June 23, 2023

Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

Dear Chair Mizner and Members of the Board:

The Colorado BioScience Association (CBSA) and Biotechnology Innovation Organization (BIO) write to convey some observations and urge caution following the public release of the list of products eligible for affordability review and the dashboard ranking products based on the Prescription Drug Affordability Board's (Board) selection criteria.

CBSA represents Colorado's life sciences companies, including the biopharmaceutical companies with nearly 500 drugs in development. We advocate for a supportive business climate to help companies in our ecosystem drive global health innovations, products, and services that improve and save lives from concept to commercialization. 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.

Many members of CBSA and BIO are small, emerging companies developing novel, truly life-saving treatment platforms. They take on extraordinary risk and significant investments to fund research and development, which takes on average 10-15 years and costs on average $2.5B to advance one medicine to the clinic. Price control programs that create unpredictability for Colorado companies and investors negatively impact these companies' ability to raise enough money to bring therapeutics from the bench to patients with critical unmet medical needs.

Concern Regarding Economic Impact

Several early-stage biopharma companies in Colorado, including STAQ Pharma, SiVEC Biotechnologies, Vona Oncology, and FreshTrack Therapeutics have emphasized these concerns in letters to lawmakers and continue to be highly concerned about the viability of their therapeutic programs for cancers, infectious diseases, and genetic disorders.

Recent economic impact studies have estimated the impact of pricing controls from the federal Inflation Reduction Act on investments and innovation in the US biopharmaceutical ecosystem. If pricing controls had been in place 10 years ago, 24 to 49 therapies currently available today would most likely not have come to market and therefore would not be available for patients and their providers. Conservatively, as many as another 139 drugs over the next 10 years are at risk of not being developed at all, and 66,000 to 136,000 direct jobs are expected to be lost the

in US biopharma ecosystem. While these numbers are specific to the Inflation Reduction Act, any form of artificial price control threatens reduced investment in biotech R&D.

Additionally, biopharmaceutical companies based in and doing business in Colorado are faced with the simultaneous implementation of the Board's Upper Payment Limits and the federal Inflation Reduction Act. We remain very concerned about the impact of these price control mechanisms and urge the Board to gather state economic impact data and consider this at each stage of implementing Upper Payment Limits—in the selection of products for review, in the determination to establish a UPL, and in setting a specific UPL. The Board's primary goal is to improve affordability for patients, but must also consider the impact on access to medications. The economic impact on prescription drug supply chain entities will certainly disrupt patient access to necessary medicines.

Release of New Information and Resources

The public release of the Board's list of products eligible for affordability review ("eligible drug list") and process for selecting drugs to undergo affordability reviews has exacerbated the uncertainty for development-stage companies and investors. Particularly with regard to (1) a lack of clarity regarding the Board's process and methodology, (2) the accuracy and reliability of data sources informing the Board's methodology, (3) concerns about material errors in calculations, and (4) public disclosure and handling of confidential information, among others.

CBSA and BIO are also concerned about potential damage to the credibility and perception of instability for biopharmaceutical companies whose drugs were included on the original eligible drug list and subsequently removed due to calculation errors. We would like to better understand the Board's plan for minimizing inconsistencies and errors in the methodology in the future, leading to even more unpredictable outcomes for our companies.

Separately, the release of the Eligible Drug Dashboard has provided the Board, the public, and stakeholders with a valuable tool for considering the selection of drugs for affordability review, but also presents its own challenges. CBSA, BIO, and our members are still trying to explore the dashboard so we understand how these products are being looked at by the Board and also to ensure accuracy of the data. We need time to do this correctly. We have already been informed that some products' rank on the "Prioritized Ranked & Weighted List" vs the "Drug Lookup Tool" are inconsistent. Additionally, some WAC percentage increases listed on individual product pages do not match manufacturers' records of their own price increases.

To help minimize problems and inconsistencies with publicly facing information, and to ensure accurate information is being considered by the Board, we encourage the creation of an inquiry form or other process for manufacturers and other stakeholders to submit questions, comments, and/or objections to data on the dashboard and in other materials, and to ensure a timely response from the Board.

Given the significant impacts and potential unintended consequences of additional missteps in a new, unproven and highly complex program, we strongly urge the Board to slow down and

methodically address the stakeholder concerns that have been expressed by numerous organizations and individuals from supply chain entities and patient groups before selecting any products for affordability reviews. It is important that the Board take its time with discussions regarding the eligible drug list and how individual products are ranked using the weighted averages resulting from prioritized selection criteria. Lastly, from a process standpoint, when the Board does identify products for selection, a final vote on those selections should not occur until the meeting after they are identified and discussed so that stakeholders can provide input.

Thank you for your time and consideration, and for your commitment to making prescription drugs more accessible to Colorado patients.

Sincerely,

Elyse Blazevich
President & CEO
Colorado BioScience Association

Brian Warren
Senior Director, State Government Affairs
Biotechnology Innovation Organization