AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

January 23rd, 2024

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Public Comments - Maryland Prescription Drug Affordability Board Meeting, January 29th, 2024

Dear Members of the Maryland Prescription Drug Affordability Board:

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, is grateful for the opportunity to submit public comments throughout this drug affordability process. We hope the Board will consider these statements as you continue forward with your drug affordability program.

About AiArthritis. AiArthritis is a leader in advancing education, advocacy, and research for those impacted by autoimmune and autoinflammatory arthritis (AiArthritis) diseases through peer-led guidance, collaboration, and resources that are driven by patient-identified issues and patient-infused solutions. As we are led by patients we understand how important it is to be able to access safe, efficacious, and affordable treatments. As patients living with heterogeneous conditions, we also understand there is no one-size-fits-all drug - even for those diagnosed with the same disease. Through lived experience, we also know that disrupting continuity of care often leads to uncontrolled disease, comorbidities, and significantly decreased rates of remission.

On behalf of patients and care partners residing in Maryland, we thank the state for recognizing a need to address the high costs of prescription drugs**.** We appreciate the MD PDAB for your dedication to ensuring patients who have or who are utilizing the drugs that will be up for review will have adequate opportunity to provide input. **In saying this, as a group led by patients who represented 40% of those participating in the CO PDAB and CMS Listening Sessions (Enbrel & Stelara), we feel positioned to share lessons learned and request the opportunity to work with the MD PDAB and Stakeholder Council as you set up processes to ensure clear and meaningful participation.**

For the purpose of this meeting, we will focus on the following agenda items: Cost Review Study Process COMAR 14.01.04: "Identify" and "Select" Phases

"Identify" Phase

- **Public Reporting of Drug Affordability Issues (COMAR 14.01.04.01).** We are eager to learn more about data collection plans associated with the affordability reporting phase**.** During a brief conversation we had with MD PDAB staff, it was disclosed that there are plans to refer to what was done at both CMS and the CO PDAB when developing these processes. We encourage you to consider feedback from stakeholders who participated in these regarding what worked, what did not, and recommendations for improvement. Some highlights:
    - **Learning from the CO PDAB.** CO did some things right – for example, their staff – Callie and Lila – were accessible for questions and always willing and eager to provide answers.

Especially given all PDABs operate slightly different, which includes patient engagement opportunities, it is highly recommended to engage with patients/caregivers and patient organizations often to provide clarity and encourage input.

- **Perhaps the biggest mistake the CO PDAB made was not obtaining patient input on their survey design (which were also the questions used for the live Discussion Group sessions).** Questions like, "Have you ever skipped a dose because your drug wasn't affordable?" or "Have you ever stretched out a dose because your drug wasn't affordable?" are two separate questions. As a person who is on biologics and who participated in the Cosentyx sessions, I was unable to answer the question as phrased. I explained that, "Yes, I have skipped a dose and, yes, I have stretched out doses. But it has zero to do with affordability. Because of the manufacturer support program, I pay $0 out of pocket. But if I have to skip or stretch it's because my insurance company is enforcing prior authorization or step therapy."
    - Unfortunately, the data that will be collected from the survey will lack some statistical significance due to question design issues.
    - See all of AiArthritis recommendations for the CO PDAB here.

- **Learning from CMS Listening Sessions and Survey.** While we applaud CMS for their willingness to include patient voices in their data collection efforts, the difficulty around recruitment, ease of participation (both Listening Sessions and survey), and lack of realistic samples/demographic participation, it is unclear how successful these methods will prove to be.
    - One area CMS is succeeding, and we encourage the MD PDAB to follow their lead, is their willingness to continue listening to patient/Patient Organization feedback and ideas to further patient engagement and patient organization engagement more in the future.
    - See all of AiArthritis recommendations for CMS here.

"Select" Phase

- **COMAR 14.01.04.03.** We applaud the MD PDAB for considering multiple opportunities for stakeholder input throughout the Selection phase of the process, *including encouraging communication with the Stakeholder Council (in addition to the Board)*. AiArthritis has often questioned the lack of direct involvement with PDAB Council's, so we would like to commend you on these opportunities, which include:
    - **Any written or oral public comment to the Stakeholder Council concerning the drugs proposed for referral the Stakeholder Council.**
    - **Therapeutic Alternatives**. Public may provide *written comments* regarding therapeutic alternatives (30 days).
    - **Board Selects Drugs for Cost Review**. Public may provide *oral and written comments to the Board* concerning the selection of a prescription drug product for cost review.

Recommendations

Enlist patients to review outward facing materials prior to launch. Enlist those who have been diagnosed and treated with the type of drugs in review (patients/caregivers) to review question design associated with any

written or oral comment opportunities. We know from decades of work involving patients as partners in the research space (called Patient Research Partners/PRPs) that data collection and process development hugely benefit from involving patients early and throughout all phases of the initiative.[1] Failure to implement this step often results in poor recruitment, participation, and data collection.

There was little effort to try and understand patient subgroups.

- **Encourage non-MD residents to participate but have them clearly define demographic information for robust data analysis and the potential to share findings with their resident states**. In the CO PDAB, the opportunity for patient input was open to non-CO residents. However, the only residency question was, "Are you a CO resident?" or "Not a CO resident."

There was little effort to try and understand the potential cause of affordability issues, if any. Most patients are not familiar with step therapy, prior authorization, non-medical switching, accumulator or maximizer programs, or other insurance driven protocols that can limit access and impact affordability. Asking detailed questions will help the patient/caregiver craft "why" their drug was/is affordable is vital to ensuring the answers obtained. Rich data will equate data that is more representative of real affordability issues.

- **Example follow up questions:**
  - **Can you provide a story that explains your answer.** This can help assess the why rather than to simply conclude, "This drug was reported as unaffordable by x% of patients."
  - **Are you aware if your affordability issue is the result of one of the following known insurance protocols?**
    - Step Therapy
    - Accumulator
    - Maximizer
    - Alternative Payment ()
    - Medicare/Medicaid will not accept manufacturer copay assistance programs

- **Consider hosting several small, breakout meetings with both patient organizations and patient/caregiver representatives, separately and collaboratively, at each phase of the process.** At no time should patient-facing materials be distributed without the review of patients/caregivers, as only those with lived experience can judge clarity and correctness. However, do not dismiss the value patient organizations can provide from their experience developing surveys and education for their patient community.

In closing, we would like to extend gratitude again on behalf of AiArthritis, and all persons living with our diseases, for this opportunity to participate in this process and to provide comments that we hope can help as you evolve it. We appreciate every opportunity given to patients that enables us to have a voice in matters involving our healthcare.

[1] Fox, G., Lalu, M.M., Sabloff, T. et al. Recognizing patient partner contributions to health research: a systematic review of reported practices. Res Involv Engagem 9, 80 (2023). https://doi.org/10.1186/s40900-023-00488-5

Thank you for considering our suggestions and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,

Tiffany Westrich-Robertson

Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis