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By Electronic Submission to HCA_WA_PDAB@hca.wa.gov

April 11, 2024

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

Re: March 20, 2024 Meeting Materials: Draft Methodology For Identifying Drugs for Affordability Review – Second presentation

Dear Members of the Washington Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America provides the following comments on the "Methodology for Identifying Drugs for Affordability Review Part 2" presentation (the "Meeting Materials") circulated by the Prescription Drug Affordability Board in advance of its March 20, 2024 meeting. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Our comments below reiterate certain concerns that we previously raised with respect to the January 31, 2024 meeting materials and elsewhere and that continue to be pertinent to the Meeting Materials.[1]

1. Transparency and Clear Standards

PhRMA reiterates the need for transparent, specific, and comprehensive policies and processes governing the Board's activities and decision-making. As the Board continues working to implement the PDAB Statute, it is imperative that it provide stakeholders with clear guidelines to understand and provide meaningful feedback on the Board's proposed activities.[2]

In this regard, we urge the Board to adopt specific and detailed policies with respect to publication of meeting materials and submission of stakeholder comments, which should provide a comment period that gives stakeholders adequate opportunity to review and provide feedback on the Board's materials and discussion. As discussed in PhRMA's prior comments, we also urge the Board to provide draft

[1] PhRMA previously provided comments on various aspects related to HCA's implementation of SB 5532, 2022 Sess. Laws ch. 153 (the "PDAB Statute"), including the proposed regulations, Wash. Admin. Code § 182-52-0005 et seq. (the "Proposed Regulations") filed with the Washington Office of the Code Reviser by HCA on October 16, 2023. Codified at Wash. Rev. Code §§ 70.405.010 et seq.; see also Letter from PhRMA to Board (Jan. 23, 2024); Letter from PhRMA to HCA (Nov. 20, 2023); Letter from PhRMA to HCA (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 reserves all rights to legal arguments with respect to the constitutionality of the Washington PDAB statute and the regulations thereunder.

[2] We reiterate our concerns that the lack of clear and meaningful standards for the Board's processes creates a risk of inconsistent and arbitrary decision-making. *See* Letter from PhRMA to HCA (Aug. 15, 2023).

methodologies and other proposals in a fully documented form in order to allow stakeholders to give informed and comprehensive feedback on the Board's activities.[3]

2. Draft Methodology for Identifying Drugs for Affordability Review

PhRMA provides below a non-exhaustive list of specific concerns regarding the draft methodology outlined in the January and March Meeting Materials:

- Drug Definition for Selection and Affordability Reviews: PhRMA remains concerned that the Board proposes to interpret the term "drug" in an inconsistent manner for its drug selection and affordability review processes.[4] In order to provide a consistent definition, PhRMA recommends that the Board determine whether a product is a separate "drug" based on whether the product is approved under a distinct Food and Drug Administration ("FDA") New Drug Application ("NDA") or Biologics License Application ("BLA"), regardless of whether there is shared drug ingredient with another NDA or BLA.

- 7-Year Marketing Requirement for Review Eligibility: PhRMA also remains concerned that the Board proposes to determine whether a drug has "been on the market" for 7 years, and may therefore be eligible for affordability review, based on how long the relevant "drug *ingredient* has been on the market."[5] We emphasize the importance of considering drugs individually to avoid potential errors. Multiple products, approved under separate NDAs or licensed under separate BLAs, may have been marketed for varying lengths of time. By grouping those products together based on a common *drug ingredient*, the approach described in the Meeting Materials risks contravening the text of the statute by subjecting drugs to affordability review that may not have "been on the market for at least seven years."

- Cost Estimation Methodology: PhRMA remains concerned about the proposed methodology for estimating treatment costs using the "high dose by high duration of therapy" formula.[6] This approach may not be consistent with the typical course of treatment for the vast majority of patients, and presuming it is could systematically overestimate the cost for certain drugs. We continue to ask that the Board provide an explanation for why it believes its contemplated methodology will provide a reasonable and clinically appropriate estimate for a drug's course of

[3] *See* Letter from PhRMA to Board (Mar. 1, 2024), 2. Additionally, we understand based on March 20th meeting discussion that the Board does intend to publish draft rules ahead of the May meeting. Stakeholders need adequate time to review and comment on these prior to any discussion or vote.

[4] Meeting Materials at 34 ("For purposes of identifying prescription drugs that meet criteria of RCW 70.405.030, each distinct National Drug Code (NDC) is defined as a separate drug … For purposes of affordability review, all NDCs for the drug ingredient will be included in the review."). *See also* Letter from PhRMA to Board (Mar. 1, 2024), 2-3.

[5] Meeting Materials at 34 (emphasis added); January Meeting Materials at 9. *See also* PDAB Statute § 70.405.030.

[6] Meeting Materials at 9; *see also* January Meeting Materials at 20.

treatment. We also ask that the Board explain how it will mitigate the risk this methodology may pose of exacerbating health disparities.[7]

- Transparency in Data Sources: It remains critical that the Board be transparent with respect to its data sources and cognizant of the potential for errors and discrepancies that may exist in the data and information that it relies upon. PhRMA continues to request the establishment of a review process for manufacturers to address technical concerns, which should provide manufacturers the opportunity to review the Board's data and raise any questions or concerns before the Board moves forward with its affordability review.[8]

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PhRMA thanks the Board again for this opportunity to provide comments and feedback on the Meeting Materials and for your consideration of our concerns and requests for revisions. Although PhRMA continues to have concerns with the Board's proposals, we remain committed to constructive dialogue regarding the Board's ongoing implementation of the PDAB Statute. If there is additional information that we can provide, please contact dmcgrew@PhRMA.org.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[7] *See* Letter from PhRMA to Board (Mar. 1, 2024), 4.
[8] Such process should include protections for confidential, proprietary, or trade secret information against improper disclosure or use, as required by federal and state law. *See generally* Letter from PhRMA to Board (Jan. 23, 2024), 5 (providing more details on these requests).