



VIA Electronic Delivery

May 8, 2025

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Review Board
1560 Broadway, Suite 850
Denver, CO 80202

Re: CO PDAB Cost-Benefit Analysis

Dear Prescription Drug Affordability Board Members and Staff:

The Biotechnology Innovation Organization (BIO) and the Colorado BioScience Association (CBSA) appreciate the opportunity to comment on the Colorado Prescription Drug Affordability Board's (PDAB's or Board's) Cost-Benefit Analysis ahead of its May 2025 meeting.

CBSA champions Colorado's life sciences ecosystem and the patients it serves. CBSA's members include more than 720 life sciences companies and organizations employing more than 40,000 people in Colorado. Our life sciences community drives global health innovations that improve and save lives, from concept to commercialization. CBSA represents biotechnology and pharmaceutical, medical device and diagnostics, digital health, ag-bio and animal health, academic and research institutions, and the service provider companies that support the work of our ecosystem. CBSA remains committed to advancing affordability solutions that correct market failures, increase competition, and lower costs for patients while preserving patient access and supporting medical innovation.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life- saving medicines and vaccines for all individuals.

BIO and CBSA have serious concerns regarding Colorado's inadequate efforts to conduct the Cost-Benefit Analysis ahead of the proposed upper payment limit (UPL) rulemaking. As BIO and CBSA stated in our requests for the Cost-Benefit Analysis, it is imperative that the Board carefully weigh and mitigate any unintended consequences before establishing a UPL, particularly given the profound negative impacts on patient access and future innovation that are likely to result. Unfortunately, the current Cost-Benefit Analysis lacks any fundamental elements necessary for a meaningful evaluation of whether the benefits of the proposed rule justify its costs. Most notably, the Cost-Benefit Analysis fails to include any quantifiable data— an essential component of any

legitimate analysis. The absence of a single numerical estimate is unacceptable and raises concerns that UPLs will be established in an arbitrary and capricious fashion.

While the extent of supply chain impacts are still unknown, this uncertainty does not justify a complete absence of quantitative or qualitative modeling. Federal regulatory bodies, such as the Centers for Medicare & Medicaid Services (CMS) routinely develop regulatory impact analyses and fee schedules that include assumptions about ripple effects and stakeholder responses. Even in the face of uncertainty, ranges of impact estimates could be developed to provide at least a bounded understanding of potential outcomes. Simply claiming that “it is difficult to make more precise estimates of anticipated costs” is insufficient to meet the requirements or policy rationale of the underlying statute.¹ The Board’s inability to develop an analytical approach or outline any process for calculating potential impacts reinforces the fact that the Board should not move forward with a UPL at this time.

A credible Cost-Benefit Analysis should be transparent, data-driven, and methodologically sound. Colorado’s Cost-Benefit Analysis falls short of these standards and risks leading to policy decisions that are not based on evidence. Not only does the Cost-Benefit Analysis not include any projected impacts, but it also does not include any evaluation of the status quo, such as current patient coverage or current market conditions. BIO and CBSA strongly urge the Board to revisit its approach and align its analysis with best practices used by other regulatory bodies to gauge potential impacts, particularly to assess how patient access will be affected post-UPL implementation.

BIO and CBSA appreciate the opportunity to provide feedback to the Colorado PDAB. We look forward to continuing to work with the Board to ensure Colorado residents can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact us at pcastro@bio.org and agoodman@cobioscience.com.

Sincerely,

/s/

Primo J. Castro
Director
State Government Affairs – Western
Region
BIO

/s/

Amy B. Goodman
VP and Counsel
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CBSA

¹ Colorado Revised Statutes, 24-4-103(2.5)(a)