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Via Electronic Submission

March 14, 2025

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Board Chair
Washington Prescription Drug Affordability Board
HCA_WA_PDAB@hca.wa.gov

Re: Manufacturer Information Submission materials for Affordability Review, Data Submission Guide, and Manufacturer Data Submission Sheet

Dear Board Chair Cody:

Johnson & Johnson offers the following comments to the Washington Prescription Drug Affordability Board (the Board) on the PDAB's Manufacturer Information Submission materials for Affordability Review, Data Submission Guide, and Manufacturer Data Submission Sheet ("Submission Materials").[1]

At J&J, for more than 130 years, cutting-edge technologies and expert insight have helped us understand and address the serious health problems of today and unlock the potential medicines of tomorrow. We apply rigorous science and compassion to confidently address the most complex diseases of our time. We also recognize these medicines can only have an impact if patients can access them. We work tirelessly to improve access for patients across Washington.

J&J shares the PDAB's goal of improving affordability and access to lifesaving medicines for Washington patients. However, J&J opposes the affordability review process because it is unproven and may result in negative unintended consequences throughout the supply chain, including increased out-of-pocket costs and decreased access for patients.[2] Additionally, J&J is concerned that the Submission Materials pose significant challenges, including:

- Elements of the Submission Material requirements are inconsistent with and beyond the scope of Washington Statute, may be impossible for manufacturers to satisfy, and impose extensive administrative burden and costs for both manufacturers and the state.
- The content of the Submission Materials in its entirety is confidential, and the PDAB must

[1] *Prescription Drug Affordability Board*, HCA, https://www.hca.wa.gov/about-hca/programs-and-initiatives/clinical-collaboration-and-initiatives/prescription-drug-affordability-board (last visited Mar. 14, 2025).

[2] *Influence of Prescription Drug Affordability Boards and Upper Payment Limits on the State Drug Pricing Ecosystem*. Johnson & Johnson. https://transparencyreport.janssen.com/influence-of-prescription-drug-affordability-boards-and-upper-payment-limits-on-the-state-drug-pricing-ecosystem (last visited Mar. 11, 2025); *Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies and Benefit Design But Won't Reduce Patient Costs*, Partnership to Fight Chronic Disease (Mar. 2024), https://www.fightchronicdisease.org/sites/default/files/FINAL%20PFCD%20Avalere%20PDAB%20Insurer%20Research.pdf (last visited Mar. 11, 2025).

establish a submission process to protect such information before requiring submissions.

- Information such as international pricing data, ICER analyses, marketing, advertising, and lobbying is out of scope and is likely to be misleading or misinterpreted. The PDAB should remove this request for information from the Submission Materials.

A. The Submission Material requirements are beyond the scope of and inconsistent with Washington law, may be impossible for manufacturers to satisfy; and impose extensive administrative burden and costs for both manufacturers and the state.

Elements of the Submission Material requests are beyond the scope of and inconsistent with Washington law. Washington statute states that for prescription drugs chosen for an affordability review, "the board may examine publicly available information as well as collect confidential and proprietary information from the prescription drug manufacturer and other relevant sources."[3] This section of the Statute conveys that the PDAB is responsible for 1) collecting information in the public domain; and 2) examining the materials they receive whereas manufacturers are solely responsible for submitting their own data.

Contrary to the statute, the Submission Form is asking ***manufacturers*** to 1) collect information ***in the public domain*** (e.g., the Orange Book and Purple Book, lobbying disclosures, and Open Payments); and 2) ***examine information*** on the Board's behalf. For example, the PDAB is asking manufacturers to ***research and conduct a full comparative analysis*** of their own drug and their competitors' therapeutic alternatives. As pictured below, the Submission Form states that manufacturers should provide the following information on their competitors' products:

- Comparison of guideline recommendation to the reviewed drug
- Comparison of cost to reviewed drug
- Comparison of efficacy to the reviewed drug
- Comparison of safety profile to the reviewed drug
- The clinical effectiveness conclusion from Cochrane Library, ICER, NICE, CADTH, IQWiG, NHCI, and INAHTA

[3] RCW 70.405.040(2).

Summary Tables of Therapeutic Alternatives for Indication 1

Generic/ Biosimilar Name	Brand Name	Place in Therapy	Comparison of Guideline Recommendations To Therapy Drug	Cost Comparison To Reviewed Drug	Efficacy Comparison To Reviewed Drug	Safety Comparison To Reviewed Drug

Institution/ Organization	Clinical Effectiveness Conclusion	Reference Number
Cochrane Library		
ICER (US)		
NICE (UK)		
CADTH (Canada)		
IQWiG (Germany)		
NHCI (Netherlands)		
INAHTA (international)		

Not only are these requests inconsistent with the statute, but they may be impossible to satisfy. It has taken other PDABs (e.g., Colorado and Oregon) several months, and in some cases over a year, to collect some of this data. And yet, manufacturers are required to provide this information within 30 days or face steep penalties for noncompliance. Moreover, the Submission Materials include requests for information that manufacturers do not have and cannot obtain. For example, they request "cost" information on competitors' therapeutic alternatives. Yet, manufacturers cannot obtain cost or drug pricing information on competitor products.

Likewise, the Submission Materials require manufacturers to estimate a patient's out-of-pocket costs as well as average patient costs after coupons are exhausted, but this information is dependent on patients' health plans as payers ultimately determine what patients' pay out of pocket. In some instances, plans use vendors to implement alternative funding programs (AFPs), which manufacturers often do not have line of sight into. AFPs also impact a patient's out-of-pocket cost. Given out-of-pocket costs vary widely based on plan type and manufacturers may be unaware of AFP arrangements or similar programs, this information should come from payers.

Finally, the sheer volume and nature of the requested information are likely to significantly increase the administrative burden and cost not only for industry but also for the state. For example, the Colorado PDAB has cost the state approximately $1 million each year, and it took them over a year to collect and analyze affordability data for five drugs.[4] Yet, the data they requested and reviewed is not nearly as extensive as what Washington is requiring. Therefore, the PDAB should modify the Submission Materials so that they are consistent with Washington law and do not set up impossible standards to meet.

B. The content of the Submission Materials in its entirety is confidential, and the PDAB

[4] EACH PIC Coalition, Comment in Opposition to Expanding PDAB Upper Payment Limit Authority (H.B. 424), (Feb. 4, 2025), https://mgaleg.maryland.gov/cmte_testimony/2025/hgo/1wZMXj3S5kRgHKSDr-xnybs6yCe6FykXR.pdf.

must establish a secure method to transmit such information before requiring submissions.

As stated in Revised Code of Washington and reiterated in Washington Administrative Code, in conducting its affordability reviews, "all information collected [from the manufacturer] by the board . . . is confidential and not subject to public disclosure."[5] Therefore, the contents of manufacturers' completed Submission Materials in their entirety must be kept confidential.

Disclosing confidential information in the public domain (e.g., average manufacturer price (AMP), discounts, rebates, net price, patient assistance program (PAP) dollar value, and coupon savings) can negatively impact manufacturers' ability to negotiate with parties throughout the supply chain and can have unintended consequences for patients. For example, if the total dollar value of PAP and copay assistance programs is publicly disclosed, vendors that administer maximizer programs or AFPs likely will use that information to manipulate and artificially inflate patients' cost-sharing amounts. Therefore, the PDAB must confirm the contents of manufacturer-completed Submission Materials will be kept confidential in their entirety.

Additionally, the PDAB must establish a method to securely transmit highly confidential information before it can require data submissions. The method must have appropriate safeguards to ensure there are no data breaches. This step is consistent with other states. For example, Colorado PDAB has created a secure File Transfer Protocol for the submission of confidential, proprietary, or trade secret information.[6] WA PDAB must establish a similar process before the Board can require manufacturers to complete the Submission Forms.

C. Certain required information is out of scope and is likely to be misleading or misinterpreted.

The Submission Materials include a request for "Drug Price in Other Developed Countries," including Australia, Canada, France, Germany, Italy, Japan, Spain, Sweden, Switzerland, and United Kingdom.[7] Additionally, the PDAB has stated that if a manufacturer does not provide requested data, then the PDAB will use ICER data. Such data is out of scope and is likely to result in misinterpretations. First, U.S. drug pricing is not comparable to drug pricing in other countries. Other countries' prices are influenced by several factors unique to each country, including populations, preferences, economic conditions, and cultural norms that may significantly differ from those in the U.S.[8] Additionally, in many countries, governments are the primary or sole payer, and they require manufacturers to accept price controls or the country will prevent or restrict coverage for patients.[9] Some countries have discriminatory policies or even threaten to

[5] RCW 70.405.040 (7); WAC 182-52-0050(3).
[6] Colorado Prescription Drug Affordability Board, Upper Payment Limit Data Submission Guidance, https://drive.google.com/drive/folders/1dbDbYz_GBwE-UjFP1b3cGZVKoq3ulHq8 (last visited Mar. 14, 2025).
[7] https://www.hca.wa.gov/assets/program/pdab-manufacturer-form.pdf
[8] PhRMA, Comment on Minnesota Department of Health Draft Form and Manner for Prescription Drug Data Sets—Updated November 17, 2023 (Dec. 8, 2023).
[9] *Id.*

break patents on valuable new medicines to artificially lower prices, which are not permitted in the U.S.[10] These policies delay patient access to new medicines.[11] The international pricing data that manufacturers would be required to submit, therefore, reflects harmful, and in some instances, illegal practices used in other countries to set prices and that negatively impact market-based competition.[12] This competition is needed to expand patient access, improve affordability, and encourage investment in new treatments and cures.[13]

Moreover, it is unclear how international pricing information is relevant or what the PDAB intends to do with it. If the PDAB intends to set an upper payment limit (UPL) aligned to international pricing, such a price cap is likely to have a negative impact throughout the supply chain. For example, in instances where manufacturers have reduced their list prices, pharmacy benefit managers then excluded those medications from their formularies.[14]

Furthermore, price calculations by ICER as well as the listed the countries routinely utilize information from the discriminatory quality-adjusted life year (QALY) metric, either directly through cost-effectiveness analyses or indirectly through international price referencing schema.[15] However, the PDAB is prohibited from using QALYs in its methodologies due to the QALY's inherently discriminatory application, which has been shown to disadvantage older adults and individuals with disabilities.[16] Therefore, the PDAB should remove the request for international pricing information from the Submission Materials and should exclude any ICER analyses.

The Submission Forms also require manufacturers to submit information on marketing, advertising, and lobbying. However, the breadth of issues that are covered in lobbying expenditures make them wholly irrelevant to the PDAB affordability review process, and lobbying expenditures are not calculated on an NDC basis. Moreover, marketing and advertising are described as including contributions to patient advocacy groups. However, advocacy groups engage in policy and advocacy efforts, not marketing and advertising. It is inaccurate and

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[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] Lucia Mueller, Merck Lowered the Price of Januvia—Insurers Dropped It from Formularies (Mar. 6, 2025) https://www.pharmacychecker.com/askpc/januvia-merck-pbms-formulary-drop/?utm_source=costcurve.beehiiv.com&utm_medium=newsletter&utm_campaign=clearing-the-decks-walgreens-gets-sold-makary-on-drug-prices-and-the-economic-impact-of-clinical-trials&_bhlid=18a83f901bdd164018b70d28d09a2903a1e91eae#! (last visited Mar. 14, 2025); AmerisourceBergen, *Skyrocketing Growth in PBM Formulary Exclusions Continues to Raise Concerns about Patient Access*, (May 2022), https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[15] https://pmc.ncbi.nlm.nih.gov/articles/PMC10391192/
[16] RCW 70.405.050(3); National Council on Disability, *Quality-Adjusted Life Years and the Devaluation of Life with Disability*, National Council on Disability (Nov. 6, 2019), https://www.ncd.gov/assets/uploads/reports/2019/ncd_quality_adjusted_life_report_508.pdf (Mar. 5, 2025).

inappropriate to categorize their work as marketing or advertising. Such contributions are also out of scope.

As one of the nation's leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address these gaps in affordability and access, as well as protect our nation's leading role in the global innovation ecosystem.

We know that patients are counting on us to develop, bring to market, and support access to our medicines. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives.

Sincerely,

Terrell Sweat

Terrell Sweat
Director, U.S. State Government Affairs
Johnson & Johnson Services, Inc.