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May 4, 2026

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

Re: Oregon Prescription Drug Affordability Board: April 15, 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") April 15, 2026, meeting, including the "Presentation on data methodology for 2026 drug review" ("Presentation on Data Methodology") (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.

PhRMA remains 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.[2] 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]."[3] This language categorically exempts orphan designated *drugs* from affordability review, not just the drugs' orphan designated *indications*.[4] Accordingly, the Board's decision to review drugs with orphan designations is fundamentally inconsistent with the plain text of the PDAB Statute and would exceed its statutory authority and contravene the Oregon Administrative Procedures Act ("APA").[5]

Additionally, the Board explicitly adopted into regulation the categorical statutory exemption for drugs with

[1] April Meeting Materials (April 15, 2026), *available at* https://dfr.oregon.gov/pdab/Documents/20260415-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 comments, concerns, and objections that it has previously raised regarding the Board's implementation of the PDAB Statute, including all prior comment letters to the extent applicable. *See, e.g.*, Letter from PhRMA to Board (Feb. 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] Meeting Materials at 7-17; Or. Rev. Stat. § 646A.694(2); *see* Letter from PhRMA to Board (Feb. 9, 2026) at 3-4.

[3] Or. Rev. Stat. § 646A.694(2) (emphasis added).

[4] *Id.*; *see, e.g.*, Letter from PhRMA to Board (Feb. 9, 2026) at 3-4; Letter from PhRMA to Board (Jan. 7, 2025) at 4; Letter from PhRMA to Board (Apr. 16, 2023) at 4

[5] *See, e.g.*, Letter from PhRMA to Board (Feb. 9, 2026) at 3-4; 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.").

orphan designations, rendering the Board's proposed action inconsistent with its own regulations on "Conducting an Affordability Review."[6] The Board cannot save its proposal by relying on an affordability review consideration of its own design.[7] 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.[8]

In addition to the Board's lack of authority to conduct the proposed review, PhRMA notes that the Presentation on Data Methodology raises significant concerns that the Board has not adequately addressed.[9] Critically, the data used by the Board to determine drug eligibility do not allow for isolation of cost data by indication for all drugs.[10] Although the Presentation on Data Methodology asserts an ability to parse data by indication for the 2026 drug review, it fails to address whether—let alone how—it could do so in other drug reviews.[11] This heightens the risk of treating similarly situated drugs differently based on an arbitrary factor (ease of parsing data from the Oregon All Payer All Claims Database), which 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."[12]

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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,

Dharia McGrew, PhD
Senior Director, State Policy
Sacramento, CA

Alexandra Hussey
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Washington, DC

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[6] Or. Admin. Code § 925-200-0020(1)(m); *see* Letter from PhRMA to Board (Feb. 9, 2026) at 3-4.

[7] *See* Jan. 21, 2026 Meeting Materials at 22, *available at* https://dfr.oregon.gov/pdab/Documents/20260121-PDAB-document-package.pdf (asserting authority to review a drug with "for non-orphan uses" if it has "[o]rphan + non-orphan indications"); *see* Letter from PhRMA to Board (Feb. 9, 2026) at 3-4.

[8] Or. Admin. Code § 925-200-0020; *see* Letter from PhRMA to Board (Feb. 9, 2026) at 3-4.

[9] *See* Meeting Materials at 7-17.

[10] Notably, retail pharmacy claims submitted to the Oregon All Payer All Claims ("APAC") 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." 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. *See also* Meeting Materials at 11 noting APAC data limitations, namely that "[m]edical claims may not always include NDC's for physician-administered drugs" and "[p]harmacy claims do not include ICD-10 codes."

[11] *See* Meeting Materials at 7-17; *see also* Meeting Recording at 2:38:50–2:39:30 (Jan. 21, 2026), *available at* https://www.youtube.com/watch?v=cbykiLL17YE. If the Board proceeds with its contemplated review, contrary to the categorical statutory exemption (*see supra* p. 1), PhRMA urges the Board to further consider whether it is possible to parse the data for each affordability review consideration by indication to exclude data related to orphan indications.

[12] *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).