



February 4, 2025

Senator Pamela Beidle
Chair
3 East Miller Senate Office Building
Annapolis, Maryland 21401

Delegate Joseline A. Pena-Melnyk
Chair
240 Taylor House Office Building
Annapolis, Maryland 21401

Senator Antonio Hayes
Vice Chair
3 East Miller Senate Office Building
Annapolis, Maryland 21401

Delegate Bonnie Cullison
Vice Chair
241 Taylor House Office Building
Annapolis, Maryland 21401

Dear Chair Beidle, Vice Chair Hayes, Chair Pena-Melnyk and Vice Chair Cullison:

I am writing on behalf of the Color of Gastrointestinal Illness (COGI) to share my concerns about SB357 and HB424 requiring the Prescription Drug Affordability Board to establish a process for setting upper payment limits for all purchases and payor reimbursements of prescription drug products in the State that the Board determines have led or will lead to affordability challenges. As the founder and CEO of COGI, I can attest to my personal experience and the experiences of so many patients that we represent that access to affordable care is the most important challenge we face. We are very concerned that the PDAB has ignored concerns shared by patients, has no plans to meaningfully engage patients and has failed to communicate how patients will be protected from egregious utilization management strategies because of UPLs.

I founded COGI based on my own personal experience. I have been on 16 medications, from pills to injections to suppositories. I started having rectal bleeding at the age of 13, yet was not diagnosed with Crohn's disease until 2018 after a 30-year journey. And even with diagnosis, I did not get an advanced therapy prescribed, Skyrizi, until December, 2023. That medication changed my life. Yet, I also recognize that I have a progressive disease and my health has been forever impacted by a delayed diagnosis and delayed prescribing of the advanced therapy I needed.

Based on my experience and so many like me, it is imperative that the activities of the PDAB do not result in patients experiencing further delays in receiving the drugs needed to achieve the outcomes that matter most to them and that evidence demonstrates to be most effective for them based on their personal characteristics. These drugs do not have the same impact on different patients and we should be making sure patients and their physicians are not being steered by payers into prescribing decisions.

The Board has failed to provide any information on how patients will be protected from adverse formulary placement and utilization management strategies in response to an upper payment limit (UPL) that will make patient access to affordable care that much more challenging. In August, 2024, COGI sent a letter to the Board expressing concerns about its ongoing cost review activities, particularly as it

pertains to Skyrizi. COGI represents Black, indigenous and other people of color (BIPOC) who are affected by inflammatory bowel disease (IBD), digestive disorders, gastrointestinal cancer and associated chronic illnesses. Skyrizi is a highly effective and needed treatment for many in our community.

Our letter expressed serious concerns about health equity and access to care.^{1,2} Yet, upon review of the Board's website, we noticed that our comment letter was not posted. It is not clear to me that it was ever shared with the Board or its advisory committee. And it was not mentioned in the Board or advisory committee proceedings. It was posted at a point long after consideration of Skyrizi.

Another letter from COGI and 37 other organizations to the Board specifically commented on the draft UPL Plan and also seems to have been ignored, as none of the concerns it raised were addressed in the revised plan nor was it posted on the website as a letter considered by the Board until long after the meeting.³ For this process to be trusted and credible, the Board cannot simply hope to get this right and ignore the real-world experiences of patients that are the source of our legitimate questions and concerns.

To date, the Maryland Prescription Drug Affordability Board (PDAB) has ignored the pleas of so many in the patient and disability communities for reassurances that their affordability review process will not use discriminatory value assessments that devalue people with disabilities and serious chronic conditions. Instead, we are aware that the Board is being supported by entities that are on record supporting the use of value assessment measures that are barred by federal law under Section 504 of the Rehabilitation Act. The Board has explicitly invited and referenced input from the Institute for Clinical and Economic Review and the Program on Regulation, Therapeutics and Law (PORTAL), both entities supported by Arnold Ventures which has a long history of supporting the generation and use of value assessments that utilize discriminatory measures.^{4,5} Federal law bars use of "any measure, assessment, or tool that discounts the value of life extension on the basis of disability" by an entity receiving federal financial assistance, including Medicaid.⁶ It also bars denying care based on "bias or stereotypes about a patient's disability."⁷ The final rule explains, "Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates."⁸ Therefore, any reference to measures such as quality-adjusted life years (QALYs) or equal value of life year gained (evLYG) are contrary to federal law.

To help meaningfully engage patients, we were pleased to work with the Ensuring Access through Collaborative Health (EACH) Coalition on a new survey for patients that elicits real-world information about their challenges accessing affordable medications. We do not have reassurances that the PDAB will meaningfully incorporate this data into its decisions.⁹ For now, real-world information is not being

¹ Borum ML. Racial and Ethnic Disparities in Inflammatory Bowel Disease. *Gastroenterol Hepatol (N Y)*. 2023 May;19(5):281-283. PMID: 37799459; PMCID: PMC10548245.

² Liu JJ, Abraham BP, Adamson P, Barnes EL, Brister KA, Damas OM, Glover SC, Hooks K, Ingram A, Kaplan GG, Loftus EV, McGovern DPB, Narain-Blackwell M, Odufalu FD, Quezada S, Reeves V, Shen B, Stappenbeck TS, Ward L. The Current State of Care for Black and Hispanic Inflammatory Bowel Disease Patients. *Inflamm Bowel Dis*. 2023 Feb 1;29(2):297-307. doi: 10.1093/ibd/izac124. PMID: 35816130; PMCID: PMC10210746.

³ http://www.pipccpatients.org/uploads/1/2/9/0/12902828/maryland_pdab_comments_final.pdf

⁴ ICER submissions at https://pdab.maryland.gov/Pages/cost_review_process.aspx

⁵ PORTAL presentation at https://pdab.maryland.gov/documents/stakeholders/2023/havard_med_brigm_prst.pdf

⁶ Section 504 of the Rehabilitation Act, final regulations at 84.57.

⁷ Section 504 of the Rehabilitation Act, final regulations at 84.56.

⁸ 45 CFR Part 84 at 40102.

⁹ <https://eachpic.org/pic-launches-patient-created-survey-on-drug-affordability-and-access/>

considered, and with it the real-world consequences for patients who consistently face barriers to care imposed by payer utilization management strategies.

We support the legislative intent to help patients afford and access the care they need. We do not support the activity of a PDAB to conduct affordability reviews that are discriminatory and that fails to address the tough questions being asked by patients. As it stands, the PDAB does not protect patients or advance health equity. Therefore, we urge the legislature to oppose this bill. Instead, the legislature should be restricting the impact of the PDAB until it provides reassurances that patients are meaningfully engaged and protected against discrimination, with safeguards in place against unintended consequences for patient access to care. In our experience, when payers do not cover the drugs we need, they do not become more affordable – only less.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in cursive script that reads "Melodie N. Blackwell". The signature is written in black ink and is positioned above the printed name.

Melodie Narain-Blackwell

Founder and CEO

Color of Gastrointestinal Illnesses (COGI)