August 22, 2025

VIA ELECTRONIC MAIL

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

Re: PDAB Preliminary Affordability Determination

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. appreciates the opportunity to submit these comments in advance of the PDASC's meeting on August 25, 2025. We write to raise our significant concerns regarding the PDAB's preliminary determinations for FARXIGA® and JARDIANCE® made during the Board's July 28, 2025 meeting — specifically, that the use of each product has either led to affordability challenges for the Maryland State health care system or high out-of-pocket costs for patients under the following circumstances:[1]

- For both FARXIGA® and JARDIANCE®, the Board found that (i) the percentage change in the wholesale acquisition cost ("WAC") of each drug, over time, is substantially larger than the relative percentage change in inflation (*i.e.*, rate of increase in inflation), and that (ii) at the 90th percentile, patient out of pocket ("OOP") costs in certain markets is disproportionate to the net cost paid by "payors;"
    - For FARXIGA® only, the Board concluded that total gross spending on the product for state and local governments exceeds 1% of gross prescription drug spend for state and local governments; and
    - For JARDIANCE® only, the Board found that total gross spending for the product for state and local governments exceeds 1.8% of gross prescription drug spend for state and local governments.

We analyze the fundamental flaws of each of the Board's preliminary determinations for FARXIGA® and JARDIANCE® in turn below.

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I. The Board's Decision-Making Processes and Other PDAB Activities Continue to Lack Sufficient Transparency

As an initial matter, and as we have communicated in many prior submissions to the PDAB and PDASC, the Board's implementation and administration of the Maryland PDAB statute is

[1] *See* Maryland Prescription Drug Affordability Stakeholder Council, August 25, 2025 Meeting Materials, "Cost Review Study Process Update and Next Steps Presentation," at 9, at https://pdab.maryland.gov/Documents/meetings/2025/August%2025%20PDASC%20-%20Cost%20Review%20Overview%20%282%29.pdf.

inconsistent with Maryland's Administrative Procedure Act. Among other examples, the Board's lack of transparency regarding its decision-making processes and other PDAB activities is contrary to the public interest and has deprived AbbVie and all other impacted stakeholders, including Maryland resident patients of the ability to effectively and predictably participate in the Board's cost and policy review processes.[2]

II. 'WAC Growth Exceeding Inflation' Is Not a Useful Factor For Assessing a Drug's Affordability

At the Board's July 28, 2025 meeting, PDAB members discussed how over time, the rate of increase for FARXIGA®'s and JARDIANCE®'s WACs has purportedly risen higher relative to the rate of inflation during the same time period and concluded during this oral readout that it meant or indicated that the drugs presented a potential affordability challenge. At this juncture, such a conclusion is, at best, an unsupported logical leap that stakeholders have not been afforded the opportunity to vet further (*i.e.*, the Board delivered this finding in an oral readout during the PDAB's July 28 meeting, and no supporting data has been disclosed by the Board to date).

Without more, the Board concluded that a circumstance for which FARXIGA® and JARDIANCE® have led to **"affordability challenges"** (an undefined term with an undefined scope) for Maryland's **"State health care system"** (the scope of which is also undefined) is the fact that the percentage change, **"over time"** (an undefined term) in the list prices of FARXIGA® and JARDIANCE®, respectively, is **"substantially higher."** The Board offers no further clarification regarding what constitutes "substantially higher" (*e.g.*, statistical significance?) or the scope of the relevant time period, and the Board has not made relevant data or other information publicly available to interested stakeholders to vet these claims further.

As a threshold matter, the Board remains arbitrarily and stubbornly wed to list price as a purportedly meaningful gauge of, and means to assess, the "affordability" of drugs. The Board's comparison of the rate of the drugs' WAC growth (*i.e.*, list price increases) to the rate of inflation is inherently flawed and an inappropriate measure for affordability assessments. The Board has failed to explain how a WAC that has increased at a higher rate than inflation makes a drug "unaffordable." Indeed, to reiterate, a drug's WAC generally represents a manufacturer's undiscounted list (*i.e.*, gross) price for the product to wholesalers and direct purchasers. ***It is neither an actual price paid, nor a representation of the true cost of a drug for a given transaction***. In contrast, the net price of a drug reflects actual prices paid in the U.S. market

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[2] *See, e.g.*, AbbVie's Comments on MD PDAB Draft UPL Action Plan (August 26, 2024), at https://pdab.maryland.gov/Documents/reports/UPL%20Final%20Comment%20Packet%20%281%29.pdf; AbbVie's Written Testimony to MD Legislative Policy Committee (October 18, 2024)), at https://mgaleg.maryland.gov/meeting_material/2024/lpc%20-%20133746007389905217%20-%20All%20Meeting%20Materials.pdf; AbbVie's Comments on MD PDAB Proposed Regulations Issued October 28, 2024 (November 8, 2024), at https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf; AbbVie's Comments on MD PDAB Proposed Amended MD PDAB Cost Review Regulations (December 2, 2024), at https://pdab.maryland.gov/Documents/comments/2024.12.02-%20Regulations%20Comments%20%281%29.pdf; AbbVie's Comments on MD PDAB Proposed Regulations (February 10, 2025), at https://pdab.maryland.gov/Documents/comments/2025/January%2010%2c%202025%20Register%20Comment%20Packet.pdf. *See also* AbbVie's Comments on MD PDAB Dossier for FARXIGA® (July 3, 2025), at https://pdab.maryland.gov/Documents/comments/2025/Farxiga%20Dossier%20Comments%207.3.2025.pdf.

including, for example, but not limited to: rebates and coverage gap discounts in Medicare Part D; rebates to the Medicaid Program; discounts under the 340B Drug Pricing Program; manufacturers' payments to drug channel participants, including administrative and other fees to PBMs as well as fees and discounts to pharmacies, wholesalers, and other purchasers; patient assistance and copayment support funds; and negotiated and statutory rebates to third-party payers are the largest and most significant components of gross-to-net difference.

WAC also does not reflect what patients pay for a drug. A patient's out-of-pocket ("OOP") costs are influenced by their insurance coverage, deductibles, copayments, and coinsurance, which are determined by their health plan's benefit design. None of these variables has any relation to a drug's WAC. Moreover, even insured patients might pay the full retail price if they have not met their deductible or a lower price if the patient participates in a manufacturer discount program. Uninsured patients may pay a pharmacy's "usual and customary" price, which can be higher than the net prices paid by other payers.

It is misleading to assess the affordability of a drug through the lens of its list price. A drug's list price generally does not reflect the nuance and complexities of the pharmaceutical supply chain, including a wide variety of transactional elements that have the practical effect of lowering the price of a drug (*e.g.*, that which is ultimately realized by a patient, reimbursed by a payor, or otherwise). Such transactional elements may include, for example, without limitation: rebates and coverage gap discounts in Medicare Part D; rebates to the Medicaid Program; discounts under the 340B Drug Pricing Program; manufacturers' payments to drug channel participants, including administrative and other fees to PBMs as well as fees and discounts to pharmacies, wholesalers, and other purchasers; patient assistance and copayment support funds (*e.g.*, sponsored by manufacturers or other 3rd party assistance programs/foundations).

Critically, while the PDAB broadly asserts on the one hand that the percentage change in FARXIGA®'s and JARDIANCE®'s relative WAC growth rates have posed an affordability challenge to the Maryland State healthcare system, on the other hand, the Board has neither established any sort of causal link between the two distinct growth rates (*i.e.*, WAC and inflation), for example:

- What segment of the "State health care program" does the PDAB claim faces an affordability challenge?
- What exactly is that challenge?

To begin with, stakeholders have no visibility into what the Board views as constituting, conceptually, the "State health care system." To the extent Maryland views its "State health care system" as including state-sponsored health plans, stakeholders likewise have no visibility into how such health plans' benefit designs may be impacting Maryland's expenditures on drug costs, and whether and to what extent the Board has or should consider investigating those plan benefit designs.

Aside from these fiscal considerations, the Board's preoccupation with changes to WAC almost entirely disregards the value the product at issue delivers to patients and Maryland's "State health care system," including a product's role in improving health outcomes and generating cost savings across the broader healthcare system. Concerns about the use of wholesale acquisition price or "list price" as the sole or primary pricing metric for affordability were repeatedly raised during 2019 legislative deliberations during the initial formation of the

PDAB, as that metric does not accurately reflect the actual acquisition price of a prescription drug and fails to take into consideration the affordability impact of the full supply chain. At that time, the General Assembly acknowledged those concerns and assured stakeholders that wholesale acquisition price would not be the sole basis for affordability determinations, going so far as to amend Section 21-2C-09(b)(2)(i) of the original legislation to ensure that wholesale acquisition price be considered in combination with "other relevant prescription drugs cost indexes" in both drug selection and conducting cost review.

Furthermore, the only references to inflation and consumer price indexing included in the original legislation are to ensure that prices are accurately reflected. Nowhere does the legislation indicate that the rate of inflation serves as a bar by which any price changes should be judged for affordability determinations. The legislative intent and the consideration of the complexity and impact of the "full supply chain" is reflected throughout the General Assembly's comments on the bill and by the members and staff of the PDAB throughout its tenure, and yet now affordability determinations are being made based on an overly simplified and flawed view of a drug's wholesale acquisition cost and its relation to inflation, fulfilling the concerns that were raised and addressed during the original PDAB debate. The Board's review violates the spirit of the legislative intent of the law.

Not only do the numerous deficiencies in the logic underpinning the Board's preliminary determinations for FARXIGA® and JARDIANCE® raise serious concerns and questions regarding the validity of the Board's reasoning, judgment, and conclusions more broadly, the PDAB's analysis regarding this particular circumstance identified by the PDAB is simply inaccurate and unsupported by actual, objective data. Indeed, price increases for FARXIGA® and JARDIANCE® have generally remained at or below inflation levels over the past five years. For example, the 2022-2024 cumulative rate of inflation was 13.3%[3]; FARXIGA® and JARDIANCE®'s price increases over the same period totaled well under, at 9.3% and 11.4% respectively.[4]

Under Maryland's APA, an agency's decision or action is unlawful if it is "arbitrary and capricious."[5] This legal standard requires agencies to engage in reasoned decision-making. An agency acts arbitrarily and capriciously when its decisions lack a rational basis, or "when decisions are made impulsively, at random, or according to individual preference."[6] Agencies must consider relevant information and factors and make their decisions according to objective standards.[7] Courts

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3 U.S. Bureau of Labor Statistics, "Consumer Price Index," at https://www.bls.gov/cpi.

4 See AnalySource- First Databank https://www.fdbhealth.com/solutions/analysource-drug-pricing-software.

5 Md. Code, State Gov't § 10-222(h)(3)(vii).

6 *Harvey v. Marshall*, 389 Md. 243, 299, 884 A.2d 1171, 1205 (2005) (emphasis added); *see also id.* (stating that agency actions must be "reasonable [and] rationally motivated"); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that agency action is arbitrary and capricious if the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise").

7 *Compare Maryland Dep't of the Env't v. Cty. Comm'rs of Carroll Cty.*, 465 Md. 169, 227, 214 A.3d 61, 96 (2019) (upholding the Maryland Department of the Environment's permit requirement because it derived from two standards that "were the result of significant deliberation among various stakeholders" and a discussion of the practicability and feasibility of the requirement that spanned at least three years) *with Baltimore Policy Department v. Open Justice Baltimore*, 485 Md. 605, 620, 666, 301 A.3d 201, 209, 236 (2023) (holding the Department's decision to deny a fee waiver was arbitrary and capricious because it based its denial "on mere conclusory

have invalidated agency decisions and actions where the agency considered irrelevant factors, failed to identify the factors guiding its determination, or failed to identify objective standards governing its decisions.[8] The Board's decisions and actions to date are in violation of Maryland's APA, as well as the statutes authorizing the Board's actions, Md. Code, Health-Gen. §§ 21-2C-01 *et seq*.

III. Assessing Drug Affordability Based Solely on High-Deductible Health Plans is Misleading and Fails to Recognize the Differences in Insurance Benefit Designs

A major concern with using high patient OOP cost metrics — particularly those at the 90th percentile — is that they do not account for differences in insurance benefit design, such as variations in deductibles and co-payments, which can significantly impact individual patient expenses. This lack of context means the metric fails to accurately represent cost burdens across different insurance plans and instead disproportionately highlights high-deductible health plans – which, as the name clearly indicates, have higher deductibles and OOP maximums. By focusing solely on the highest patient OOP costs without accounting for insurance benefit design, financial assistance programs, or variations across plan types, the Board further distorts its affordability analysis and fails to accurately represent the real experiences of most patients. Additionally, comparing OOP costs for patients with commercial insurance to those for Medicaid patients is problematic, as Medicaid operates under entirely different eligibility criteria, cost structures, formularies, and benefit designs, making such comparisons misleading and inaccurate. Furthermore, this assessment doesn't consider the financial support offered by manufacturers and other entities, like patient foundations, to offset patients' out-of-pocket costs that are ultimately determined by individual plan and benefit design.

IV. Focusing on Total State and Local Drug Spend Will Inherently Identify Drugs with High Utilization, Rather than Focusing on True Affordability Issues

Prioritizing total state and local spending on prescription drug costs is a flawed way to assess affordability. This approach tends to unfairly penalize products with high utilization, without considering factors that likely drive that utilization, such as patient health benefits, clinical outcomes, and/or broader healthcare savings that these products may provide. Perversely, it favors drugs with limited utilization, often due to unfavorable clinical outcomes, which is an incredibly shortsighted perspective.

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statements" and "failed to meaningfully consider all relevant factors"); *Sheriff Ricky Cox v. Am. Civ. Liberties Union of Maryland*, 263 Md.App. 110, 138, 321 A.3d 1255, 1272 (Md. App. Ct. 2024) (holding that the Sheriff's lack of consideration of all the "other relevant factors" in his determination of a fee request was arbitrary and capricious").

[8] *State Dep't of Health v. Walker*, 238 Md. 512, 523, 209 A.2d 555, 561 (upholding conclusion that the Department's *ad hoc* decision to deny a permit application was arbitrary); *Maryland Real Estate Comm'n v. Garceau*, 234 Md.App. 324, 365, 172 A.3d 496, 521 (finding the Commission's sanction was arbitrary and capricious because it failed to consider exculpatory factors in its decision); *see Cnty. Council of Prince George's Cnty. v. Palmer Road Landfill, Inc,* 247 Md. App. 403, 419, 236 A.3d 766, (Md. Ct. Sp. App. 2020) (reversing a time limitation that the Council initially "waived and failed to abide themselves" but later sought to enforce); *Forman v. Motor Vehicle Admin.*, 332 Md. 201, 220, 630A.2d 753, 763 (1993) (reversing license revocation because agency failed to indicate what it found or how it reached the conclusion with respect to material issues); *Dashiell v. Maryland State Dept. of Health and Mental Hygiene*, 327 Md. 130, 137-38 (Md. Ct. App. 1992) (finding the Department's decision to terminate two employees were so unsupported that it renders the determination "essentially arbitrary and capricious").

Finally, the singular focus on drug prices in the Maryland PDAB's statutorily defined drug affordability review processes minimize clinical and societal benefits of pharmaceuticals and the dynamics of the industry's complex pricing and supply chain ecosystem, to the detriment of Maryland patients. The Board appeared to have no interest in assessing value-related factors, including unmet needs and comparative clinical effectiveness, among others. Improved patient access to innovative treatments — a common goal across all stakeholders — is diminished by the Board's constant focus on "affordability" (*i.e.*, cost-exclusive) without consideration of value as well.

V. The Board Needs to Expand its Focus Beyond Cost-Focused Factors in Accordance with its Complete Statutory Mandate and to Address Affordability Challenges

While we recognize that many statutorily required factors are cost-focused, including for example, the cost of administering and distributing the drug, we believe critical elements have not been appropriately captured, contemplated or discussed. We respectfully ask the Board to reconsider the factors used in determining affordability. Specifically, we urge the Council to ask additional questions and considerations, such as:

- The statute requires that the board must consider "[t]he relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives."[9] This element was missing from the dossiers and discussions, but should include the following:
    - **Comparative Effectiveness.** In assessing a selected drug relative to its alternatives, PDABs must review literature that compares these treatments' safety and effectiveness for each indication.
    - **Economic Evaluation.** Understanding a selected drug's value relative to its costs and its impact on state budgets must involve analyses that unify many criteria central to PDABs' functions. Ensuring adequate review of cost-effectiveness and budget impact literature for a selected drug is critical.
    - **Cost Relative to Therapeutic Alternatives.** Drugs prices must be viewed in terms of the totality of the value provided and concerns on affordability limited to when the "price" is higher than truly comparable therapeutic alternatives and **disproportional** to added benefit.
    - **Input from clinical experts:** Consulting with healthcare providers with clinical expertise on the range of appropriate therapeutic alternatives and potential broader benefit of medicines under review to the state.
- **Patient Costs and Access.** The size of out-of-pocket costs depends on a combination of the drug's price and formulary decisions made by health insurers and PBMs. In addition, manufacturers and patient advocacy groups sometimes offer patient assistance that offsets out-of-pocket costs. Understanding the interplay of these costs and the potential impact on patient affordability and access is crucial to PDAB work. Understanding how insurers cover a drug, the costs for patients who take the drug, and the tools patients can use to afford medications are vital considerations for PDABs when assessing a drug's affordability, including but not limited to:

[9] Md. Code, State Gov't § 21-2C-09(b)(2)(ix).

- The role of patient assistance programs: Evaluating the role of manufacturer-sponsored patient assistance programs in supporting patient access to medicines.
- Input from patients and stakeholders: Engaging with patients and other individuals with expertise to gather their perspectives and experiences on OOP impact to access
- Impact of insurance benefit design on patient access: For example, what is the patient's benefit design and how does that impact OOP costs?

- Because of this range of factors, we respectfully object to the Board's narrow focus on isolated factors. However, if the Board intends to rely primarily on these three factors, we urge the Board to reconsider the limited way it is viewing them to assess affordability. Furthermore, we request that each factor be given ample opportunity for stakeholder input and evaluation regarding its relevance to determining affordability for both patients and the state.

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In closing, it is unclear to us how the Board can proceed to the policy review process, in which it will attempt to "confirm the drivers and market conditions causing the affordability challenge phenomena" and "identify the policies that may address those drivers and redress the affordability challenges" when its determination that FARXIGA® and JARDIANCE® have led to affordability challenges is far from reasonably supported. We also maintain and reiterate our serious concerns, as detailed in the Company's prior submissions to the Board, incorporated by reference herein,[10] of the Board's reliance on flawed data, policies, and procedures and its questionable judgment displayed to date in connection with its drug selections and cost and affordability review activities.

The Board's recent deliberations continue to show us even more why we must be removed from the cost review process. We therefore request the Board to **remove SKYRIZI® from the Affordability Review process.** In the event the Board chooses to proceed with the evaluation of SKYRIZI®, we strongly urge the Board to review our comment letters and deliberate thoroughly on our submission and **request the Board to affirm that SKYRIZI® does not present an affordability challenge and is indeed affordable for the state of Maryland and its residents.**

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[10] *See, e.g.*, AbbVie's Comments on SKYRIZI®'s Selection for Cost Review (July 22, 2024), at https://pdab.maryland.gov/Documents/comments/Board%20selected%20Drugs%20Comments.pdf; AbbVie's Comments on SKYRIZI®'s Referral to the Stakeholder Council (May 10, 2024), at https://pdab.maryland.gov/Documents/comments/AbbVie_MD%20PDAB%20Comment%20Letter_May%209%2024-FINAL.pdf; AbbVie's Comments on the Board's List of SKYRIZI® Therapeutic Alternatives (May 13, 2024), at https://pdab.maryland.gov/Documents/comments/MD%20PDAB%20Therapeutic%20Alternatives%20Comments%20-%20SKYRIZI.pdf; AbbVie's Comments on SKYRIZI®'s Selection and Referral to the Stakeholder Council (April 23, 2024), at https://pdab.maryland.gov/Documents/comments/4.29.2024%20PDASC%20Comments%20combined.pdf.

Thank you for this opportunity to provide our comments on the Board's preliminary affordability determinations for FARXIGA® and JARDIANCE®. Please contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Kim Fitzpatrick
Vice President, State Government Affairs
On behalf of AbbVie Inc.