724 Columbia St. NW, Ste. 310 • Olympia, WA 98501 • PHRMA.ORG

By Electronic Submission to HCA_WA_PDAB@hca.wa.gov

October 15, 2024

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 Eligible Prescription Drugs Policy and Meeting Materials from September 18, 2024 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 revisions to the draft Eligible Prescription Drugs Policy (the "Draft Policy") and other meeting materials (collectively, the "Meeting Materials") circulated by the Prescription Drug Affordability Board ("Board") in advance of its September 18, 2024 meeting. 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 has previously commented on various aspects related to the Washington Health Care Authority's ("HCA"'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*. (the "Proposed Regulations").[1] Below, we highlight comments and concerns of particular importance regarding the updated Draft Policy and Meeting Materials from the September 18, 2024 Board meeting.

I. Draft Policy

PhRMA addresses our concerns below with the revised Draft Policy, particularly with respect to the revised provisions in the second draft:[2]

[1] *See, e.g.*, 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] As described in PhRMA's prior comment letters, we continue to request that the Board allow manufacturers an opportunity to review and comment on the data that the Board intends to rely upon and provide additional data and context for the Board's consideration, including allowing the manufacturers to meet with the Board before the Board makes any final decisions on drug selections or affordability reviews. *See* 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 Policies and Procedures (Mar. 1, 2024); Letter from PhRMA to HCA Regarding HCA Proposed Regulations (WSR 23-21-082, filed October 16, 2023) (Nov. 20, 2023).

- **Seven Year Market Requirement.** PhRMA reiterates our recommendation that the Board update its Draft Policy to consider drugs that have been on the market for "at least seven years" individually based on distinct New Drug Applications ("NDAs") and Biologics License Applications ("BLAs").[3] As stated in previous comment letters, the PDAB Statute requires that the 7-year market requirement be based on how long a given "prescription drug" has been on the market, rather than a "drug ingredient" as described in the Draft Policy.[4] By focusing on the drug ingredient, rather than distinct NDAs and BLAs, the Board risks grouping together completely distinct products for purposes of evaluating eligibility.[5] The Board should further revise the Draft Policy to clarify that the 7-year market requirement applies to the length of time that a particular prescription drug, which is approved under the relevant NDA or BLA, has been on the market.[6]

- **Use of "Drug Ingredient" for Biosimilars**. Relatedly, the revised Draft Policy states that "[a] prescription drug on the market for at least seven years means the drug ingredient has been on the market for at least seven years. *This means a biosimilar that launches with an initial drug price can be considered for review if the drug ingredient has been on the market for at least seven years*."[7] PhRMA asks the Board to clarify how it intends to determine that a biosimilar shares the same drug ingredient as another product on the market. PhRMA notes that, unlike a generic drug that would be required to have the same active ingredient as the associated brand name drug, biosimilars are not required to use identical components but instead are required to be "highly similar" to their reference products.[8]

- **Cost Estimation Methodology**. PhRMA remains concerned about the Draft Policy's methodology for estimating treatment costs, which continues to contemplate use of a "high dose and high duration of therapy" formula.[9] As described in prior comment letters, this methodology may not be consistent with the typical course of treatment for the majority of patients and could overestimate the costs for certain drugs.[10] Determining a drug's "course of treatment cost" based on outliers instead of average patient clinical experience biases the data set to overestimate the costs of drugs.[11]

II. Confidentiality

PhRMA reiterates the need for more robust confidentiality protections, especially given the volume of proprietary information that the Board appears to be considering using as part of its processes.[12] As described in prior comment letters, the Board should establish a process for it to individually evaluate all information received from all parties—not merely manufacturer-provided information—to identify potential confidential, proprietary, and trade secret information. The Meeting Materials contemplate the Board drawing from a broad

[3] *See* Letter from PhRMA to Board Regarding the Draft Eligible Prescription Drugs Policy (July 12, 2024); Letter from PhRMA to Board Regarding Draft Methodology (Apr. 11, 2024).
[4] *Id.*; PDAB Statute § 70.405.030.
[5] PhRMA also observes the Board's methodology note added to the Draft Policy, which explains why the Board "defines a 'prescription drug' as a 'drug ingredient.'" Draft Policy at 4. However, we are concerned that this methodology relies on a single element of the multi-pronged definitions of "drug" in Wash. Rev. Code §§ 69.41.010(10) and 69.50.101(x) as well as the Board's characterization of the listings in the United States Pharmacopeia.
[6] *See Potter v. Dep't Lab & Indus.*, 101 Wash. App. 399, 408 (2000) (explaining that a statute cannot be given "an interpretation that is inconsistent with its plain language").
[7] Draft Policy at 2 (emphasis added).
[8] *See* FDA, *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, available at* https://www.fda.gov/media/82647/download.
[9] *Id.*
[10] *See* Letter from PhRMA to Board Regarding Draft Policies and Procedures (Mar. 1, 2024).
[11] *Id.*; Draft Policy at 2.
[12] PhRMA also refers HCA and the Board to our more complete discussion of confidentiality considerations in its January 2024 comment letter. *See* Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024).

range of potential data sources.[13] The Board's work may also involve soliciting information from multiple stakeholders that may possess relevant information, including information obtained by the stakeholder from third party entities. In the absence of particularized processes, this creates a serious risk of a breach of the confidentiality protections guaranteed under the PDAB Statute.[14] There is an especially significant risk of such issues arising where a stakeholder is submitting sensitive information obtained from a third party, as the submitter may not appropriately label the confidential, proprietary, or trade secret information appropriately, including because the submitter may not recognize that the information is treated as such by the other entity.[15]

In addition, as expressed in prior comments to the Washington Health Care Authority regarding the Board's policies and procedures, in order to guard against inadvertent disclosure of protected information, the Board should establish a mechanism for advance judicial review of the Board's determination that information is subject to public release, especially for information previously marked as confidential.[16] This process should afford affected stakeholders the opportunity for pre-disclosure appeal of any such determination. Without such an opportunity, the PDAB Statute's protection of confidential, proprietary, and trade secret information would be illusory—raising serious due process, takings, and other constitutional concerns.

III. "Selecting Drugs for Affordability Review (Part 3)" and "Introduction to Affordability Review Outline"

Below, PhRMA addresses considerations related to the staff presentations to the Board at the September PDAB meeting regarding selecting drugs for affordability reviews and conducting affordability reviews.[17] PhRMA again requests that methodologies related to these discussion be provided in a fully documented form—including the selection of drugs for affordability reviews and for performing affordability reviews, which the Board has so far provided only in slide decks.[18] It is difficult for stakeholders to provide meaningful feedback if these materials are not presented in a complete and comprehensive manner.

A. Data Sources

PhRMA again urges HCA and the Board to be cognizant of the potential for errors and discrepancies that may exist in the data and information that the Board relies upon, especially given that HCA's regulations and Draft Policies contemplate application of a complex methodology that involves compiling and analyzing data from a potentially broad and diverse set of data sources.[19] Given this potential for errors and discrepancies, PhRMA urges HCA to establish a process for manufacturers to review the Board's data and raise any technical questions or concerns with the Board before it moves forward with the affordability review process. This process should include a mechanism to protect confidential, proprietary, or trade secret information submitted to the Board against improper disclosure or use, as required consistent with the confidentiality obligations imposed on the Board by federal and state law.

[13] *See* Affordability Review Outline at 5.
[14] Wash. Rev. Code § 70.405.040(7) "All information collected by the board pursuant to this section is confidential and not subject to public disclosure."
[15] *See, e.g.*, Board, Affordability Review Outline at 5, 10 (listing several data sources and metrics that the Board intends to use in affordability reviews).
[16] *See* Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024).
[17] "Selecting Drugs For Affordability Review, Part 3," Sept. 18, 2024 (hereinafter "Selecting Prescription Drugs for Affordability Review Presentation"); "Prescription Drug Affordability Board: Introduction to the Affordability Review Outline," Sept. 18, 2024 (hereinafter "Affordability Review Outline").
[18] See Letter from PhRMA to Board (March 1, 2024).
[19] See Letter from PhRMA to Board regarding Draft Policies and Procedures (Jan. 23, 2024).

More generally, PhRMA requests that the Board provide clear definitions and sources for each of the data elements it intends to use in its drug selection and affordability review processes. Data bearing on these criteria may be drawn from a variety of sources, including reports from insurers, manufacturers, and various other sources. Certain sources of information may be unreliable or offer only a selective portion of the full picture relevant to the Board's selection of drugs for affordability review. It is therefore important that the Board provide clarity on the different information sources that it intends to rely upon as part of its prioritization process. Use of erroneous or incomplete data would impact the reliability of the Board's assessments, and it is therefore critical that the Board provide transparency as to its intended data sources.

PhRMA also highlights the following considerations related to specific data sources under consideration:

- **Use of All Payers Claim Database ("APCD")**. PhRMA remains concerned with the Board's use of the Washington State APCD. As discussed at the board's September meeting and in our prior comment letters, the APCD does not include data from all payers, and therefore, does not capture claims data for all insured individuals in Washington.[20] Furthermore, APCD data on prescription drugs do not account for net costs (e.g., after rebates and discounts) and skews costs upwards due to hospital markups on drugs. PhRMA continues to urge the Board to recognize the limitation of APCD data as it implements its processes.[21] PhRMA also recommends that the Board adopt mechanisms to verify APCD-based data points in light of the recognized limitations of these databases. Additionally, PhRMA recommends that the Board allow stakeholders the opportunity to review and comment on any APCD data that the Board intends to rely upon.

- **Use of Commercial Databases**. The Board has proposed to rely on certain commercial data sources as part of its drug identification and affordability review processes, such as Medi-Span and First Databank.[22] As described in our prior comment letter, the use of commercial databases increases the risk that data relied upon by the Board may contain inaccuracies.[23] PhRMA urges the Board to clarify how it will ensure that the data it considers is accurate and, where applicable, clinically-based.[24]

- **Out of Pocket (OOP) Costs.** The Board's Presentation on Selecting Prescription Drugs for Affordability Review references "OOP costs" as a measure that may be used for selecting drugs for affordability review.[25] Consistent with our prior comments, PhRMA encourages the Board to consider OOP costs within the full context of the range of factors driving OOP costs, including benefit design (e.g., coinsurance and deductibles, and accumulator adjustment and copay maximizer programs).[26] These factors, which are determined by insurers, plans, and pharmacy benefit managers (PBMs), are creating barriers for Washington citizens to afford health care. Additionally, the Board's presentation displays the average OOP cost through a simple average.[27] PhRMA recommends that the Board utilize other measures of tendency that show more nuanced representation of what patients are paying. The Board

[20] *See* Board, Webinar recording of Sept. 18, 2024 meeting, *available at* https://www.youtube.com/watch?v=Fe-rWn5QY8Q. See *also* Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials (June 18, 2024); Letter from PhRMA to HCA Regarding August 2023 Draft Regulations (Aug. 15, 2023).
[21] Selecting Prescription Drugs for Affordability Review Presentation at 10-24.
[22] *Id.* at 3, 26-27; Affordability Review Outline at 5, 10; Draft Policy at 1.
[23] *See* Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials (June 18, 2024).
[24] *See, e.g.*, Letter from PhRMA to Board (June 18, 2024), at 3.
[25] Selecting Prescription Drugs for Affordability Review Presentation at 9.
[26] *See* 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).
[27] Selecting Prescription Drugs for Affordability Review Presentation at 19.

could also consider displaying the data in a histogram, to provide a more complete visual representation of what patients are paying.

- **Calculation of "Net Price."** PhRMA asks the Board to clarify how it will determine the manufacturer and wholesaler net price as part of the affordability review process.[28] Additional details are needed to provide more specific comments on the Board's approach. Among other things, PhRMA requests that the Board identify the data sources it would use to identify the net price of a particular drug.

- **Data Sources for Affordability Review.** We note that medical providers have not been specifically included as a potential data source for affordability reviews.[29] PhRMA encourages the Board to create greater opportunities for input from clinical experts. These stakeholders are critical voices that should be duly considered in the affordability review process, and PhRMA is concerned that their input is not an area of emphasis in the Meeting Materials, especially because consideration of their feedback is required by the PDAB Statute.[30]

B. Price Effects and Patient Access.

PhRMA requests clarification on the Board's potential consideration of "price effect[s] on patient access to drugs in [Washington]" as part of affordability reviews.[31] Specifically, we ask that the Board clarify how it intends to use the listed factors to analyze price effects on patient access in Washington state in a consistent and coherent manner.[32] There are myriad and intersecting systemic social and structural barriers that may impede a patient's equitable access to medicines. Inequities are often rooted in community-level factors like where we live, work, and play; lack of adequate coverage and access to providers; and systemic racism and discrimination. We encourage the Board to consider the full range of factors across the continuum of care that can affect Washington patients' access to drugs.

Many patients in the U.S., including those with insurance coverage, face exorbitant out-of-pocket costs for their medicines. For disadvantaged and socioeconomically deprived communities, the eroding value of health insurance can exacerbate delays in diagnosis and access to medicine, further widening disparities in health outcomes. Research has demonstrated that rates of medicine abandonment increase as cost sharing increases.[33] PhRMA urges any analysis to give due weight to patient out-of-pocket costs, as well the range of factors driving such out-of-pocket costs, including benefit design. For example, patient out-of-pocket cost are impacted by cost-sharing requirements such as coinsurance and deductibles; copay accumulator adjustment[34] and maximizer programs[35]; and fees, rebates, and other price concessions paid by drug manufacturers to PBMs and plans that

[28] Affordability Review Outline at 10 ("Manufacturer net price of drug purchases after all discounts, rebates, and other price concessions; [w]holesaler net price after all discounts, rebates, and other price concessions").
[29] Affordability Review Outline at 18 ("TBD: Stakeholder surveys … Summary input from individuals with medical or scientific expertise.").
[30] PDAB Statute § 70.405.040 5(g)(i)-(ii) ("When conducting a review, the board shall consider ... [i]nput from ... [i]ndividuals with medical or scientific expertise related to the condition or disease treated by the drug.").
[31] Affordability Review Outline at 13.
[32] *Id.* ("[a] Prevalence and Incidence of Indicated Condition(s) in the State; [b] Estimated Patient's Drug Cost and Utilization in the Nation vs. the State; [c] Recent Utilization in the State").
[33] IQVIA. "Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025," May 2021. *Available at* https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us.
[34] Accumulator adjustment programs are insurance benefit designs that exclude the value of manufacturer-sponsored cost-sharing assistance from a patient's accrual of out-of-pocket expenses toward out-of-pocket limits through a plan benefit year.
[35] Copay maximizer programs are insurance benefit designs that generally restructure patients' cost sharing obligations for a particular drug to equal the full value of manufacturer cost sharing assistance available for that drug. Such programs skirt the protection of the Affordable Care Act's annual limit on cost sharing for some plans by designating medications as non-Essential Health Benefits.

are not shared directly with patients at the point of sale. These factors, which are determined by PBMs and plans, are contributing to the inability of Washingtonians to afford their health care needs and should be given due weight in the Board's selection process. PhRMA emphasizes that there would be an especially high risk of the Board drawing erroneous causal linkages if its analysis of price effects focuses on Wholesale Acquisition Cost ("WAC"), without accounting for net price paid by payors or plan design.

C. Use of International Pricing Information

The Affordability Review Outline indicates the Board may consider, as part of the affordability review process, "[d]rug prices in other developed countries."[36] While the details of the Board's contemplated use of international pricing data are unclear, the potential use of international pricing data as part of affordability reviews is nonetheless very concerning. If the Board considers this information, PhRMA encourages the Board to also take into account the demonstrated negative effect of international prices on patient access. The prices in many non-U.S. countries are the result of government price setting that have significantly limited patient access to new drugs. For instance, while 85 percent of all new medicines launched between 2012 and 2021 are reimbursed in the Medicare and Medicaid programs, only 61 percent of new medicines are reimbursed in Germany, 48 percent in the United Kingdom, 43 percent in France, and 21 percent in Canada.[37]

PhRMA also asks that the Board provide more details on the sources it would use to collect international pricing information. If the Board intends to rely on public or proprietary sources for such data, it should be aware that there are numerous issues with international pricing data, including that international pricing data is generally collected at different levels in each country. For example, in some countries data is collected at the hospital level, while in other countries it is collected only at a higher level, such as the wholesale level. International pricing data aggregators often then use proprietary methods to estimate whole-country sales volumes and prices. As a result, the data represents proprietary and non-transparent estimates of drug sales and volume and is not reflective of actual transaction or volume information. These proprietary estimates would be an unreliable source for affordability reviews. Further, many sources of international pricing data are licensed on a confidential basis to subscribers for their internal use, and it is unclear how the Board's approach would plan to use the data in affordability reviews, given such restrictions on use.[38]

D. Price and Availability of Therapeutic Alternatives

PhRMA remains concerned that the unduly broad approach contemplated by the Board for determining "therapeutic alternatives" includes a reference to therapeutic classes.[39] Therapeutic classes are exceedingly broad and cut across distinct therapies used for a wide range of indications. Drugs within a particular therapeutic class will often have significant differences, including in their chemical formulas, mechanism of action, and safety and effectiveness profiles, even though the drugs treat a similar clinical indication. Further, even drug products that have the same or similar indication often cannot be considered a therapeutic alternative: drugs can have significant differences, including in their chemical formulas, mechanism of action, and safety and effectiveness

[36] *See* Affordability Review Outline at 10 ("Drug price in other developed countries").

[37] *See* PhRMA analysis of IQVIA MIDAS and country regulatory data, October 2022 (Note: New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021). A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where the medicine is reimbursed by the public plan. A medicine is considered publicly reimbursed in the United Kingdom if the medicine is recommended by England's National Institute for Health and Care Excellence (NICE) for funding by England's National Health Services (NHS).

[38] PhRMA also notes that average manufacturer price ("AMP") is a federal pricing metric that is treated as confidential and proprietary under the Medicaid rebate statute, with disclosure permitted only in limited circumstances concerning certain Medicaid-related uses of the data. 42 U.S.C. § 1396r-8(b)(3)(D).

[39] Affordability Review Outline at 16. *See* Letter from PhRMA to HCA (Nov. 20, 2023), at 4-5. *See also* the adopted regulatory definition of "Therapeutic alternative," which does not refer to drugs within the same therapeutic class. Wash. Admin. Code § 182-52-0010.

profiles, even though the drugs may treat the same or a similar clinical indication. Treatments that are the best option for some individuals are not as effective for others. PhRMA urges the Board to carefully consider and refine its contemplated approach to therapeutic alternatives to avoid misleading comparisons between meaningfully distinct products. Specifically, the Board should establish a consistent process that each drug must be evaluated under for purposes to determine whether it can be appropriately considered to be in the same "therapeutic class." The process should include:

- Meaningful engagement with the manufacturer and local medical professionals on potential therapeutic class members;
- Review of clinician guidance, including physician-driven evidence-based clinical guidelines, as a resource; and
- Review of other widely recognized, scientifically rigorous, evidence-driven resources to identify therapeutic class members.

E. Cost-Effectiveness Analysis ("CEA")

The Meeting Materials describe the potential use of CEAs as part of affordability reviews.[40] Though the Board has not provided sufficient detail to fully evaluate its draft approach, PhRMA encourages the Board to exercise caution in its contemplated use of CEAs.

While the Meeting Materials do not specify the types of CEAs that the Board would rely on, the materials do reference CEAs developed by the Institute for Clinical and Economic Review ("ICER").[41] ICER often utilizes CEAs that rely on QALYs and similar measures. PhRMA emphasizes that the PDAB Statute prohibits using certain types of CEAs in the Board's upper payment limit "UPL" methodology, including CEAs that use Quality Adjusted Life Years ("QALYs") or "a measure or metric which assigns a reduced value to the life extension provided by a treatment based on a preexisting disability or chronic health condition of the individuals whom the treatment would benefit."[42] As we have described previously, the selection and affordability review processes are inherently linked to the process of UPL-setting because a UPL cannot be set for a prescription drug without that drug having been determined to be unaffordable by the Board.[43] As such, any consideration by the Board of QALYs or a similar methodology during the selection and affordability review processes, including reliance on ICER QALY analyses, may violate the PDAB Statute's prohibition on the use of QALYs by inappropriately factoring into the outcome of the Board's UPL-setting methodology.

Further, QALYs and other metrics like "equal value of life year gained" ("evLYG") raise significant equity concerns, as these metrics have been shown to discriminate against people with disabilities, the elderly, and communities of color by placing lower value on their lives and the preservation of life.[44] For this reason, PhRMA believes that the use of QALYs is inappropriate in setting a potential UPL. More broadly, policies that are based on cost-effectiveness determinations can prevent patients from accessing the treatments that best meet their personal needs and preferences, and override physician judgment in making individualized treatment decisions. By

[40] Affordability Review Outline at 17. PhRMA also requests clarity on what the Board means by "interactive model."
[41] PORTAL PDAB Slides at 25.
[42] PDAB Statute § 70.405.050(3).
[43] *See* Letter from PhRMA to HCA Regarding August 2023 Draft Regulations (Aug. 15, 2023).
[44] National Council on Disability, *Quality-Adjusted Life Years and the Devaluation of Life with Disability* 3 (Nov. 2019), *available at* https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf; Broder, M., Ortendahl, J., *Is Cost-Effectiveness Analysis Racist? Partnership for Health Analytic Research* (2021), *available at* https://blogsite.healtheconomics.com/2021/08/iscost-effectiveness-analysis-racist/.

combining average study results into a single numeric judgment of value, CEAs overlook the significant differences in the needs of individual patients, many of whom do not fit the average. As one patient group has noted, "[i]t is widely acknowledged that a summary measure such as [those used in CEAs] will never be able to adequately capture the vast differences in individual preferences and values."[45] It has also been widely noted by stakeholders that CEAs discriminate against individuals with disabilities and chronic illnesses by undervaluing their lives.[46] Experts in tfhe field of CEAs recently acknowledged that "the problem of whether CEA unjustly discriminates against the disabled remains a deep and unresolved difficulty for the use of CEA."[47]

Cost-effectiveness analysis can also contribute to perpetuating longstanding inequities in health care and health outcomes. The assumptions used in CEAs disadvantage marginalized populations through use of QALYs, health care costs, as well as assumptions around lost productivity.[48] These assumptions undermine health interventions that may improve health for marginalized populations and favor interventions that will further the status quo of inequity. PhRMA urges the Board to reconsider its potential use of CEAs, as these methods result in "systematic underestimation of cost-effectiveness for marginalized populations [and] can contribute to further entrenchment of health inequities."[49]

F. Determining "Excess Costs"

As part of the discussion of "excess costs" in the draft Affordability Review Outline, the Board has included reference to the impact of drug spending on the budget of state public and private payers and Washingtonians as a potential "[p]erspective to consider."[50] PhRMA requests that the Board provide additional detail about this potential approach, including information on how the Board would determine the budget that the spending would be measured against, and how the Board would determine what percentage or threshold of the budget that the expenditure on a particular drug would be capped at. PhRMA notes that payers and other analysts have historically overestimated the potential costs of providing access to new medicines, and the speculative nature of such projections makes them inappropriate to use in affordability reviews.[51]

G. Additional Information from Manufacturer.

PhRMA asks the Board to provide additional information and details about information that may be considered under this section. For example, PhRMA requests clarity on the Board's intended data source for "an

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[45] Partnership to Improve Patient Care, Measuring Value in Medicine: Uses and Misuses of QALYs (2017), available at http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_white_paper_-_measuring_value_in_medicine_-_uses_and_misuses_of_the_qaly.pdf.

[46] *Id.*

[47] P. Neumann, G. Sanders, et al., *Cost Effectiveness in Health and Medicine* (2d. ed., 2017).

[48] Sanjay Basu, Atheendar S. Venkataramani, & Dean Schillinger, *The Risk Of Perpetuating Health Disparities Through Cost-Effectiveness Analyses*, 43 Health Affairs 1165–72 (2024).

[49] *Id.*

[50] Affordability Review Outline at 22. PhRMA notes that the third "perspective" described in the Board's presentation refers to "the drug's budgetary impact on the state's public and private payers, as well as Washingtonians E.g. Impact on insurance premiums for Washingtonians." *Id*. The budgetary impact described in this perspective appears to be an expansion of the statutory and regulatory considerations for "excess costs" and PhRMA asks the Board to clarify how it intends to reflect these perspectives in its excess cost determinations. PDAB Statute § 70.405.010(5); Wash. Admin. Code § 182-52-0010 ("'Excess costs' means: (a) Costs of appropriate utilization of a prescription drug that exceed the therapeutic benefit relative to other alternative treatments; or (b) Costs of appropriate utilization of a prescription drug that are not sustainable to public and private health care systems over a 10-year time frame.").

[51] *See*, *e.g.*, ICER, "ICER Releases Final Report on Use of PCSK9 Inhibitors for Treatment of High Cholesterol," Nov. 24, 2015, *available at* https://icer.org/news-insights/press-releases/icer-releases-final-report-on-use-of-pcsk9-inhibitors-fortreatment-of-high-cholesterol-2/; Drug Discovery & Development, "Analysis Finds Actual Cost of New Drugs Is Far Less than Predicted," Apr. 25, 2017, *available at* https://www.drugdiscoverytrends.com/analysis-finds-actual-cost-of-new-drugs-is-far-lessthan-predicted.

interactive model for the budget impact analysis."[52] The Board's presentation materials provide minimal detail regarding use of an "interactive model" but any such tool should be open source, meet basic transparency principles and avoid the use of discriminatory QALYs or similar measures. PhRMA refers the Board to previous discussion and concerns about systemic inclusion of prohibited QALY or QALY-like measures.[53]

The Board's presentation materials also describe that the Board may consider information regarding "Life-Cycle Management."[54] PhRMA requests clarification regarding how it defines "Life-Cycle Management" and how it may utilize that information as part of its affordability review process.[55]

H. Off-label Usage of the Drug.

In considering off-label uses as part of the affordability review process, the Board lists manufacturers as a potential data source.[56] The FDA imposes significant restrictions on manufacturer communications around unapproved uses of approved products.[57] PhRMA requests that the Board provide additional information about what information it intends to collect.

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PhRMA thanks the PDAB for this opportunity to provide comments and feedback on these Meeting Materials 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
Director, State Policy
Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[52] Affordability Review Outline at 19.
[53] *See* section III.G, above.
[54] *Id.*
[55] To the extent the Board intends to include information regarding post-approval research and development in this category, it should also consider the vital role that post-approval research and development plays in developing additional indications for existing medicines. For example, of the 155 oncology drugs approved between 2000 and 2021, 57 percent of labeled indications approved by the FDA and 68 percent of industry-sponsored clinical trials occurred post-approval. Henry G. Grabowski, Joseph A. DiMasi, Genia Long, Postapproval Innovation For Oncology Drugs And The Inflation Reduction Act, HealthAffairs, Volume 43, Number 10, Oct. 2024, https://doi.org/10.1377/hlthaff.2024.00202. Research shows more than half of small molecule medicines approved a decade ago received additional indications in later years, and nearly half of those occurred seven or more years after initial approval. Partnership for Health Analytic Research, Implications of the Inflation Reduction Act Price Setting Provisions on Post-approval Indications for Small Molecule Medicines, June 2023. https://www.pharllc.com/wp-content/uploads/2023/05/Implications-of-the-IRA-on-Post-Approval-Small-Molecules-2006-2012_Final.pdf.
[56] *Id.* at 21.
[57] *See, e.g.*, 88 Fed. Reg. 73,031 (Oct. 24, 2023).