VIA Electronic Delivery February 27, 2025

Washington Prescription Drug Affordability Board
Washington Health Care Authority
Cherry Street Plaza
626 8th Avenue SE
Olympia, WA 98501

**Re: WA PDAB Manufacturer Data Submission Guide, Data Submission Sheet, and Submission Form for Affordability Review**

Dear Washington Prescription Drug Affordability Board (PDAB)

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Washington Prescription Drug Affordability Board's (PDAB or Board)'s Manufacturer Data Submission Guide, Manufacturer Data Submission Sheet, and Manufacturer Submission Form for Affordability Review (hereafter collectively referred to as 'Draft Submission Materials') ahead of its February 2025 meeting.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

**General Comments**

BIO has long argued that the Board's premise behind establishing an affordability review process is flawed. An overt focus on cost savings for the state rather than patient value will harm patient access to lifesaving medication while failing to protect patients from harmful coverage restrictions imposed by plans and PBMs. The Draft Submission Materials augment these concerns by modeling after ex-US HTA entities to request a significant volume of sensitive information. It is evident that the level of evidence and the sensitive nature of the evidence requested is extremely problematic and exceeds the Board's authority. The volume, scope, and level of detail of the Draft Submission Materials is particularly concerning given the WA PDAB statute's 30-day turnaround time for manufacturer submissions and penalty for non-compliance. Further, much of the information requested is irrelevant to the affordability review process or beyond the ability of a manufacturer to report and thus could lead to inaccurate assessments of affordability. Given our critical concerns with the Draft Submission Materials, BIO urges the Board to make significant changes and carefully consider stakeholder impacts before finalizing any materials.

While BIO strongly disagrees with WA's approach and information gathering process for conducting affordability reviews, our comments are intended to ensure that the PDAB provides the necessary transparency and accountability to stakeholders and does not act outside of its statutory limits. Please note our recommendations on these Draft Submission Materials do not resolve the more fundamental issues of price controls, and BIO's positioning remains that the Board should not implement its affordability review process.

**Overly Burdensome and Inappropriate Scope of Information Requested**

It is highly burdensome for manufacturers to provide or estimate the information requested in the Draft Submission Materials. BIO notes that the administrative burden imposed on manufacturers through the Draft Submission Materials are far more extensive than the information requested from other stakeholders. The resource toll for a manufacturer to collect, synthesize and share all this information is extremely high. Further, manufacturers are only provided 30 days with which to respond to the Board's significant volume of data requested. This is especially problematic since, in contrast to other PDABs where submissions from manufacturers are voluntary, the WA PDAB imposes civil penalties for non-compliance. BIO maintains that it is unreasonable for the Board to impose penalties for noncompliance when the breadth and depth of data being requested is coupled with insufficient turnaround time. BIO notes that while CMS also requests data from manufacturers within 30 days in the Maximum Fair Price (MFP) process, the predictability of MFP drug selection permits forecasting activities that provide manufacturers with more than 30 days to prepare for such requests for information.

Not only is the information resource-intensive and administratively burdensome to collect, but some of the information is also infeasible for manufacturers to report. As BIO has previously commented, manufacturers do not have insight into, nor should be required to report on, information on another manufacturer. Accordingly, it is infeasible for manufacturers to report on the price, efficacy, safety, or other information on therapeutic alternatives, as therapeutic alternatives are usually separate products manufactured by another company or even competitor products. The non-voluntary nature of submissions elevates the concerns of the inappropriate scope of this information request. At a minimum, it is essential that the Board provide a means by which a manufacturer can attest that certain requested information is unavailable, and the manufacturer should therefore not be accountable for providing such information.

With a statutory 30-day turnaround and associated penalties for non-compliance, the WA PDAB should re-consider the volume, scope, and level of detail in the information they propose to request. It is essential that the Board needs to carefully consider and clearly outline how they will reasonably review and incorporate the information provided in the affordability review. As it stands, the Draft Submission Materials request extraneous information that is not relevant to how manufacturers price their medicines or how patient out-of-pocket costs are determined. Specifically, the PDAB should explain to stakeholders how they plan to use the information they seek in order to determine "whether a drug has led or will lead to excess costs to patients" in Washington. The PDAB should also provide a rationale for each data element they are requesting and note the statutory authority to collect such data. As noted above, in many cases, a manufacturer may not have access to the requested information. Instead of an unnecessary de novo effort, the PDAB should

consider using existing databases, such as publicly available FDA resources, for this information. BIO also encourages the PDAB to make every effort to combine repetitive data requests and reevaluate areas where the word count limit is too restrictive to adequately summarize information as requested.

As it stands, the PDAB's request for historical data, current data, *and* future data projections creates an excessive burden for manufacturers, and it would be unmanageable for the Board to incorporate all of these elements into their drug review discussions. BIO urges the Board to instead focus data requisitions on a specific and appropriate length of time such as the prior calendar year. In addition, the Board should not request any future data projections because each organization may use different methodologies, assumptions, and models to estimate future trends. These inconsistencies would not allow for meaningful comparisons and could potentially lead to flawed conclusions.

**Problematic Comparisons with Foreign HTA Processes**

BIO is extremely concerned by the volume and sensitivity of the information requested, which appears to replicate information being requested by foreign (ex-US) Health Technology Assessment (HTA) agencies. Within the Manufacturer Information Submission Form for Affordability Review, the Board references ex-US agencies including NICE (UK), CADTH (Canada), and IQWiG (Germany), and attempts to reference those agencies in the extent of their information request. It is extremely problematic to compare and reference the practices of ex-US agencies when nearly all foreign countries operate on nationalized healthcare systems where prices are set and controlled by the government. When imposed on medicines, price controls, including those set by ex-US agencies, suppress innovation and access to new medicines. According to one study, 40% of medicines to treat rare diseases between 2002 and 2014 were rejected for coverage in the United Kingdom.[1] It is clear that the price control policies set by ex-US agencies deter the development and supply of new life saving and life improving medicines to the detriment of patients and doctors. In addition, the Board's consideration of ex-US HTA processes is inappropriate and could lead to inaccurate assessments of affordability. Ex-US HTA agencies inform access decisions at launch for a new intervention and rely on modeling to predict impacts. However, the WA PDAB is requesting information on drugs which have been on the market for at least seven years, which necessitates information on real-world evidence (RWE) rather than predicted impacts. Applying the predictive models of ex-US HTA agencies to well-established drugs would be misguided and inappropriate; instead, it is critical that the Board utilize RWE throughout the affordability review process.

BIO opposes the PDAB's request for information on drug pricing in other developed countries and the repeated reference to ex-US HTA agencies that set price controls based on the use of quality- adjusted life years (QALYs). The federal government recognizes that QALYs are inherently discriminatory to patients with chronic disease and disability. In its November 2022 report on QALYs, the National Council on Disability (NCD) reiterated "ethical concerns and discriminatory aspects of the QALY" given that QALY results in "undervaluing prescription drugs that extend the lives of people with disabilities."[2] While the Manufacturer Form states that "the board must not use quality-adjusted life years that

[1] Mardiguian, S., Stefanidou, M., et al. "Trends and key decision drivers for rejecting an orphan drug submission across five different HTA agencies." *Value in Health Journal*. 2014.
[2] Alternatives to QALY-Based Cost-Effectiveness Analysis for Determining the Value of Prescription Drugs and Other Health Interventions. National Council on Disability Policy Brief. November 28, 2022.

take into account a patient's age or severity of illness or disability," the Board continues to use QALY-influenced data as a part of the affordability review, as evidenced by repeated mentions of ex-US HTA organizations and requests for information on drug prices in other developed countries that use QALYs. Utilizing international pricing data and ex-US HTA practices is problematic and inappropriate given that different countries have different system designs, HTA processes, patient characteristics, unit costs, and variations in standards of care. BIO objects to use of comparisons of health care systems and international pricing in other countries that use QALYs, as they are not comparable to Washington state and should not be used in the affordability review process.

**Issues with Interactive Modeler**

The Manufacturer Information Submission Form for Affordability Review endorses ICER's Interactive Modeler, a commercial tool that amounts to a paid subscription service offered by ICER. BIO strongly opposes the PDAB's recommendation to use the Modeler, which has high access fees and relies on QALY-based estimates to measure efficacy. High access fees could disadvantage companies, particularly smaller companies that may not have available resources to pay for ICER's service. Many companies also do not have the resources to create brand new economic models that are very resource intensive and require nuanced, technical expertise that may not be available in house. Further, it is unclear why the Modeler would be required when the state should have actual cost data for its state programs and for commercial plans from the state's APCD. Criticisms of ICER's modeling have been well-documented in previous meetings, with patients and patient groups noting concerns with the lack of consideration for RWE and potential conflicts of interest. In addition, BIO is concerned that the Modeler's results would be inaccurate given that the Modeler cannot be changed to add in societal costs, to input different assumptions, or to run additional scenarios. As an alternative to the Modeler, the board has requested a modifiable version of an Excel model from the manufacturer. However, this method also presents challenges with significant resource commitment by both the manufacturer and the Board. For instance, the Board would need to ensure correct and valid use of the model, sufficient reporting of model specifications, additional reporting to review and respond to model changes, adequate protections of intellectual property, and more. With its current resource capacity, it is infeasible for the Board to collect all this information, ensure safety of sensitive information, update the models as needed, and engage in deliberations on all this information across all indications.

**Need for Confidentiality within Submission Process**

In light of the substantial volume of sensitive, proprietary, and trade secret data that is being collected, it is essential that the Board must provide further details, processes, and assurances for how the data will be managed and statutory protections will be achieved. For instance, appropriate data designations should be provided to denote information as proprietary/trade secret to protect from disclosure. The PDAB should identify the minimum amount of confidential and/or proprietary information necessary and sufficient to inform its review. BIO also reminds the Board that, should any third-party entities work with the Board on affordability reviews, any potential conflicts of interest should be noted, given that these entities could receive proprietary information on net pricing, pricing projections, or other data, while simultaneously receiving funding from payers that could benefit from this data.

**Dashboard Requires Refinement**

As noted in previous meetings, the Board should refine the Dashboard to combine the list of specialty and non-specialty drugs. Rather than the current setup where the prioritized list is sorted at the NDC-11 level, the list should have the drugs aggregated and sorted by the drug labeler. This aggregation is important because factors used to determine affordability, including net-of-rebate prices and patient out-of-pocket costs, are generally determined at a more granular level by health plans. Health plans are the entities that negotiate rebates, shape benefit designs, and put drugs in preferred tiers on a plan's formulary based on this drug level. These decisions made by health plans at the drug-level drive the variations in patient out-of-pocket costs. In addition, BIO notes that for some of the included NDCs on the Dashboard, many of the calculated metrics are not visible. Our members have also observed data errors in the dashboard and have verified from internal data that certain figures, such as the total number of patients on a specific drug in a given year, are incorrect by orders of magnitude. We request that the Board revisit and refine the Dashboard accordingly.

**Specific Recommendations on Manufacturer Information Submission Form for Affordability Review**

Throughout the Manufacturer Information Submission Form, the Board requests indication-specific information on drug efficacy and safety, the price and availability of therapeutic alternatives, cost-effectiveness analysis data, and other sections. BIO opposes this request for indication-specific information given that the Board cannot review or establish a UPL at an indication-specific level. Accordingly, indication-specific data would be unnecessary and inefficient to collect when the data would not directly inform the Board's work nor create any actionable insights. BIO also encourages the Board to clarify throughout the Form when Washington-specific data is being requested. As it stands, in various areas throughout the Form, including the section on Manufacturer Patient Assistance Program and Coupons, do not indicate whether manufacturers should submit national data, Washington-specific data, or both.

Our specific comments on the Manufacturer Information Submission Form for Affordability Review are as follows.

*Drug Shortage Status (p.5)*

BIO believes that information collection regarding shortage status should be monitored by the PDAB and sourced directly from the FDA.

*Drug Efficacy and Safety (p.7)*

BIO notes that the statute RCW 70.405.040 provides no mention of drug efficacy and safety, and submission of full-text manuscripts and reports, as requested, may duplicate and/or exceed federal FDA approval processes and requirements. It is also unreasonable to request an exhaustive list of references related to studies and other materials concerning each indication of a drug's efficacy and safety. BIO urges the Board to carefully explain how they plan to use information on drug efficacy and safety to inform a determination of whether a drug has led or will lead to excess costs to patients. It is also important that the Board provide enough space to appropriately communicate the requested information, since

the word limits are too restrictive to adequately summarize trial data.

*Clinical Efficacy (p.7)*

The Manufacturer Submission Form notes that "any interim data, preliminary data analyses, and publications without a full description of methodology…are not to be included (e.g. preliminary reports, conference posters.)" BIO remains concerned about the potential exclusion of critical RWE studies where the authors may have difficulties publishing their work due to time constraints, bias by peer reviewers, or other factors beyond the study's control.

Within Clinical Efficacy and similar sections, the Board should clearly distinguish whether/if the PDAB intended to request United States Prescribing Information (USPI), clinical trial data, and/or RWE. These are distinct types of data and should not be conflated. For example, clinical trials are usually randomized control trials or open label under very controlled environments. RWE is, by definition, not conducted in a controlled environment and often includes large datasets with limited information or retrospective cohorts. Depending on the drug and the manufacturer, certain medicines and stakeholders may have different volumes of studies in each category to support the science base for a particular medicine. We encourage the PDAB to become familiar with the many types of data available to the scientific community, ranging from peer-reviewed manuscripts to conference publications.

*Safety Profile (p.7)*

BIO notes that safety and efficacy data are available in a drug's USPI and typically reported together in FDA approvals and in clinical trial data. Similar to above, clarification is needed on what type of scientific information- USPI, clinical trial data, and/or RWE- that the PDAB intends to request.

*Drug Price Information (p.9)*

As noted previously, the Board should detail processes for secure handling of any confidential and/or proprietary information, including but not limited to rebates, price concessions, and net price metrics. For proprietary pricing metrics that are already reported elsewhere, the PDAB should consider utilizing and citing existing trusted data sources (e.g. for WAC, NADAC) to reduce administrative burden and to prevent duplicate reporting requirements for stakeholders who are already required to report some of these data.

BIO recommends that the Board should add data fields addressing the number of patients/units of the drug affected by these various price concessions and discounts. This information is important to determine how a particular discount or rebate affects the drug's average price. For instance, a discount that applies to most of the drug's patients is very different than one that applies to only a handful of patients.

Throughout this section, the Board requests data up to the previous five years or the five most current price changes, whichever is longer. However, the Board does not provide any rationale for this duration. BIO believes that five years of pricing data history is extensive. Instead, the Board should seek the most up-to-date information representing the prior calendar year.

*National Average Drug Acquisition Cost (NADAC) (p.9)*

BIO urges the Board to be cognizant of the inappropriateness of this request given that manufacturers do not calculate NADAC. Further, NADAC does not exist for all drugs. As outlined earlier, manufacturers should have the ability to state that the requested data is not applicable. Instead, when available, the Board should obtain this information directly from CMS.

*The Most Current WAC for a Therapy Duration (p.9)*

BIO notes that the number of units needed for therapy duration will be immensely difficult to provide for drugs where dosing varies by weight, age, or other factors.

*Drug Price in Other Developed Countries (p.10)*

As stated earlier, BIO opposes the PDAB's request for information on drug pricing in other developed countries. Prices in other global markets are subject to multiple factors, including areas outside of manufacturer control, that are not applicable or relevant for the state level. It is also impractical for manufacturers to provide this extent of rationale and data associated with ex-US pricing due to confidentiality across lines of business, depending on a company's structure. If Board proceeds with this unreasonable request, the Board should explain how they plan to use information on incomparable health care systems and other patient populations that are not representative of Washingtonians to inform a determination of whether a drug has led or will lead to excess costs to US patients in the state.

*Manufacturing, Delivery, and Administration Cost (p.11)*

The Board requests unnecessarily extensive R&D data using metrics that are highly burdensome and imprecise. For instance, the proposed R&D metrics do not capture the full scope of investment necessary for drug development, which often builds on discovery and study of hundreds if not thousands of potential molecules. The Board should not penalize manufacturers for intellectual propriety rights intended to incentivize R&D. The proposed R&D metrics also do not account for drug failures which are inevitably part of R&D spending and price. In a global company, investments in R&D are made across multiple years if not decades, across many company affiliates or even many countries. As such, it will be challenging or impossible for manufacturers to identify and break down R&D by indication and report it with precision. The request for rate of recovery of R&D amounts to an estimate of future profits, which is extremely uncertain. Drug development is a continuous process that involves constant innovation and multiple improvements for each product.

Given that R&D metrics are limited in scope as well as highly burdensome to report, the PDAB should rely on broad publicly reported R&D metrics such as those in Securities and Exchange Commission (SEC) filings and allow manufacturers to use reasonable assumptions to allocate a percentage of total R&D costs to the R&D that led to a drug's approval and supports ongoing discovery.

In addition, the Board should recognize that post-marketing investment such as Phase IV research- while not being considered by the PDAB's for R&D metrics- is pertinent for understanding safety, efficacy, and effectiveness in the real-world, including diverse populations not included in clinical trials.

*Funding Sources (p.11)*

As mentioned previously, the Board's affordability review approach has the potential to reduce investment incentives, including future collaborations in research. The vast majority of R&D in the U.S. is privately funded. The federal government primarily supports basic or applied science and has no ability to develop and commercialize a product, including the additional studies required. Such transactions are an important aspect of biopharmaceutical development in the U.S. However, the PDAB's proposed approach would disincentivize future collaboration between government agencies and pharmaceutical manufacturers. Moreover, perpetuating a stigma based on prior federal financial support fails to recognize the significant investments manufacturers make in drug development with no guarantees of success.

*Acquisition Cost (p.11)*

The Board should recognize that this section does not apply to all drugs. Moreover, the development pathway for drugs can represent multiple and intersecting mechanisms.

*Recurring Cost of Drug Manufacturing (p.12)*

BIO is concerned that this section will be challenging, if not impossible, for manufacturers to report with precision and within the word limit. Future costs of manufacturing are difficult to report given the many unknown external factors, including federal tariffs and other costs that may increase over the years. Similar to the concerns with R&D metrics, the cost of manufacturing may not be specific to a particular drug, and manufacturing only represents one component of the various risks and responsibilities assumed by a manufacturer in bringing a medicine to market.

*Marketing, Advertising, and Lobbying Budget and Expenditures (p.12)*

BIO notes that the information in this section is being requested "in the aggregate and for the drug," which exceeds the scope of authority for the PDAB. Moreover, inappropriate scrutiny of business and community practices that ignore existing guardrails and relevant context perpetuates misunderstandings about the role and responsibilities assumed by relevant stakeholders to advance innovation and enable access to appropriate health care options. Forcing manufacturers to divide their marketing spending into these categories will lead to inaccurate data.

*Cost of Delivering/Administering the Drug to Patients (p.13)*

It is critical that the Board add necessary definitions in these sections, including a definition for "special mechanism." Depending on the definitions of key terms, the information requested may or may not be appropriate for a manufacturer to report.

*Other Administrative Costs (p.13)*

The Board should clarify necessary definitions in this section to determine whether manufacturers may be the most appropriate entity to report administration costs. As it stands, it is unclear why the Board would expect to receive information on the administration costs for a drug from a manufacturer.

*Prevalence and Incidence of Indicated Condition(s) in the State (p.14)*

BIO notes that this section is not related to price or access to a drug.

*Estimated Patient's Drug Cost and Utilization in the Nation vs. the State (p.14)*

BIO urges the Board to recognize that manufacturers do not have purview into patient out of pocket costs and are unable to calculate this information, as patient out of pocket is determined by plan benefit design and can vary significantly across payers. It is unreasonable for the Board to request this information from manufacturers; this information should solely be included in the Payer Data Submission Guide. If included in the Payer Submission Guide, it is important for the Board to consider the nuances of patient out of pocket costs, including differences in prevalence, incidence, payer segmentation and their respective coverage policies, etc. between the national level vs the state.

*Manufacturer Patient Assistance Program and Coupons (p.15)*

Throughout the Manufacturer Information Submission Form, requests regarding patient out-of-pocket costs, coupons, and patient assistance programs are spread out and disaggregated across multiple sections. BIO recommends that the Board should add a standalone section for patient out-of-pocket costs and include a metric that considers all forms of patient assistance, including coupons and patient assistance programs together. This will provide the Board with a more complete picture of the actual out-of-pocket costs paid by patients. In addition, BIO encourages the Board to define 'Patient Assistance Program' to clarify whether the Board is only requesting information on direct assistance from the manufacturer or whether the PDAB intended to include information collection on patient assistance programs that are not directly provided by manufacturers. BIO also recommends for the Board to increase the word allowance for this section, as the current word limits are too restrictive to adequately summarize program information as requested.

*Price and Availability of Therapeutic Alternatives (p.17)*

As stated earlier, BIO opposes the request for information from domestic or foreign HTA organizations. These organizations are an unreliable source for affordability reviews due to the significant differences between countries' healthcare systems and different methodologies for calculating pricing information, including the use of discriminatory QALYs. It is clear that information from incomparable health care systems and other patient populations that are not representative of Washingtonians will not reliably assist the Board with its goal of conducting affordability reviews.

BIO also opposes the request for information on therapeutically equivalent drugs and therapeutic alternatives. As stated earlier, manufacturers should not be required to submit reporting that pertains to the price, efficacy, safety, etc. of other drugs produced by other manufacturers that may be competitors. In addition, there may be many reasons why another product is not a therapeutic alternative. For instance, some products have stricter guidelines for use in certain populations and therefore cannot be substituted for each other across all patient types. BIO encourages the Board to expand the word limits in this section so that manufacturers can adequately summarize how products may not be therapeutic alternatives, or explain other information as requested.

*Cost-Effectiveness Analysis (p.21)*

As stated previously, BIO is opposed to using CEAs as a part of affordability reviews due to its widely inappropriate and discriminatory nature. Although the Form states that the board will not use QALYs, cost effectiveness analysis inherently estimates how much it costs to gain a unit of a health outcome, including a life year gained or a death prevented. It is also evident that ICER, including the ICER Analytics Interactive Modeler, uses QALYs in its analysis. BIO urges the Board to reconsider the excessive request for CEA data, particularly when the data is compared to a standard of care that doesn't reflect current practice in WA and relies on modeled impacts that may lead to inaccurate conclusions.

**Payer Information Submission Form for Affordability Review**

Given the direct impacts of payer decisions toward patient out-of-pocket costs, BIO urges the Board to use this opportunity to seek more information from payers, including utilization management and exceptions requests granted/denied to provide necessary context to accompany cost data. Rather than solely requesting information on average copay and co-insurance, the Board should also seek information to better understand different benefit designs across payers and how those designs impact patient out of pocket costs, including formulary and non-formulary management.

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BIO appreciates the opportunity to provide feedback to the Washington PDAB through these meeting materials. We look forward to continuing to work with the Board to ensure Washington residents can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

/s/

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