

Colorado Prescription Drug Affordability Board  
Colorado Division of Insurance  
1560 Broadway, Suite 360  
Denver, CO 80202

June 21, 2025

Dear Member of the Colorado Drug Affordability Board,

As a private practice gastroenterologist serving a large population of patients with inflammatory bowel disease who require expensive and complex medical therapy, I believe your board needs to have appropriate representation of stakeholders. The patient is at the center of medical care, and so I would like to commend Dr. Diab for his recommendation of including a patient on the PDAB.

Many patients with inflammatory bowel disease benefit greatly from evolving medical technologies. Sure, these are expensive therapies, but the benefit is far reaching. The biggest challenge for providers and patients relates to the coverage determination and ultimate financial impact of these medications. It is critical to have all parties impacted by the PDAB decisions including our patients.

Sincerely,

A handwritten signature in blue ink, appearing to read 'F. Carreira', with a stylized flourish at the end.

Fernando Carreira, MD

South Denver Gastroenterology

fcarreira@gutfeelings.com

*Via Electronic Submission*

July 9, 2025

Gail Mizner, MD  
Colorado Prescription Drug Affordability Board Chair  
Colorado Division of Insurance  
1560 Broadway, Suite 850  
Denver, CO 80202  
[dora\\_ins\\_pdab@state.co.us](mailto:dora_ins_pdab@state.co.us)

Dear Dr. Mizner:

Johnson & Johnson Innovative Medicine (“J&J”) thanks the Colorado Prescription Drug Affordability Board (“PDAB” or “Board”) for responding to our oral testimony during the May 23, 2025 Board meeting. We also thank the PDAB for adding STELARA® and ustekinumab biosimilars to the agenda for the July 11, 2025 Board meeting. Following the discussion on STELARA AND Ustekinumab biosimilars, we respectfully ask the Board to terminate its planned STELARA UPL rulemaking.

During the May 23, 2025 meeting, J&J asked the Board not to move forward with upper payment limit (“UPL”) rulemaking for STELARA. Among other reasons, we noted the U.S. Food and Drug Administration has approved seven biosimilars and an unbranded biologic of STELARA since affordability reviews began.<sup>1</sup> J&J reminded the Board that it initially ranked HUMIRA® first on its list of eligible drugs but ultimately excluded HUMIRA due to the availability of biosimilars.<sup>2</sup> In response, you noted that J&J “raised a good point regarding biosimilars and excluding HUMIRA” and asked the Board to revisit this issue at the next meeting. **In response, the PDAB has added a “Presentation on STELARA Biosimilars by PORTAL” to the agenda for the July 11, 2025 Board meeting.<sup>3</sup> We further request that the Board treat STELARA in a consistent manner as HUMIRA by cancelling any planned UPL hearings for STELARA after the PORTAL presentation.**

As one of the nation’s leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address gaps in affordability and access as well as protect our nation’s leading role in the global biopharmaceutical innovation ecosystem. We know that patients are counting on us to develop, bring to market, and support access to our

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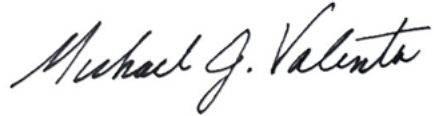
<sup>1</sup> FDA, *Purple Book: Database of Licensed Biological Products*, Keyword “Ustekinumab,” <https://purplebooksearch.fda.gov/> (last visited June 20, 2025).

<sup>2</sup> CO PDAB 2023 Eligible Drug Dashboard, Tableau, [https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/2\\_PrioritizedSummaryList](https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/2_PrioritizedSummaryList) (last visited June 20, 2025).

<sup>3</sup> CO PDAB, Prescription Drug Affordability Board Meeting Agenda, Friday, July 11, 2025 from 10:00 am – 1:00 pm, chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://doi.colorado.gov/sites/doi/files/documents/July%2011%20Draft%20Agenda.pdf (last visited July 8, 2025).

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. We thank you in advance for taking our recommendations into account.

Sincerely,

A handwritten signature in black ink that reads "Michael J. Valenta". The signature is written in a cursive, flowing style.

Michael Valenta  
Vice President, Value, Access & Pricing, Strategic Customer Group  
Johnson & Johnson Healthcare Systems, Inc.