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By Electronic Submission to HCA_WA_PDAB@hca.wa.gov

May 19, 2025

Washington Prescription Drug Affordability Board
Washington Health Care Authority
PO Box 42716
Olympia, Washington 98504-2716

Re: Washington Prescription Drug Affordability Board: Comments on Draft Methodology for Selecting Prescription Drugs for Affordability Review for May 21, 2025 Meeting

Dear Members of the Washington Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the meeting materials circulated by the Prescription Drug Affordability Board ("Board") for the Board's May 21, 2025 meeting, including the Board's draft Methodology for Selecting Prescription Drugs for Affordability Review and accompanying presentation (the "Draft Selection Methodology"). PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser 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 is concerned that the Draft Selection Methodology for grouping drugs is overly broad and could risk inappropriate comparisons.[1] NDCs should be grouped by Food and Drug Administration New Drug Application ("NDA") or Biologics License Application ("BLA") rather than shared generic ingredient.

PhRMA opposes the Board's proposal to aggregate NDCs by "labeler code and generic names," effectively grouping products together by active ingredient. PhRMA is concerned that aggregating products with the same active ingredient ignores the significant benefits that flow from new innovations involving distinct products that share an active ingredient. These new innovations can revolutionize treatment options for patients by achieving breakthroughs that improve upon prior treatments by eliminating substantial practical challenges associated with administering treatment, reducing side effects, or even treating entirely different diseases.[2] It would devalue the immense benefits and vast investment associated with developing such products if the Board grouped the products with one of the individual counterpart drugs simply because they share an active ingredient.

[1] PhRMA has previously commented on various aspects related to the Washington Health Care Authority's and the Board's implementation of SB 5532, 2022 Sess. Laws ch. 153 (the "PDAB Statute"), codified at Wash. Rev. Code §§ 70.405.010 *et seq*., and its implementing regulations codified at Wash. Admin. Code § 182-52-0005 *et seq*. *See, e.g.*, Letter from PhRMA to Board Regarding Comments on Draft Submission Guidance for February 27, 2025 Meeting (Mar. 14, 2025); Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials (Dec. 9, 2024); Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials (Oct. 15, 2024); Letter from PhRMA to Board Regarding the Draft Eligible Prescription Drugs Policy (July 12, 2024); Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials (June 18, 2024); Letter from PhRMA to Board Regarding Draft Methodology (Apr. 11, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures (Mar. 1, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024); Letter from PhRMA to HCA Regarding HCA Proposed Regulations (WSR 23-21-082, filed October 16, 2023) (Nov. 20, 2023); Letter from PhRMA to HCA Regarding August 2023 Draft Regulations (Aug. 15, 2023); Letter from PhRMA to HCA Regarding HCA Advance Notice (Aug. 25, 2020). In filing this comment letter, PhRMA reserves all rights associated with its prior comment letters and, to the extent applicable, incorporates by reference all comments, concerns, and objections that it has raised in its previous comments. PhRMA also reserves all rights to legal arguments with respect to the constitutionality of the PDAB Statute and its regulations.

[2] *See* Letter from PhRMA to Board Regarding Draft Policies and Procedures 3 (Mar. 1, 2024).

Furthermore, aggregating products in this way may complicate an affordability review. In some instances, distinct products that contain the same active ingredient are entirely different products treating entirely different diseases and administered in different doses that may be associated with very different prices. Additionally, they can have distinct delivery methods, for example an injectable versus oral formulation, which may be valued differently by different patient populations and their caregivers as well as payers. In these situations, out-of-pocket costs can vary and impose challenges in an affordability review.

As explained in our prior comments, PhRMA recommends that the Board determine whether a product is a separate drug based on whether the product is approved by the Food and Drug Administration under a distinct NDA or BLA, not whether the drug ingredient is approved in another NDA or BLA.[3] For example, different products may share active ingredients but have significantly different characteristics, cost of administration, and value. Accordingly, the most principled and appropriate approach is to define a distinct drug based on whether it is approved under a distinct NDA or BLA.

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PhRMA thanks the Board for this opportunity to provide comments and feedback on the Draft Selection Methodology and for your consideration of our concerns and requests for revisions. Although PhRMA continues to have concerns, we stand ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide, please contact dmcgrew@phrma.org.

Sincerely,

Dharia McGrew, PhD
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Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[3] *See* Letter from PhRMA to Board Regarding Draft Methodology 2 (Apr. 11, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures 3 (Mar. 1, 2024).