e.g.*, *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007) (describing the "legislative policy, embodied in the [Oregon Administrative Procedure Act (APA)], that decisions by administrative agencies be rational, principled, and fair, rather than *ad hoc* and arbitrary"); *Sun-Ray Drive-In Dairy, Inc. v. Or. Liquor Control. Comm'n*, 16 Or. App. 63, 72 (1973) (explaining that agencies have "discretion to make policies for even application, not discretion to treat each case on an ad hoc basis"); *see also, e.g.*, *Humane Soc. of U.S. v. Bryson,* 924 F. Supp. 2d 1228, 1236 (D. Or. 2013) (noting that an "agency's decision would be arbitrary or

In addition to the Board's flawed decision-making process, PhRMA is concerned that the PDAB Statute predetermines that the Board must identify "at least one insulin product" that may create affordability challenges each year.[4] This language sets an arbitrary threshold, forcing the Board to identify at least one insulin product regardless of the evidence before it.[5] The January Board Meeting illustrates the arbitrariness of this threshold. Despite finding on first ballot that none of the insulin products under review may create affordability challenges, the Board was nonetheless obligated to identify an insulin product to meet its statutory quota.[6]

Previously, the Oregon legislature amended the PDAB Statute to direct the identification of "*up to* nine drugs" each year—rather than arbitrarily requiring that nine drugs be identified.[7] As the Board recognized in recommending the amendment, this change allows the Board to focus on the cost criteria and available data "rather than trying to identify drugs that may or may not cause challenges to the health system or out-of-pocket costs to meet legislative thresholds."[8] For similar reasons, the Board should advocate that the Legislature amend the PDAB Statute to address the arbitrary requirement that the Board identify "at least one insulin product."

The Board's decision on insulin product affordability exemplifies the procedural deficiencies PhRMA has repeatedly raised in prior comments. We highlight examples of these concerns below:

- **Lack of clear, consistent, and meaningful standards.** PhRMA reiterates that additional work is needed to facilitate consistent and transparent assessments in the Board's affordability review process.[9] For example, the Board's scoring framework relies on vague and arbitrary cutoffs and does not clearly articulate how each metric in the framework is to be used in the affordability review process. Similarly, after several years of work, the Board has yet to establish a definition of affordability.[10] Without clear standards to guide its determinations, the Board risks arbitrary decision-making and inhibits the public's ability to validate and meaningfully engage with Board decisions.[11]

- **Errors and inconsistencies in information considered by the Board.** PhRMA continues to emphasize the lack of clarity surrounding the data the Board relies upon to produce affordability review reports,

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capricious, for example, if the agency 'relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise'") (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983)).

[4] Or. Rev. Stat. § 646A.694(1).

[5] *See, e.g.*, *Feitelson v. City of Salem*, 46 Or. App. 815, 822 (1980) ("If there is to be any meaningful judicial review, an agency must demonstrate that it has considered the factors prescribed by statute and its own regulations and has not acted in an arbitrary manner or on an ad hoc basis").

[6] *See* Board, Meeting Recording at 46:00–51:55 (Jan. 21, 2026), *available at* https://www.youtube.com/watch?v=cbykiLL17YE.

[7] Oregon Senate Bill 289 § 2 (emphasis added) (amending Or. Rev. Stat. § 646A.694(1)); *see also* Letter from PhRMA to Board at 8 (Sept. 15, 2024); Letter from PhRMA to Board at 4–5 (Jan. 7, 2025); Letter from PhRMA to Board at 1–2 (Sept. 16, 2023).

[8] Board, 2024 Annual Report for the Oregon Legislature at 11 (Dec. 2024), *available at* https://dfr.oregon.gov/pdab/Documents/reports/2024-PDAB-Annual-Report.pdf (further noting that "[t]he initial review process revealed challenges in identifying specific drugs, as some may not actually cause affordability issues").

[9] *See, e.g.*, Letter from PhRMA to Board at 2–3 (Nov. 5, 2025); Letter from PhRMA to Board at 2–5 (Oct. 3, 2025); Letter from PhRMA to Board at 1–4 (Aug. 18, 2025); Letter from PhRMA to Board at 1–2 (May 2, 2025).

[10] *See, e.g.*, Letter from PhRMA to Board at 3 (Nov. 16, 2025); Letter from PhRMA to Board (Jan. 7, 2025) at 3.

[11] *See, e.g.*, *Sun-Ray Drive-In Dairy, Inc.*, 16 Or. App. at 72 ("The danger of inconsistent, subjective and ad hominem decision making is minimized by the deliberate adoption of written, published policy standards applicable alike to all[.]).

raising serious questions about those reports' reliability.[12] While the Board has improved how it describes data compilation, PhRMA remains concerned that the Board does not provide enough information regarding how specific calculations are performed and analyzed in order to allow for stakeholder evaluation and validation.

II. Review of Drugs with Orphan Indications

PhRMA is deeply concerned that the Board intends to conduct affordability reviews of drugs with orphan designations that are approved for non-orphan indications, as this would violate the PDAB Statute's provision expressly exempting orphan designated drugs from affordability review.[13] The statute is clear: "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* under [the PDAB Statute]."[14] It categorically exempts orphan designated *drugs* from affordability review, not just the drugs' orphan designated *indications*.[15] Accordingly, the Board's contemplated review of drugs with orphan designations is fundamentally inconsistent with the plain text of the PDAB Statute and would exceed its statutory authority and contravene the APA.[16]

The Board also explicitly adopted into regulation the categorical statutory exemption for drugs with orphan designations, rendering the Board's proposed action inconsistent with its own regulations on "Conducting an Affordability Review."[17] The Board cannot save its proposal by relying on an affordability review consideration of its own design.[18] Although the Board adopted a regulation providing that, "[i]n addition to the criteria [in the regulatory exemption for drugs with orphan designations]: 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 regulation lacks statutory support and cannot be squared with the Board's adoption of the categorical statutory exemption into regulation.[19]

The contemplated review of orphan designated drugs approved for non-orphan indications also raises practical concerns. The Board has previously stated that it lacked technical capability to isolate affordability review data by indication.[20] Board staff now indicate that they can parse data by indication in some cases—

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[12] *See, e.g.*, Letter from PhRMA to Board at 2 (Nov. 16, 2025); Letter from PhRMA to Board at 3 (Nov. 5, 2025); Letter from PhRMA to Board at 4–5 (Oct. 3, 2025); Letter from PhRMA to Board at 4–7 (Aug. 18, 2025).

[13] Meeting Materials at 14-24; Or. Rev. Stat. § 646A.694(2).

[14] Or. Rev. Stat. § 646A.694(2) (emphasis added); *see, e.g.*, Letter from PhRMA to Board at 4 (Jan. 7, 2025); Letter from PhRMA to Board at 4 (Apr. 16, 2023).

[15] Or. Rev. Stat. § 646A.694(2).

[16] See, e.g., Letter from PhRMA to Board (Feb. 17, 2024) at 1-2; Letter from PhRMA to Board (Apr. 16, 2023) at 1-2; Letter from PhRMA to Board (Feb. 11, 2023) at 1-2. *See also* Ore. Rev. Stat., ch. 183; *Lane Cnty. v. Land Conservation & Dev. Comm'n*, 138 Or. App. 635, 641 (1996) (It is a "fundamental" principle of administrative law that agencies may not act in a manner contrary to their statutory authority); *Gouge v. David*, 185 Or. 437, 455 (1949) ("An administrative agency cannot construe statutes which need no construction, and cannot alter the meaning of unambiguous passages."); *Johnson v. Dep't of Pub. Safety Standards & Training*, 253 Or. App. 307, 317 (2012) (Agency actions cannot be upheld where they "violate a statute or constitutional provision.").

[17] Or. Admin. Code § 925-200-0020(1)(m).

[18] *See* Meeting Materials at 22.

[19] Or. Admin. Code § 925-200-0020.

[20] *See, e.g.*, Board, PDAB Meeting Minutes at 3 (Aug. 23, 2023), *available at* https://dfr.oregon.gov/pdab/Documents/20230823-PDAB-approved-minutes.pdf (confirming that the Board "would remove drugs with orphan designation" from the lists of drugs for review); Board, PDAB Meeting Minutes at 3 (July 19, 2023), *available at* https://dfr.oregon.gov/pdab/Documents/20230719-PDAB-approved-minutes.pdf ("[Board Member] Shelly Bailey asked, since pharmacies do not have to submit a diagnosis code for transactions, how will the board determine when a drug is being used to treat a rare disease and when it is not. [Executive Director] Ralph Magrish said staff doesn't know specifically how to make that determination but they want to keep it as an option[.]").

such as for a drug with a single pediatric orphan indication—but not in others.[21] Significantly, though, retail pharmacy claims submitted to the Oregon All Payer All Claims database, one of the Board's main sources of pricing information, "do not contain data on patient diagnoses, so it is not possible to know why a medication was prescribed based on pharmacy claim lines."[22] However, treating similarly situated drugs differently based on an arbitrary factor (ease of parsing utilization data) is inconsistent with the Board's obligation under the APA to act in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary."[23]

Further, PhRMA urges the Board to consider whether it is possible to evaluate each affordability review consideration—including carrier-reported data on price concessions and utilization management, as well as data analyzing a drug's impact on health inequities—by indication. If it is not possible to isolate data by indication for each affordability review consideration, data related to orphan indications could influence the Board's decision-making.

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the Board's decision-making processes and the Meeting Materials, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

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Alexandra Hussey
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[21] *See* Board, Meeting Recording at 2:38:50–2:39:30 (Jan. 21, 2026), *available at* https://www.youtube.com/watch?v=cbykiLL17YE. Some Board members have also indicated a desire to consider off-label usage of drugs. *See* Meeting Materials at 22. The Board should similarly assess whether it could accurately distinguish such usage, how it would use this information, and how such information would be relevant to the Board's statutory mandate.

[22] Oregon Health Authority, Oregon All Payer All Claims Database (APAC) Data User Guide. Updated Nov 19, 2025. https://www.oregon.gov/oha/HPA/ANALYTICS/APAC%20Page%20Docs/APAC-Data-User-Guide.pdf.

[23] *Gordon*, 343 Or. at 633. Courts have consistently held that agency actions are arbitrary and capricious where they treat similarly situated entities or products differently without providing a reasonable justification for such differential treatment, or where they exhibit unexplained inconsistencies with the agency's prior decisions. *See, e.g., Melody Music, Inc. v. FCC,* 345 F.2d 730, 733 (D.C. Cir. 1965).