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.

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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
for Policy + Advocacy
CBSA

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

Johnson & Johnson Health Care Systems, Inc.
1125 Bear Tavern Road
Titusville, NJ 08560

T +1-800-526-7736
jnj.com

Via Email

May 21, 2025

Gail Mizner, MD
Colorado Prescription Drug Affordability Board Chair
dora_ins_pdab@state.co.us

Dear Dr. Mizner:

We write to express concern regarding the "Stelara Validated Data Presentation and Discussion," which occurred during the April 11, 2025 Prescription Drug Affordability Review Board ("Board" or "CO PDAB") meeting.[1] We request that the Board cancel its plan to initiate an upper payment limit ("UPL") rulemaking for Stelara for the following reasons:

- **Stelara's eligibility and affordability review hinged on erroneous data that significantly inflated costs to both patients and the healthcare system.**
- **The PDAB's dataset is not only erroneous, but also outdated, and the Board fails to acknowledge market factors impacting more recent data.**
- **The PDAB has excluded other drugs from review based on availability of biosimilars.**

A. Stelara's Eligibility and Affordability Review Hinged on Erroneous Data that Significantly Inflated Costs to Both Patients and the Healthcare System.

UPL rulemakings for Stelara should not move forward because Stelara's eligibility and Affordability Review hinged on erroneous data. The "validated" data shows significant decreases in costs to patients and the state healthcare system. These errors cannot be ignored. During the April 11, 2025 Board meeting, PDAB staff held an "All Payer Claims Database ("APCD") Data Validation Discussion."[2] During this discussion, staff revealed that a pharmacy benefit manager ("PBM") had miscategorized its commercial and Medicare claims data. For pharmacy claims, the PBM had mislabeled commercial claims as Medicare claims and vice versa.[3] These claims accounted for 6.9% of total pharmacy claims for ***all drugs*** in the APCD—a non-negligible percentage.[4] The PDAB relied on this erroneous data last year when it determined drug eligibility and conducted affordability reviews on five drugs—Trikafta, Genvoya, Enbrel, Stelara, and Cosentyx.

At the April 11, 2025 Board meeting, staff then presented the original, erroneous data and the

[1] Colorado Prescription Drug Affordability Board ("CO PDAB"), Prescription Drug Affordability Board Meeting Agenda, Friday, April 11, 2025 from 10:00 am – 1:00 pm, https://drive.google.com/drive/folders/1WLdrV01ShUotbXnk2_yeanCzNxUPRBCv (Last visited May 5, 2025).
[2] *Id.*
[3] *Id.*
[4] *Id.*

"validated" data for the three drugs that the PDAB had previously deemed "unaffordable"—Enbrel, Cosentyx, and Stelara. For all three drugs, several important datapoints decreased. **Notably, Stelara saw the most significant decreases in utilization and drug spend—factors that the Board heavily relied upon when it selected Stelara for review and deemed the drug "unaffordable." These decreases occurred across every single category of collected data,** and are as follows:

- Per "Table 13. 2022 Affordability Review Price & Cost Per Person Statistics for Stelara" and "Table 14. 2022 Corrected Data for Stelara":[5]
    - "Average WAC per Cost of Treatment" decreased from $150K-$160K to $140K-$150K—**a 6.25% reduction**.
    - "Average Paid per Person" decreased from $150,176 to $113,093—**a 24.69% reduction**.
    - "APPY – Plan Paid" decreased from $143,769 to $107,026—**a 25.6% reduction**.
    - "APPY – Out of Pocket" decreased from $7,365 to $5,008—**a 32% reduction**.

- Per "Table 15. 2022 Affordability Review Annual Utilization & Expenditures for Stelara" and "Table 16. 2022. Corrected Data for Stelara":[6]
    - "Patient Count" decreased from 1,606 to 1,512—**a 5.85% reduction**.
    - "Total Paid" decreased from $247,968,382 to $177,136,125—**a 28.55% reduction**.
    - "Average Paid per Person" decreased from $154,401 to $117,154—**a 24.1% reduction**.
    - "Total Patient Paid" decreased from $7,320,547 to $6,182,939—**a 15.5% reduction**.
    - "Average OOP" decreased from $7,365 to $5,008—**a 32% reduction**.

Without these errors, the PDAB could have considered more accurate data in reviewing the entire eligibility list and making affordability review determinations, and likely would have reached different conclusions.

Even more alarming, ***even the original, erroneous data*** presented during the April 11, 2025 Board meeting appears to be strikingly different than the figures used in the PDAB's Final "Affordability Review Summary Report: Stelara," dated June 7, 2024 ("Report"), which was used to deem Stelara "unaffordable."[7] The Report's Executive Summary states that Stelara was selected and found "unaffordable" based on utilization, per patient cost, total cost, and average annual out-of-pocket cost for patients with commercial insurance.[8] Yet, the figures used to make all of these determinations were inaccurate.

Examples of discrepancies between the Report; the original, erroneous data presented on April

[5] *Id.*
[6] *Id.*
[7] CO PDAB, *Affordability Review Summary Report: Stelara*, June 7, 2024, https://drive.google.com/drive/folders/1UHaYvwQzBQgon9D28X9o5heaZUgk-fPx (last visited May 20, 2025) ([Hereinafter "Stelara Affordability Report"]).
[8] *Id.*

11, 2025; and the "validated" data are as follows:

	Report	Original, Erroneous Data from 4/11/25 Slides	Difference: Report vs. Original, Erroneous Data	"Validated" Data from 4/11/25 Slides	Difference: Report vs. "Validated" Data
Drug utilization (2022)	1,700 patients	1,606 patients	572 patients / 5.69% decrease	1,512 patients	687 patients / **11.71% decrease**
Percentage Increase in Utilization	"Over 200%" (from 2018 to 2022)	122.3% (from 2019 to 2022; staff did not report 2018 data on 4/11/25)	Decrease by 44%	100% (from 2019 to 2022; staff did not report 2018 data on 4/11/25)	**Decrease by 100%**
Per Patient (2022)	$150,176	$154,401	A 2.8% increase	$117,154	**A 21.98% decrease**
Total Paid (2022)	$255,298,495	$247,968,382	$7,330,113 – a 2.9% decrease	$177,136,125	$78,162,370 – **a 30.6% decrease**

Additionally, the Report states that the 2022 average annual out-of-pocket cost for patients with commercial insurance was $5,875. It is entirely unclear how accurate this figure is. Despite the PDAB admitting that certain Medicare and commercial claims data had been swapped, staff did not disclose a "validated" figure for out-of-pocket costs for patients with commercial insurance—a figure that the PDAB has deemed imperative to an unaffordability determination.

Nevertheless, Board members and staff asserted that the "validated" numbers would not impact their UPL analyses and that they would proceed as planned with UPL hearings. We ask that the Board cancel its plans for a Stelara UPL rulemaking and reset its list as the Oregon PDAB did last year when they identified flaws with their methodologies and processes. Errors this substantial further call into question the Board's lack of evidence-based processes and methodologies and must not be ignored.

B. The PDAB's dataset is not only erroneous, but also outdated, and the Board fails to acknowledge market factors impacting more recent data.

Not only did the Board rely upon substantially erroneous APCD data, but the data is also significantly outdated, and the Board has failed to consider multiple market factors that have occurred since affordability reviews began. The PDAB used data from 2022 to conduct its affordability reviews—data that is now three years old. Several developments have occurred over the past three years that impact Stelara claims data. For example, last year, CMS imposed

a "Maximum Fair Price" ("MFP") on Stelara, which could go into effect as early January 2026.[9] Additionally, since 2022, the FDA has approved several biosimilars and an unbranded biologic of Stelara.[10] Drug Channels recently noted that the FDA has approved six non-interchangeable biosimilars, and that "PBMs are leading with their private label versions" of Stelara, creating "meaningful competition."[11] All of these factors impact more recent claims data. Therefore, a UPL for Stelara is inappropriate, and the Board should not move forward with Stelara's UPL rulemaking.

C. The PDAB Has Excluded Other Drugs from Review Based on Availability of Biosimilars.

To reiterate, the FDA has approved several biosimilars and an unbranded biologic of Stelara.[12] As part of its affordability reviews, the Board was required to evaluate the availability of "therapeutic equivalent" prescription drugs.[13] The Board was aware of biosimilars coming to market when it conducted its affordability review for Stelara and chose to dismiss this very relevant consideration.[14] In contrast, the Board excluded other drugs from affordability reviews based on the availability of biosimilar products. For example, according to the "CO PDAB 2023 Eligible Drug Dashboard," Humira was the first drug on the prioritized ranked and weighted list of eligible drugs in June 9, 2023, and yet, the Board excluded Humira from affordability reviews due to the availability of biosimilars.[15] As such, moving forward with Stelara's UPL rulemaking would be arbitrary and capricious, and the Board should refrain from doing so.

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 innovation ecosystem. We know that patients are counting on us to develop and bring medicines to market. 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.

Sincerely,

Mike Valenta

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

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[9] CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf (last visited May 20, 2025).

[10] FDA, *Purple Book: Database of Licensed Biological Products, Keyword "Ustekinumab,"* https://purplebooksearch.fda.gov/ (last visited May 20, 2025).

[11] Drug Channels, *The Big Three PBMs' 2025 Formulary Exclusions: Humira, Stelara, Private Labels, and the Shaky Future for Pharmacy Biosimilars*, Apr. 1, 2025), https://www.drugchannels.net/2025/04/the-big-three-pbms-2025-formulary.html (last visited May 20, 2025).

[12] *Id.*

[13] Co. Rev. Stat. § 10-16-1406; 3 CCR 702-9-3.1(D).

[14] Stelara Affordability Report, *supra* note 7.

[15] CO PDAB 2023 Eligible Drug Dashboard, Tableau, https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/2_PrioritzedSummaryList (last visited May 20, 20250.

March 2025

Payer Perspectives Confirm UPLs Will Likely Raise Costs and Hinder Patient Access to Medicines

This report is based on research conducted by Avalere under contract to the Partnership to Fight Chronic Disease.

Key Findings

Prescription Drug Affordability Boards (PDABs) aim to improve affordability for prescription drugs, but payers believe that PDABs setting upper payment limits (UPLs) would likely raise patient out-of-pocket medicine and premium costs while disrupting medicine access for patients and the state healthcare system overall.

- 77% of health plan payers surveyed believe that UPLs would disrupt patient access to prescription drugs due to changes in coverage, tiering, cost sharing, or broader supply chain issues, such as pharmacies not stocking products with UPLs.
- 67% of health plan payers anticipate that patient cost sharing for UPL drugs will increase (50%) or stay the same (17%). Similarly, most payers (70%) anticipate that out-of-pocket (OOP) costs for drugs in the same class as a UPL drug will increase (53%) or stay the same (17%).
- 57% of payers surveyed anticipated changing premiums if a UPL is implemented.
- 50% of payers surveyed indicated their plan would increase utilization management on the UPL drug.

In addition, plans anticipate disruption affecting pharmacy and provider reimbursement, further exacerbating harms to patient access.

- 60% of respondents believe that pharmacies may not stock UPL drugs; Even more respondents (73%) expressed concerns that UPLs could lead to shortages of critical medicines, all of which leading to access challenges for patients.
- 57% of respondents agreed that if a UPL were to be implemented on a provider-administered product, a provider would be reimbursed less for a drug with a UPL than what the provider would otherwise be paid for that product.

Overview of PDABs and UPLs

State policymakers are touting PDABs and UPLs as ways to control state spending and lower patient costs on prescription drugs. As of March 2025, eight states (Colorado, Maine, Maryland, Minnesota, New Hampshire, New Jersey, Oregon, and Washington) had enacted PDAB laws, with four of those (Colorado, Maryland, Minnesota, and Washington) also authorized to set UPLs on drugs determined to be "unaffordable".[1] Concepts of "unaffordable" vary by state, with at least one PDAB noting they have been unable to define unaffordability.

PDABs may identify products to target for "affordability" review or a UPL based on pricing thresholds or other more subjective criteria. UPLs would impose a limit on how much purchasers (such as health plans, pharmacy benefit managers (PBMs), or public payers) within a state may pay or reimburse for drugs found to be "unaffordable" after review by the PDAB. The laws limit "payment" or reimbursement as opposed to drug prices. As a result, they raise several challenges and unanswered questions, which may lead to unanticipated impacts on plan benefit design, patient OOP costs, pharmacy reimbursement, and a pharmacy's ability to stock medicines.

[1] This analysis only included states that have passed legislation that establish PDABs that are required to conduct affordability reviews. For example, VT's Green Mountain Care Board has the option to conduct an affordability review of a set selection of drugs, but it is not a requirement.

State lawmakers supporting PDABs and UPLs intend to reduce what patients pay for prescription drugs but may see the opposite happen if OOP costs rise or fail to decline and new access restrictions, product exclusions, or shortages appear in markets with UPLs in place.

Research Background & Methodology

Health plans have a unique perspective to inform the possible implications of a UPL on coverage decisions and consequences for other stakeholders that may affect patient costs and access. To understand the implications, PFCD commissioned Avalere to gather insight into plan perceptions and preparedness for PDABs and UPLs.

Avalere updated and built on previous payer interviews done in 2023, released by PFCD in 2024. The previous research revealed doubts among payers that UPLs would be implemented, but this update shows that payers are now paying closer attention to PDABs and UPLs. Issues raised in the previous payer interviews prompted concern that patients would not benefit from UPLs, and those issues remain unresolved today. Payers were more focused on system-wide impacts this year, including concern that administrative burdens related to UPL implementation would raise costs. Clearly, Boards need to do more work and research to address unintended consequences of PDABs.

As payers refer to the cost of the drug throughout the responses described in this paper, it is important to note that they may be referring to their organization's cost – not the cost to the patient. Considering those plan costs, some interviewees implied that they believe PDABs could deem a drug unaffordable but simultaneously set a UPL higher than what payers already negotiate, negating the impact of the UPL and highlighting the savings in the system without UPLs that do not reach the patient or plan sponsor.

Interviews

Between January and February 2025, Avalere conducted six, in-depth, 30-to-45-minute interviews with current and recent representatives from national and regional plans who 1) had experience with plan decision-making on formularies and prescription drug benefit design and 2) were able to speak to their plan's perceptions of UPLs. Cumulatively, interviewees represented health plans with 115.2 million covered lives. The interviews were double-blinded and did not include interviewees from the 2023 project. Interview questions were asked consistently across interviewees and covered benefit design, patient costs and access, contracting, pharmacy access, reimbursement, and UPL implementation.

Surveys

In February 2025, Avalere conducted a survey with a different pool of 30 representatives from national and regional plans who 1) had experience with plan decision-making on formularies and 2) were able to speak to their plan's perceptions of UPLs. Cumulatively, survey respondents represented health plans with 476.3 million total enrollees.[2] The survey was double-blinded and did not include individuals who were interviewed in 2023 or 2025. The 37 survey questions focused on benefit design, patient access and costs, contracting, pharmacy access, reimbursement, appeals process, and UPL implementation.

[2] Surveyed payers did not identify their organization, thus there may be overlap of covered lives.

Detailed Findings

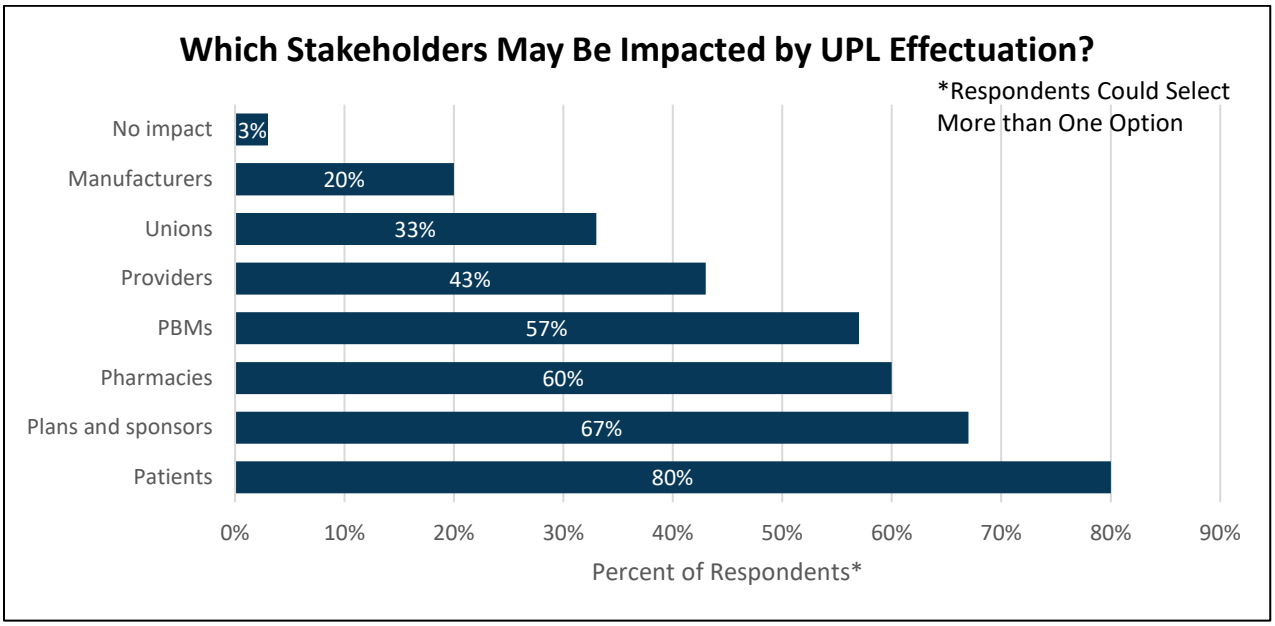
Disruption to Prescription Drug Ecosystem

Payers suggested that PDABs have "noble" goals but also raised concerns about unintended consequences of UPLs. For example, 77% of payers surveyed believe that effectuation of a UPL would disrupt patient access to prescription drugs. This disruption could come in the form of plan changes, such as adjustments to coverage, tiering, or cost sharing, or broader supply chain issues, such as pharmacies not stocking products with UPLs. The Analytics Lead at a national plan illustrated this idea, saying:

> ***"If a drug is out of stock or low stock in a specific state, depending on the formulary design, patients may not be able to get their preferred drugs, and the other alternative drugs may have higher out of pocket costs and require a prior authorization."***

When provided with a list of stakeholders susceptible to disruption due to UPLs, patients were identified most often by surveyed payers (80%) – higher than any other stakeholder group. Specifically, patients could see higher OOP costs, disruption to access, increased premiums, and added utilization management (UM).

Figure 1. Stakeholders That May be Impacted by UPL Effectuation



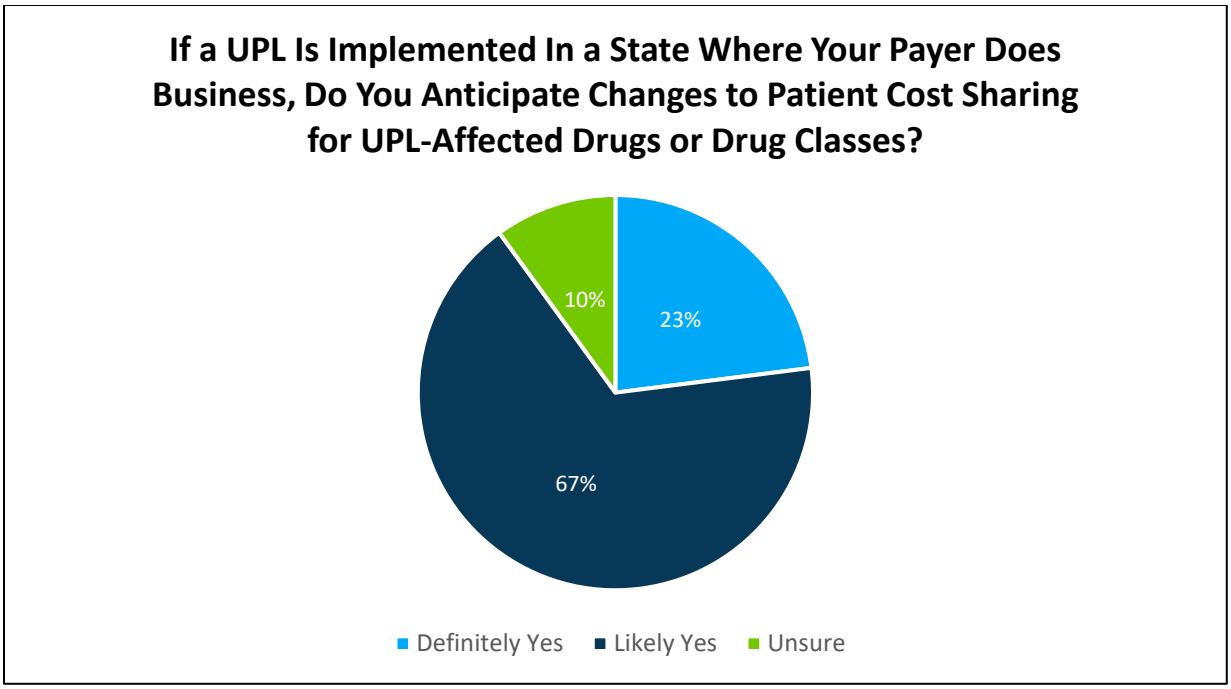
Considering plan and PBM impacts, payers highlighted that UPLs would necessitate changes to PBM contracts and that UPLs would impact plan profits—both of which could contribute to patient impact. The Senior Product Director of Consumer Experience at a national plan noted, "[*Setting a UPL lower than current price] would have an impact on access for sure, just because of the trickle effect it's going to have on plans and PBMs needing to remain sustainable.*"

Payers noted that plans will not absorb additional costs generated by UPLs but will instead pass those costs along to others in the system including enrollees. In the words of the Vice President of Operations at a regional plan, "*that cost has to be absorbed by somebody, and … the carrier is not going to absorb it because we might reduce our profitability*."

Respondents anticipate these additional costs will be driven by changes to claims systems and reimbursement practices, timing of implementation, and changes to cost sharing or formularies which were all identified as the primary challenges resulting from effectuation. More broadly, 63% of payers believe that a UPL would lead to disruption in the state's health insurance market. Respondents identified changes in reimbursements to pharmacies or providers, higher administrative burden, and changes to rebating as the primary disruptions.

Surveyed and interviewed payers both discussed the administrative burden likely to be incurred from UPL implementation. 40% of survey respondents agreed that UPL implementation would result in higher administrative burden on plans, provider, pharmacies, or even patients.

Figure 2: Changes to Patient Cost Sharing



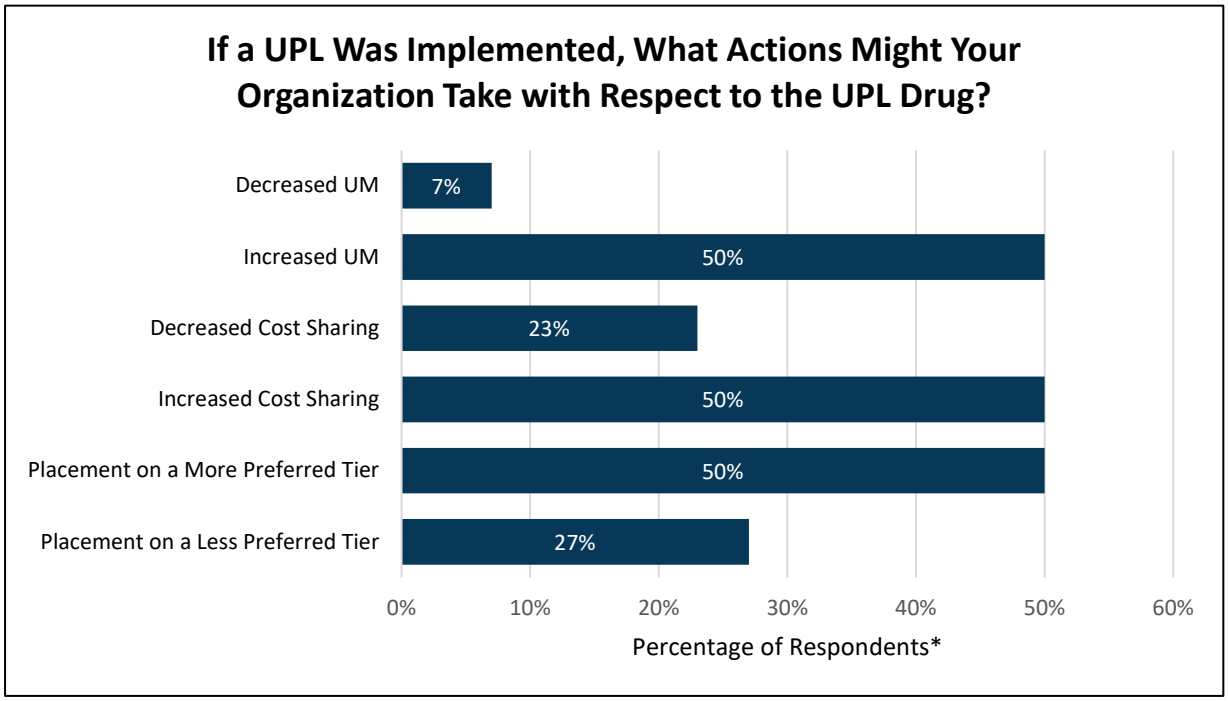
Benefit Design

Benefit design could change significantly in the face of UPLs. As shown in Figure 2, plans expect that patients will face changes to their costs as a result of UPL implementation, such as increased premiums or cost sharing. 90% of respondents said that there would "definitely" or "likely" be changes to patient cost sharing for UPL-affected drugs or drug classes, with interviewees noting complex negotiation and contracting dynamics as changes that could increase patient costs. Overall, payers (60%) expected changes to OOP costs, with 50% of all surveyed payers expecting increased copays or coinsurance on the UPL drug. Specifically with regard to premiums, 57%

anticipated increasing premiums if a UPL is implemented, and only 10% said they would decrease premiums for enrollees.

Payers also noted increased use of prior authorization (PA) and other UM techniques in the event of UPL effectuation. 50% of respondents indicated their plan would increase UM on the UPL drug. Increased UM could extend even to provider-administered products if PDABs place UPLs on those types of drugs. A Technical Product Director at a National Plan, referring to physician-administered products, noted that "stricter utilization management criteria and medical necessity criteria and possible site of care restrictions [would be needed]" in the case of a UPL.

Figure 3: Plan Responses to UPL Implementation



Pharmacy Access and Provider Payment

Payers expressed concerns that setting UPLs below current prices* could disrupt pharmacy contracts. Since PDAB legislation establishes a reimbursement cap on drugs with UPLs, PBMs would likely only be able to reimburse pharmacies up to the UPL while pharmacies' acquisition costs could exceed UPL. In line with this, 70% of respondents agreed that pharmacy reimbursement would decrease due to UPL effectuation. This could lead to strain on pharmacy operations. 60% of respondents thought that negative impacts to pharmacy reimbursement would decrease the likelihood that the pharmacy keeps the UPL drug in stock, leading to access challenges for patients. An even greater number of respondents (73%) believe that lower stock of UPL drugs

*Participants considered the impact of a UPL compared to the price the plan is currently paying for a drug. Because the amount paid by a plan varies widely, it is likely that some UPLs could be below the current cost to some payers but above other payers' current cost for a drug.

could lead to shortages in states with a UPL. When asked to elaborate on the impact of UPLs on pharmacies, payers responded:

> ***"If reimbursement is impacted, pharmacies will be less likely to stock the medication as they cannot afford to lose money on every fill."*** **– Mail Order Pharmacy Lead, National Plan**
>
> ***"I think there could be pharmacies that say that they don't want to participate because they can't do it at a loss because they're the last transaction in the supply chain."*** **– Vice President of Pharmacy Operations, Regional Plan**

The survey also asked specifically about physician-administered drugs. 57% of respondents agreed that if a UPL were to be implemented on a provider-administered product, a provider would be reimbursed less for a drug with a UPL than what the provider would otherwise be paid for that product. When asked who would make up the difference to the provider, 47% indicated that patients would be responsible for making up the difference, and 6% noted that providers would be responsible, i.e. that providers would not be made whole.

> **A Vice President of Operations at a regional plan emphasized this idea, saying,**
>
> ***"That cost has to be absorbed by somebody, and … the carrier is not going to absorb it because we might reduce our profitability."***

Conclusion

While PDABs have a goal of improving patient affordability and overall financial sustainability for the state and larger healthcare system, these interviews and surveys demonstrate that UPLs would not achieve that goal, but rather could result in higher premiums, increased UM, and decreased patient access.

Payers agreed that PDABs often simplify or fail to understand the complexities of the prescription drug supply chain, and that has led to proposed UPL effectuation plans that threaten to push a new administrative burden and cost onto various players in the system, including patients.

Biosimilars FORUM

May 20, 2025
Colorado Prescription Drug Affordability Board
1560 Broadway, Suite 850
Denver, CO 80202

Submitted via e- mail: dora_ins_pdab@state.co.us

PDAB Programs May Prevent Americans from Accessing Lower-Cost Medicines

Biosimilars Are the Answer to Skyrocketing Drug Costs for American Patients

Dear Members of the Colorado Prescription Drug Affordability Board:

Colorado lawmakers can lower prescription drug costs for the patients by championing lower-cost, U.S. Food and Drug Administration (FDA)-approved biosimilars. These medicines, which reference originator biologics, are a free-market solution to rising drug prices plaguing Americans and the U.S. healthcare system. The biosimilars industry continues to prioritize cost-savings to both patients and the healthcare system as the healthcare affordability crisis worsens. The Board should consider when a biosimilar is going to be launched. Biosimilar competition has led to decreases in costs for both biosimilars and their reference products. However, many biosimilars remain more affordable than their reference products and could be more widely used.

The Biosimilars Forum was incorporated in Washington, DC, as a nonprofit organization to advance biosimilars in the United States with the intent of expanding access and availability of biological medicines, and improving health care. In 2024, nearly 30% of Americans said they were unable to take their medication as prescribed due to unaffordable prices. In the last ten years, biosimilars have been associated with savings of $56 billion compared to what spending would have been without biosimilars. The next five years could result in an increase in savings up to $181 billion as newly approved biosimilars launch and existing biosimilars see continued uptake and price reductions because of patent expirations on branded products expected through the end of the decade.

Our organization is concerned with the ability of the Prescription Drug Affordability Board (PDAB) to review and place artificial price controls on biosimilars. This ability will negatively impact patients that need access to lower-cost medicines. It is crucial for patients to have the ability to access FDA-approved, lower-cost biosimilars. Biosimilars should not be included as potential products that may be subject to an Upper Payment Limit (UPL), which will serve only to inhibit the development of lower cost biosimilar options and their availability to patients. Instead, state policy should focus on changes that support patients and access to biosimilars. PDABs should also consider when a biosimilar is being launched for a reference product.

Beyond its direct impact on patient access to necessary medicines, potential application of a UPL to biosimilars raises serious concerns about whether biosimilars can continue to exert

competitive pressures on prices of reference products, on other biosimilars, and maintain sustainable product supply and manufacturing operations. In turn, this has the potential to cause biosimilar manufacturers to reduce or eliminate important patient support programs. It could also cause drug shortages and supply chain interruption that would further harm patients.

The PDAB process of evaluating products and determining reimbursement limits must be completely transparent and subject to scrutiny and input from all affected parties. The complexity of the market, supply chain, benefit design and the implications of impacts in these areas on patients demand this.

The process of adopting a UPL methodology should require the rationale for adopting the methodology, including why it was determined to be the most relevant or effective, and how it minimizes the risks of negative unintended consequences to enable a process of continuous improvement.

The board should also recognize differences within patient populations and disease in deciding whether to include or exclude a product from the reference basket. The addition of patient advisers to the process should be considered.

The introduction of biosimilars leads to lower costs and offers increased access to patients – a clear win for patients. Biosimilars are, on average, more than 50% lower-cost than the biologics they reference. Powered by the work of American biopharmaceutical companies, the emerging biosimilars industry celebrated a milestone earlier this year, with more than 60 biosimilars approved for use by the FDA.

As the Executive Director of the Biosimilars Forum, I represent the companies with the most significant U.S. biosimilar development portfolios, specifically Amneal Pharmaceuticals, Biocon Biologics, Henlius, Meitheal Pharmaceuticals, Organon, Pfizer Inc., Samsung Bioepis, Sandoz, and Teva Pharmaceuticals. Together, we are eager to roll up our sleeves and work on solutions that help patients.

The Biosimilars Forum appreciates the opportunity to share our concerns over the PDAB and urges the Legislature to consider the long term negative consequences for patients and the viability of biosimilars development.

If you have any questions about biosimilars and how they can lower prescription drug prices, please reach out to me. I am happy to meet with your office to provide an overview of biosimilars and answer any questions you may have.

Thank you so much for your time,
Juliana M. Reed, Executive Director
Biosimilars Forum
juliana@biosimilarsforum.org

HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

April 25, 2023

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

Chair Mizner and Members of the Colorado Prescription Drug Affordability Board,

On behalf of the Healthcare Distribution Alliance (HDA), we would like to share the below information to bring further awareness to the Board on the precise role that wholesale distributors play within the supply chain and to share our industry's comments on the Draft Data Submission Guide specific to the "Wholesaler Submission" section.

HDA is the national trade association representing healthcare wholesale distributors — the vital link between the nation's pharmaceutical manufacturers and more than 330,000 pharmacies, hospitals, and other healthcare settings nationwide, including over 3,600 across Colorado. Each day, wholesale distributors work around the clock to ship nearly 10 million healthcare products (medicines, medical supplies, durable medical equipment, etc.) to pharmacies, hospitals, and other healthcare providers daily in order to keep their shelves stocked with the medications and products they need to treat and serve their patients.

Wholesale distributors are unlike any other supply chain participants. In their role as a wholesale distributor, HDA members do not manufacture, market, prescribe or dispense medicines, nor do they set the list price of prescription drugs, set third party payor reimbursement or coverage for prescription drugs, influence prescribing patterns, or determine patient-benefit designs. Further, wholesale distributors have no insight into patient-level data, the price the patient pays, nor are they privy to how products are dispensed at the patient-level by the pharmacy. Simply put, a wholesale distributor's primary objective is to fulfil pharmacy customer orders and ensure their safe and efficient delivery.

Wholesale distributors typically operate under fee-for-service contracts with the manufacturer. For the services they provide, distributors charge manufacturers a bona fide service fee, which is not passed along to the subsequent purchaser. These service fees, as defined by federal statute, typically underwrite the cost of warehousing, ordering, special product handling services and transporting products to the thousands of ship-to points each distributor serves every day. Due to their business model, wholesale distributors' revenues are almost entirely and immediately offset by the costs of purchasing medicines, resulting in razor-thin profit margins consistently less than 1 percent across the industry, with little notable change over the last several years despite market volatility.

Since the initial legislation, HDA has expressed concern regarding the establishment of an upper payment limit (UPL) on identified drug products and the potential impact this policy could have on the physical supply chain of pharmaceutical products. State-level UPLs fail to adequately reflect how prescription drugs are bought and paid for in the United States. A state-level UPL would place caps on in-state purchases but not out-of-state purchases, ultimately limiting the ability of pharmacies, clinics or other points of care to recoup costs for administering or dispensing these products, which could result in sites of care being unable to stock these medications. Even when allowing for a nominal fee, a healthcare provider could be unable to recoup costs for administering a product or ensure they are properly reimbursed, leaving little incentive or ability for them to continue to stock these medications. It is also important to note that independent pharmacies are already struggling to sustain their businesses, reducing their ability to maintain overhead when dealing with specific medications would undoubtedly lead to further consolidation in the pharmacy and provider community.

Wholesale distributors are also concerned with the overall disruption that establishing a UPL could have on the supply chain. It is probable that manufacturers may choose to no longer allow products with an established UPL to be sold into the state or simply cease producing certain drug products. This could lead to a disruption in patient care,

the need to identify new drugs to offset the product being removed from market, and potential shortages of products given the instability in the marketplace.

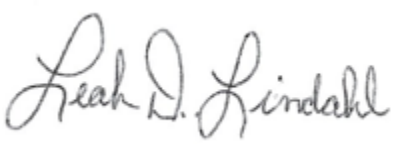
Furthermore, as more states consider enacting PDAB legislation and UPL authority, this will ultimately lead to a patchwork of state policies and pricing metrics for a variety of pharmaceutical products. This further exacerbates the overall cost in the supply chain and creates unpredictability in the marketplace as a whole. The industry is already undergoing significant and unpredictable federal actions, the implementation of the federal Inflation Reduction Act (IRA), the national implementation of the Drug Supply Chain Security Act, etc. – each of which will have a fundamental impact on the overall pharmaceutical supply chain.

Regarding the Draft Data Submission Guide, we believe there remains significant uncertainty surrounding how an Upper Payment Limit (UPL) will be implemented, as well as its potential impact on each segment of the pharmaceutical supply chain. This lack of clarity limits any stakeholder's ability to accurately assess or comment on how a UPL might affect their operations.

Additionally, wholesale distributors are not positioned to report information related to "payor types," as they fulfill orders on behalf of pharmacy customers without access to patient-level data or insight into how the product is ultimately dispensed. Operating on a national scale, discounts are not allocated on a drug- or state-specific manner. As noted above, it is also important to clarify and understand that wholesalers typically function under fee-for-service agreements with manufacturers. In this model, chargeback represents a purchase price adjustment necessitated by a pre-existing contract between the manufacturer and the distributor's customer, which the distributor is legally bound to honor (e.g., under the 340B program) – this process allows the supply chain to function more efficiently and ensures patients and pharmacies do not have delays in access to care while waiting on price concessions or reimbursements directly.

Thank you for the opportunity to highlight the unique and critical role that wholesale distributors play in the supply chain and to share our comments related to the Draft Data Submission Guide. As noted in prior Board meetings, we would welcome the opportunity to provide further information on the wholesale distribution industry, clarify any misconceptions or inaccuracies, and help answer any questions that you may have.

Sincerely,



Leah Lindahl
Vice President, State Government Affairs
LLindahl@hda.org