

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:24-cv-00810-NYW

AMGEN, INC., et al.,

Plaintiffs,

v.

GAIL MIZNER, M.D., in her official
capacity as Chair of the Colorado
Prescription Drug Affordability Review
Board, et al.,

Defendants.

**BRIEF OF *AMICI CURIAE* COLORADO CENTER ON LAW AND POLICY
IN SUPPORT OF DEFENDANTS' COMBINED CROSS-MOTION FOR SUMMARY
JUDGMENT AND MEMORANDUM IN SUPPORT AND RESPONSE IN
OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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IDENTITY AND STATEMENT OF INTEREST OF *AMICI CURIAE*¹

The Colorado Center on Law and Policy (CCLP), established in 1998, is a nonprofit organization dedicated to eradicating poverty across Colorado through research, legislation, and legal advocacy. To achieve these goals, CCLP focuses on four main areas: food, housing, income, and health. CCLP employs its expertise in public health to promote equitable access to medical services by advocating at the legislature, in rulemaking, and the courtroom.

A major priority for CCLP is ensuring that all Coloradans can access lifesaving medications to navigate chronic conditions and other daily health care needs. Nobody should have to choose between affording a life-changing drug and putting food on the table for their family. To that end, CCLP was pleased that the Colorado legislature established the Colorado Prescription Drug Affordability Board (PDAB). CCLP has actively participated as a stakeholder, advocating for reasonable and responsible policies that allow the PDAB to fulfill its statutory mandate and advance consumer protections that help ensure access to affordable medication.

As an advocate for Coloradans, CCLP submits this amicus brief because a ruling for the Plaintiffs would severely restrict the ability of the state's legislature to craft policies to help Coloradans access affordable prescription drugs.

¹ Counsel for CCLP have consulted with counsel for all parties, there are no objections to CCLP filing this brief as *amici curiae*. No counsel for any party authored this brief in whole or in part; no such counsel or any party made a monetary contribution intended to fund the preparation or submission of this brief. A \$6,500 contribution by Hopewell Foundation was provided to CCLP in support of the preparing and submitting of this brief. No other person or entity, other than *amici*, made a monetary contribution intended to fund the preparation or submission of this brief.

INTRODUCTION

The primary purpose of the Colorado law at issue (C.R.S. § 10-16-1401 *et seq.*) is to improve Coloradans' access to certain lifesaving and life-improving drugs through addressing market dysfunction. As Defendants state, "no harm befalls" Plaintiffs because the law at issue does not regulate or lead to enforcement against drug manufacturers directly, ECF No. 29, and Defendants are correct that there is no constitutional requirement that Colorado "stand idly by" as its residents "are left without information or leverage to negotiate lower prices." *Id.*

The stakes of this lawsuit are extremely high; if Plaintiffs prevail, consumers, especially Coloradans from lower-income households and marginalized communities, will continue to struggle to afford Enbrel, a medication that is essential to ensuring a reasonable quality of life for a substantial number of Coloradans with rheumatoid arthritis (RA) and similar conditions. Across the United States, roughly 1.3 million adults suffer from RA.² The Enbrel Affordability Review Summary Report (Enbrel Report)³ discussed the PDAB's consideration of the Colorado All Payer Claims Database and survey responses from patients and caregivers, highlighting the difficulties Coloradans faced to access the drug. The Enbrel Report also examined relevant literature showing that those most likely to struggle affording Enbrel, African Americans and those from lower-income families, also "had a significantly higher RA risk." *Id.* An analysis from the U.S. Department of Health and Human Services concerning utilization of Enbrel among Medicare Part D

² Yingke Xu and Qing Wu, *Prevalence Trend and Disparities in Rheumatoid Arthritis among US Adults, 2005-2018*, J Clin Med. (July 26, 2021), <https://pubmed.ncbi.nlm.nih.gov/34362073/>.

³ PDAB, 2023 Affordability Review Report: Enbrel (Feb. 23, 2024), https://drive.google.com/drive/folders/1xdHNz_KHSB5uL6o2DDSqCkOZbCsmRXq2?usp=drive_link

enrollees found a greater share of Enbrel users were women and Latinos compared to the total Part D population.⁴ Latinos in Colorado are also three times more likely to have no health insurance.⁵ Generally, lower-income households are more likely to lack coverage. Nationally, nearly half of those uninsured in 2022 had incomes under 200% of the federal poverty level.⁶ Amid that context, Plaintiffs are facially challenging a democratically negotiated policy aimed at protecting vulnerable Coloradans from a broken prescription drug market.

To continue saddling Coloradans with excessive drug costs, Plaintiffs have asked the court to declare that the law creating the PDAB violates the Fourteenth Amendment's Due Process Clause. In that vein, Plaintiffs claim the PDAB's "decision making is not governed by ascertainable standards," ECF No. 24 at 24, thus preventing Plaintiffs from obtaining "a fair and reasonable rate of return on investment." *Id.* at 26 (quoting *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 597 (6th Cir. 2001)).

Plaintiffs' reliance on *Mich. Bell*, however, is misplaced. Plaintiffs cannot show that establishing an upper payment limit (UPL) for downstream market actors would be confiscatory and fail to guarantee a constitutional rate of return, thus depriving them of their property interest. Their unilateral expectation that Coloradans pay excessive prices

⁴ U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, FACT SHEET: —Inflation Reduction Act Research Series—Enbrel: Medicare Enrollee Use and Spending (Oct. 2023), <https://aspe.hhs.gov/sites/default/files/documents/9a83c694a036b1a1e55ff8763f674b8c/Enbrel.pdf>.

⁵ 2023 CHAS: Insurance Coverage. Feb 15, 2024, updated May 8, 2024. <https://www.coloradohealthinstitute.org/research/2023-chas-insurance-coverage#:~:text=Roughly%20one%20in%2020%20Coloradans,Medicaid%20drove%20the%20improvement>

⁶ Tolbert, J., Singh, R., Drake, P. *The Uninsured Population and Health Coverage*. KFF, May 28, 2024. <https://www.kff.org/health-policy/101-the-uninsured-population-and-health-coverage/?entry=table-of-contents-introduction#>

while the state acts as a passive observer is not a constitutionally protected property interest. *Cf* ECF No. 29.

SUMMARY OF ARGUMENT

Drug manufacturers do not have a constitutionally protected right to being paid inflated drug prices. Assuming they even had such a right, Colorado law provides sufficient procedural avenues in which Plaintiffs and other stakeholders have been actively engaged to ensure that their economic interests and concerns are addressed. Here, the Colorado legislature and the PDAB have gone above and beyond the constitutional due process requirements to ensure a robust, transparent, and accessible affordability review process was conducted, of which *amici*, patient groups, providers, and Plaintiffs were all active participants. The PDAB considered various views in conducting its work since its establishment, including the affordability review of Enbrel.

Unhappy with their inability to stop the PDAB from finding that Enbrel is indeed “unaffordable,” Plaintiffs seek to circumvent the legislative and administrative channels undergirding the PDAB process by turning to the courts. But in the end, this case is little more than “a dispute with the policy choices” over the State acting in the public’s interest re the prescription drug market masquerading as a constitutional challenge. *See Franklin Mem’l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009). Because Plaintiffs’ concerns can be best addressed through the political process, the Court should grant Defendants’ cross-motion for summary judgment and reject Plaintiffs’ claims.

ARGUMENT

I. Colorado’s Duty to Ensure Public Welfare Outweighs Amgen’s Professed Patent Interest in Profiting from Uncontrolled Drug Prices

a. *Drug Manufacturers are not Constitutionally Entitled to Charge Coloradan’s Exorbitant Prices for Their Products*

The Fourteenth Amendment requires the State to follow a fair process only if there is a deprivation of a protected right. U.S. Const. amdt. XIV. Plaintiffs make a due-process facial challenge to this law. To establish a due process claim, drug manufacturers must first show that they have a protected property right or interest because procedural due process is not itself an independent right. Property rights subject to procedural due process are not created by the constitution; they “are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law.” *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972). A constitutionally protected property interest entails “more than an abstract need or desire for it.” *Id.* “A unilateral expectation” is not a protected property interest. *Id.* One “must have a legitimate claim of entitlement” to the right. *Id.*

Here, Plaintiffs cannot show that they have a legitimate claim of entitlement to Enbrel’s high reimbursement rates—which stem from a complex prescription drug supply chain—because nothing in federal or Colorado law establishes that entitlement. The purported “protected property interest in their patent-protected medication, Enbrel,” (ECF No. 1 at ¶ 76; ECF No. 24 at 23) does not insulate that medication from politically negotiated economic regulations, including the law at the center of this legal dispute that

tasks the PDAB with determining whether a drug is unaffordable and establishing an UPL. Similar to what the Supreme Court said in *Roth*, the drug manufacturers' so-called property interest in patent-protected medication is not more than an "abstract need," "desire," or "unilateral expectation." *Roth*, 408 U.S. at 557. While federal law may provide certain temporal protections for their patents and market exclusivities, it does not follow that such laws insulate their drugs from reasonable intrastate regulation of the increasingly opaque prescription drug market. "The Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases." *Nebbia v. New York*, 291 U.S. 502, 527-28 (1934). Nothing in federal or Colorado law confers an unrestricted legal entitlement to reimbursement by Coloradans for excessive prices.

For their claim that the PDAB law violates the Due Process Clause, Plaintiffs rely on a handful of cases addressing price regulation. ECF No. 24 at 23—27. But those cases are irrelevant because they do not deal with the complexities of the prescription drug market and the actors in the prescription drug supply chain that consequently saddle patients with unconscionable costs. Moreover, even a limitation on what Coloradans can pay for a particular drug, such as the UPL (if it were even to be established) would not apply to a sale by Plaintiffs directly: rather the UPL would apply to certain downstream actors separate from Plaintiffs.

b. *The State Has a Duty to Provide for Public Welfare*

Even if the PDAB law was, for argument's sake, characterized as a price regulation,⁷ Plaintiffs' claims would still fail because price regulation is a rooted national tradition and lies in the nucleus of the State of Colorado's constitutional and statutory obligations to protect the health, welfare, and economic interests of its residents. *Pennell v. City of San Jose*, 485 U.S. 1, 11 (1988). "[W]e have recognized that the government may intervene in the marketplace to regulate rates or prices that are artificially inflated." Colorado is committed to a policy framework that aligns with ensuring that every Coloradan has equitable access to health care with a state office since 2019 led by the Lt. Governor that is dedicated to coordinating efforts to improve affordability across agencies.

Indeed, almost 150 years ago, in *Munn v. Illinois*, the Supreme Court upheld an Illinois law regulating grain storage prices against a due process challenge and declared that businesses "affected with a public interest" fell within the state's police power. *Munn v. Illinois*, 94 U.S. 113, 130 (1876). The Court emphasized that "when private property is devoted to a public use, it is subject to public regulation." Even at an historical point when state authority to regulate business was in question, the Supreme Court upheld a New York law regulating milk prices, underscoring the inherent power of the State "to promote the general welfare". *Nebbia*, 291 U.S. at 524. The Court found that New York's economic regulation was valid under the Due Process Clause because the "evils [of the milk market] . . . could not be expected to right themselves through the ordinary play of the forces of

⁷ As Defendants point out at ECF No. 29, this law is not a price regulation statute because it does not in any way dictate the prices wholesalers or distributors may pay Amgen or any other drug manufacturer. The law addresses various "downstream actors" in the supply chain and actual sales reimbursements of drugs sold or dispensed to some Colorado consumers. Moreover, the law does not affect all actors. For example, federal or sovereign actors, such as Medicare, are exempt.

supply and demand, owing to the peculiar and uncontrollable factors affecting the [milk] industry.” *Id.* at 518.

The Court has maintained that price regulation offends the Due Process Clause only if it is “arbitrary, discriminatory, or demonstrably irrelevant to the policy the Legislature is free to adopt.” *Id.* at 539. So even in contexts involving direct price regulation—not consumer protection laws like Colorado’s that affect market participants only incidentally and indirectly—the Supreme Court has been loath to interfere in states’ exercise of their police powers.

It is important that the State ensures its residents are not financially barred from accessing necessary medications. Thus, the establishment of the Colorado Prescription Drug Affordability Board (PDAB), and its authority to set upper payment limits for high-cost drugs like Enbrel, are not merely policy choices, but are a critical manifestation of the fulfillment of these commitments.

Establishing PDAB is a legitimate exercise of Constitutionally granted or mandated policing powers to enact laws ensuring the health, safety, and welfare of its citizens (*Webber v. Virginia*, 103 U.S. 344, 347-48 (1880); *Colorado Medical Society v. Hickenlooper*, 353 P.3d 396 (2016)). This authority is crucial in addressing public health challenges and must not be upended. Colorado’s exercise of its police power to regulate the reimbursement rates for prescription drugs is on par with the Illinois and New York laws that the Supreme Court upheld in *Munn* and *Nebbia* against due process challenges.

The Colorado legislature found excessive costs of prescription drugs prevent Coloradans from obtaining such drugs, thus endangering their health and threatening

their wellbeing.⁸ Excessive prescription drug costs also “contribute significantly to a dramatic and unsustainable rise in health-care costs and health insurance premiums that threatens the financial health of Coloradans and their ability to maintain their physical health.”⁹ The harms of excessive costs of prescription drugs are disproportionately borne by Coloradans with low incomes and put a huge burden on the public fisc, which consequently affects government spending and delivery of public services, such as education and safety. *Cf Bowles v. Willingham*, 321 U.S. 503, 513, n. 9 (1944) (one purpose of constraining exposure to high costs is “to protect persons with relatively fixed and limited incomes, consumers, wage earners . . . from undue impairment of their standard of living”). Moreover, because of the lack of transparency and gamesmanship in the prescription drug pricing market, policy makers and the public generally are unable to understand how prescription drug pricing works. The Colorado legislature adopted this law to address these concerns and protect consumers and entities in Colorado from the harms of excessively priced drugs.

*c. The State Legislature Has Established a Rational and Transparent System
For Protecting the Public Welfare*

To achieve these goals, the Colorado legislature established a PDAB (composed of subject-matter experts in clinical medicine or health care economics), laid out specific guidelines the PDAB must follow, and set benchmarks for the PDAB to consider in determining unaffordability and how an UPL may be set. Colorado law limits the number

⁸ SB 21-175, 73rd Leg., Reg. Sess. (Colo. 2021) (Legislative Declaration, ¶¶ I & II).

⁹ *Id.* at ¶ III.

of drugs the PDAB may consider each year to twelve. C.R.S. § 10-16-1407(1)(a)(I). The law further requires the PBAB to adopt a methodology for determining the UPL and lays out the factors the PDAB must consider. Such factors include costs related to administering, dispensing, and distributing the drug; shortages in the drug's supply; and the impact on older people and persons with disabilities. Still more, for a drug with an UPL, the law requires the PDAB to inquire from the drug manufacturer whether the manufacturer can make the drug available in the state and the reasons therefor.

Most importantly for due process purposes, at the back end, the Colorado law provides aggrieved parties a mechanism through which they may challenge the PDAB's decision, including judicial review. That the law provides an additional check on the PDAB's discretion an avenue for drug manufacturers to challenge a final agency action in court belies Plaintiffs' claim that the law fails to protect them against "arbitrary, confiscatory, or discriminatory deprivations." *See Nebbia*, 291 U.S. at 539.

Far from being "arbitrary, discriminatory, or demonstrably irrelevant to" drug pricing policy, the law challenged here is a rational consumer protection measure that ensures access to affordable lifesaving drugs. This thoughtful measure does not offend procedural due process. At bottom, Plaintiffs' due process claim is a dispute with the policy choices made by Colorado's politically accountable branches. The appropriate channel to address those grievances is the political process, not the federal judiciary.

Colorado's constitutional and statutory obligations to protect the health, welfare, and economic interests of its residents are clear and compelling. The establishment of the Prescription Drug Affordability Board and its authority to set upper payment limits for

drugs like Enbrel are critical to fulfilling these obligations. By regulating drug prices, Colorado not only ensures the protection of public health but also promotes equity in healthcare, protects consumers from excessive pricing, and manages the economic impacts on both individual households and the state budget.

II. The Statute Provides Robust Opportunities for Stakeholder Engagement, Including Consumer Groups and the Pharmaceutical Industry

Even if plaintiffs have a property interest protected under the Due Process Clause (which they do not), the statute and related administrative processes afford them sufficient protections against arbitrary deprivation. When a party properly alleges the existence of a property interest, “the question remains what process is due.” *Morrissey v. Brewer*, 408 U.S. 471, 481 (1972). The Due Process Clause does not impose rigid requirements. Due process “is not a technical conception with a fixed content unrelated to time, place, and circumstances.” *Matthews v. Eldridge*, 424 U.S. 319, 334 (1976). For that reason the Court articulated three factors to guide the determination: (i) “the private interest that will be affected by the official action;” (ii) “the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any of additional or substitute procedural safeguards;” and (iii) “the Government’s interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.” *Id.* at 334–35. The statute requires that the PDAB establish an UPL through a traditional rulemaking process under the Colorado Administrative Procedure Act (APA). See C.R.S. § 10-16-1403(5); C.R.S. § 24-4-101.

This process is elaborate and involves extensive involvement by various stakeholders—thus Plaintiffs would be hard-pressed to show that it fails the *Matthews* test.

Plaintiffs make various arguments to suggest that the law violates the Due Process Clause of the Fourteenth Amendment, including the claims that the law “does not provide any meaningful standards for the Board to apply”; that Plaintiffs are deprived of “the opportunity to be heard at a meaningful time and in a meaningful manner;” and that the statute “leaves regulated parties subject to the whims of the Board.” ECF No. 24 at 3. But those claims lack vital context. In fact, Plaintiffs’ description of the PDAB’s affordability review process fails to properly account for the statutory scheme and how the PDAB has actually worked. In line with the statutory scheme, the PDAB has engaged in an elaborate, often-public process that has carefully weighed all the competing interests.

a. The PDAB Allowed Extensive Opportunities for Stakeholder Engagement

First, the law and its implementation have allowed for extensive opportunities for many stakeholders to participate and shape the approach adopted by the PDAB, including establishing the UPL. Policy debates related to prescription drugs can be contentious, but disagreement with a policy decision does not amount to a constitutional flaw.

Under the Colorado APA, the PDAB’s rulemaking activities have allowed many stakeholders to submit comments for the PDAB’s consideration and shape the policies finalized by the PDAB. In 2022, the PDAB promulgated five regulations through which the

relevant proceedings exceeded the requirements under the Colorado APA.¹⁰ The PDAB acknowledged that it “received, evaluated, and in some cases incorporated suggested changes from 32 written comments on rules.” *Id.* Those comments were from various stakeholders actively involved in the PDAB’s work and affordability reviews.

CCLP contributed to comments submitted by a coalition of consumer and small business advocates that included targeted recommendations related to provisions in proposed regulations.¹¹ CCLP also separately made specific recommendations during the rulemaking process to inform the PDAB’s approach to the UPL methodology.¹² Not all of CCLP’s recommendations were adopted. That is reasonable and to be expected in administrative rulemaking. At the same time, leading pharmaceutical industry trade associations also participated in the administrative process and submitted multiple comments regarding proposed rules.¹³ Notably, at least one of the Plaintiffs (Amgen, Inc.) is a member of both PhRMA and BIO.¹⁴ So, beyond their own opportunities to directly engage the PDAB (more on that below), Plaintiffs, in collaboration with their representative associations, took steps to influence the rulemaking process.

Beyond rulemaking, the PDAB has also allowed several other paths for stakeholders to actively engage following the establishment of the PDAB and throughout

¹⁰ PDAB, 2022 Activities Summary Report (July 1, 2023), <https://drive.google.com/drive/folders/1LYcsjeyVaWr2q18G82TX6mFYZiztdZ1G>.

¹¹ Comment Letter from Colorado Consumer Health Initiative et al. (Aug. 24, 2022), <https://drive.google.com/drive/folders/1gknv-OCbQ-Hael2N7FbSXyRnwNes9wCu>.

¹² Comment Letter from CCLP, (Oct. 3, 2022), <https://drive.google.com/drive/folders/1iyh5kEElajLvjIXdfi2FzFQ9Q12QJPCv>; Comment Letter from CCLP, (Nov. 13, 2022), <https://drive.google.com/drive/folders/1iyh5kEElajLvjIXdfi2FzFQ9Q12QJPCv>.

¹³ See, e.g., Comment Letter from PhRMA (Nov. 14, 2022), <https://drive.google.com/drive/folders/1iyh5kEElajLvjIXdfi2FzFQ9Q12QJPCv>; Comment Letter from Colorado Bioscience Association and Biotechnology Innovation Organization (BIO) (Nov. 14, 2022), <https://drive.google.com/drive/folders/1iyh5kEElajLvjIXdfi2FzFQ9Q12QJPCv>.

¹⁴ See PhRMA, *About*, <https://phrma.org/en/About> (last accessed August 13, 2024); BIO, *Member Directory*, <https://www.bio.org/member/bio-member-directory> (last accessed August 13, 2024).

the affordability review process. In the spring of 2022, the PDAB held a five-part Prescription Drug Affordability Learning Series on various issues, including data, the supply chain, comparative effectiveness, and other state models to allow interested stakeholders better inform the PDAB's work.¹⁵ As required by statute, C.R.S. § 10-16-1409, the PDAB also appointed a fifteen-member Prescription Drug Affordability Advisory Council (PDAAC) in December 2021. The PDAAC comprises consumer representatives, patients with chronic diseases, labor unions, insurance carriers, pharmacy benefit managers, wholesalers, pharmacists, researchers, health care providers, and manufacturers of both branded and generic prescription drugs. PDAB, 2022 Activities Summary Report. The PDAAC met ten times in 2022 and six times in 2023.¹⁶ In short, the process established by the law guiding the PDAB's work is so robust in practice that it cannot be said that additional or substitute procedural safeguards (if any) would be necessary.

b. Industry's Broad and Meaningful Interactions with the PDAB

Second, opportunities to engage with the PDAB, including by consumer advocates, researchers, the pharmaceutical industry, and other stakeholders have been "meaningful." Building on the extensive feedback and communication with different stakeholders described above, in conducting affordability reviews, the PDAB also considered information from several actors, including manufacturers, and input from

¹⁵ PDAB, 2022 Activities Summary Report (July 1, 2023), <https://drive.google.com/drive/folders/1LYcsjeyVaWr2q18G82TX6mFYZitdZ1G>.

¹⁶ *Id.*; PDAB, 2023 Activities Summary Report (July 1, 2024), <https://drive.google.com/drive/folders/1LYcsjeyVaWr2q18G82TX6mFYZitdZ1G>.

patients as well as individuals with scientific or medical training.¹⁷ Over the course of the affordability reviews for the five drugs selected, the PDAB received input from hundreds of patients, caregivers, and those with scientific or medical training.¹⁸

The PDAB held meaningful public meetings and created space for office hours with its staff at critical stages of the eligibility and selection processes of the affordability reviews. This included public meetings to walk through the 2023 Colorado Eligible Drug Dashboard, and facilitating a stakeholder meeting to dive deeper into the affordability review process and relevant criteria used to select prescription drugs for consideration.¹⁹

Even Plaintiffs themselves engaged with the PDAB throughout this entire process. On August 10, 2023, in addition to a public posting on the PDAB website, PDAB informed various stakeholders that they could submit information related to Enbrel for 60 days following the drug's selection for affordability review.²⁰ In response, Amgen Inc. submitted public and confidential information to the PDAB.²¹; ECF No. 29, Exhibit 2. In its October 2, 2023 letter to the PDAB, Amgen, Inc. stated that it “appreciates and shares Colorado’s interest in ensuring medications are affordable,” and “recognize[s] the importance of dialogue on this topic.”²² In addition, on December 5, 2023, Amgen, Inc. sent a letter to the PDAB regarding certain process issues stemming from a public PDAB meeting in late October 2023.²³ On February 1, 2024, Amgen, Inc. sent a letter to the PDAB to “raise

¹⁷ PDAB, 2023 Activities Summary Report.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ PDAB, 2023 Affordability Review Report: Enbrel at J-2.

²¹ *Id.*

²² Enbrel Report at J11.

²³ Amgen Letter to Colorado Department of Regulatory Agencies, Division of Insurance (ATTN: Dr. Gail Mizner) (Dec. 5, 2023), <https://drive.google.com/drive/folders/19dcezKJG6uecdBPRDBMNZPaOL6O5ropJ>.

serious concerns about the fairness and legality of the Board's review process."²⁴ Amgen, Inc. followed up with another letter to the PDAB a few weeks later to repeat similar themes and urge the PDAB to postpone its upcoming meeting.²⁵ Plaintiffs' own active participation in the PDAB process belies their claim that the nature of the program does not contain sufficient guardrails for purposes of the Due Process Clause.

The PDAB held multiple public meetings specific to the consideration of Enbrel, relevant data, and its affordability review.²⁶ As Plaintiffs highlighted for this Court, at ECF No. 25, an employee from Amgen was able to directly express their views and concerns with the PDAB members at the February 16, 2024 meeting. Such opportunities exemplify the range of options that the pharmaceutical industry and Plaintiffs in particular had to fully participate in the PDAB's affordability review process and the ultimate decision about Enbrel.

c. PDAB's Thoughtful and Balanced Approach

Last, the PDAB does not leave members of the pharmaceutical industry "subject to the whims of the Board." Rather, the PDAB has pursued a balanced approach that incorporates patient, industry, and other stakeholder concerns to act within the PDAB's statutory mandate and address the affordability of prescription drugs. *Amici* do not agree with all of the PDAB's decisions, and that is to be expected with any state board

²⁴ Amgen Letter to Colorado Department of Regulatory Agencies, Division of Insurance (ATTN: Dr. Gail Mizner) (Feb. 1, 2024), https://drive.google.com/file/d/1xHmoeBEI4fGDZ2KzcZABSW_9ngnP1vQv/view.

²⁵ Amgen Letter to Colorado Department of Regulatory Agencies, Division of Insurance (Feb. 22, 2024), https://drive.google.com/drive/folders/1PVEGzU8yES2t8qJ0IU_otvrM2GeMfusU.

²⁶ PDAB, Prescription Drug Affordability Board Meeting (Dec. 8, 2023), https://drive.google.com/drive/folders/1CeipcmI6V1Bq_qk8J00xe_i36g_HQLQD; PDAB, Prescription Drug Affordability Board Meeting (Feb. 16, 2024), <https://drive.google.com/drive/folders/1BnowaPZaqjX-r8u-4U3X9lv4wO3RL7UK>; PDAB, Prescription Drug Affordability Board Meeting (Feb. 23, 2024), https://drive.google.com/drive/folders/1KQaWinfssNWvTQp26lOjeLE_4j-pz1Cl.

composed of subject-matter experts entrusted with complex policy decisions. That said, *amici* recognize that the PDAB is acting within its authority and strives to balance competing interests in doing its work.

A clear example of this dynamic is the PDAB's decision that the cystic fibrosis drug, Trikafta, was not "unaffordable." In December 2023, CCLP staff submitted a public comment urging that the PDAB designate Trikafta as "unaffordable" and proceed with identifying an UPL.²⁷ Other stakeholders raised concerns with designating Trikafta as "unaffordable," including the Cystic Fibrosis Foundation, a group of 19 Colorado legislators, and the pharmaceutical industry.²⁸ Ultimately, the PDAB found that Trikafta was not "unaffordable."²⁹ While *amici* desired that the PDAB examine the relevant statutory factors and make such a designation to allow the PDAB to identify an UPL and help more consumers afford their prescription drugs, that is the inevitable consequence of a balanced process that weighs input from stakeholders on all sides before issuing their final decision.

Similarly, the Colorado legislature has been mindful of various concerns that stakeholders have raised in connection with the implementation of the PDAB. For example, the law was recently amended and, going forward, requires the PDAB to consider whether a drug has an approved orphan drug designation for one or more rare

²⁷ Bethany Pray, *CCLP's public comment on cystic fibrosis drug, Trikafta* (Dec. 5, 2023), <https://copolicy.org/news/trikafta-public-comment/>.

²⁸ Comment Letter From Cystic Fibrosis Foundation (Oct. 3, 2023), <https://drive.google.com/drive/folders/1WTB-qFzUI-eyvUxEx2MjuEx1zoXmghQG>; Comment Letter from Colorado Legislators (Sept. 27, 2023), https://drive.google.com/drive/folders/1LDjGiSkluSrKd0PBOKyQ5PBH_kPgccLZ; Comment Letter from Colorado Bioscience Foundation (Sept. 28, 2023), <https://cobioscience.com/wp-content/uploads/2024/01/CBSA-Letter-to-Governor-Polis-092823.pdf>.

²⁹ PDAB, Prescription Drug Affordability Board DRAFT Meeting Minutes (Dec. 8, 2023), <https://drive.google.com/drive/folders/1BnowaPZaqiX-r8u-4U3X9lv4wO3RL7UK>.

diseases when conducting its affordability review, as well as the input from the Colorado rare disease advisory council.³⁰ This does not reflect an unaccountable PDAB with unfettered power that has the pharmaceutical industry at its mercy. Rather, the actions of the Colorado legislature reflect an effort to learn from stakeholder feedback and ensure that the state has a functioning prescription drug market that protects consumers.

III. Evolving Moral and Public Policy Norms Dictate that States Act and Ensure Access to Affordable Lifesaving Drugs

It is a well-established public health principle and a determination made by the United Nations that health care is a basic human right.³¹ Vital to this right is access to affordable prescription drugs. In the United States, access to prescription drugs exists in a for-profit system which frequently presents an immense financial barrier for vulnerable consumers. Indeed, consumers of prescription medications are dependent on these life-changing and lifesaving medications, and patent exclusivity takes away any meaningful ability to shop. If a consumer exits this marketplace, they risk death or poor quality of life. This Hobson's choice, either pay an exorbitant amount or go without, becomes problematic in the context of prescription drugs, when "going without" results in an overall poorer quality of life.³² The difference in consumer participation between the traditional market and the prescription drug market requires a difference in approach. Arguably the

³⁰ See SB 24-203, 74th Leg., Reg. Sess. (Colo. 2024).

³¹ United Nations. International covenant on economic, social and cultural rights. Available at: 372 <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx>. Accessed August 13, 2024

³² *Natl. Acad. Sci. Eng. Med. 2017. Making medicines affordable: a national imperative. Rep., Natl. Acad. Sci. Eng. Med., Washington, DC. <http://nationalacademies.org/hmd/Reports/2017/makingmedicines-affordable-a-national-imperative.aspx>*

power imbalance between consumer and manufacturer creates an ethical obligation on the manufacturer to consider consumer vulnerabilities when setting prices.³³

Prescription drugs, like Enbrel, are an essential part of the treatment and management of several health conditions. Yet, a recent survey of Colorado residents showed that approximately 304,000 have a somewhat difficult or very difficult time affording their prescriptions³⁴. The survey also found an increase in the risk of skipping or forgoing medication entirely, for those who expressed concern about drug prices. Of those who identified cost as a reason for not filling a prescription, 40% reported a worsening of their health condition as a result.³⁵ This is true for Enbrel, as nearly 53% of Coloradan respondents to a survey on Enbrel responded that the medications cost has caused them to “cut costs in other areas of my life” and 21% reported that “out-of-pocket costs have caused me to accrue medical debt,” and 71% reported that cost has affected their access to the drug.³⁶

Laws regarding price gouging in times of emergency provide a close analogue to the excessive-price laws for prescription drugs.³⁷ Colorado law gives the state authority to prevent unfair and deceptive practices that harm consumers, as well as against excessive pricing of medical supplies and other goods when there are disruptions in the market in the time of declared disaster. (C.R.S. § 6-1-105 and § 6-1-730). The state has a well-established interest in protecting Colorado residents against unfair and

³³ Valdman M. 2009. A theory of wrongful exploitation. *Philos. Imprint* 9:1–14

³⁴ Colorado Health Institute (CRI), Colorado Health Access Survey 2021 (2023)

³⁵ *Id.*

³⁶ Prescription Drug Affordability Board, Enbrel Affordability Review Report, 25, Appendix E-12

³⁷ *Michelle M. Mello & Rebecca E. Woltz, Legal Strategies for Reining in Unconscionable Prices for Prescription Drugs, 114 NW. U. L. REV. 859 (2020).*

unconscionable pricing, particularly when the marketplace for the pricing of consumer goods and services is not functional. Thus, the PDAB's role in setting upper payment limits is an analogous application of this authority aimed at preventing pharmaceutical companies from engaging in pricing that could be deemed exploitative or detrimental to public welfare.

The state's responsibility extends beyond general health and consumer protection to address specific issues of equity in healthcare. Colorado has recognized the significant disparities in healthcare access and outcomes, particularly among marginalized communities. Not only are individuals belonging to vulnerable or marginalized populations more likely to have issues affording Enbrel, they are also more likely to need Enbrel. As noted in the PDAB report, those belonging to historically marginalized racial-ethnic groups are more likely to be diagnosed with a condition that Enbrel treats.³⁸ Efforts by the state of Colorado to ensure the health of its residents through statutory, regulatory, political, and judicial means demonstrate that the state sees health and healthcare as fundamental to the wellbeing of residents. In fact, there has been a growing focus nationally and in Colorado on economic justice and health equity in general. Access to healthcare, including essential medications, has become a moral imperative, and the possibility of those in need of medications being unable to access them due to costs becomes morally unacceptable. When considered in this manner, it suggests that the changes in our views on healthcare are due to our "evolving standards of decency." *Trop v. Dulles*, 356 U.S. 86, 99-101 (1958). The U.S. Supreme Court and the 10th Circuit have used this phrase

³⁸ Prescription Drug Affordability Board, Enbrel Affordability Review Report, 25.

when analyzing one's 8th amendment right to be free of treatment that is "cruel and unusual," but when interpreted more broadly, it reflects the progress of a maturing society whose norms evolve over time to reflect current moral and ethical standards.

There is a growing consensus that life-altering and lifesaving medication be accessible and affordable to all. Engaging in an analysis similar to that of *Roper*, it is clear that norms on health care affordability are evolving. *Roper v. Simmons*, 543 U.S. 551 (2005). Indeed, numerous states have enacted or have proposed laws for drug pricing control and transparency, reflecting growing state concerns; currently, 24 states have laws on pricing transparency and 10 states have affordability reviews.³⁹ Moreover, most Americans support governmental intervention to reduce prescription drug prices, indicating a societal shift towards affordability.⁴⁰

CONCLUSION

The Due Process Clause does not protect Plaintiffs' property interest in receiving boundless reimbursement by Coloradans for Enbrel at whatever price Plaintiffs desire. Nor does it allow Plaintiffs to dictate the exact process by which the PDAB must undertake to set an UPL. The PDAB reflects a constitutional and reasonable approach by the Colorado legislature to consider limitations on the reimbursement of certain prescription drugs with excessive costs. Accordingly, Plaintiffs' motion for summary judgment should be denied and Defendants' cross-motion for summary judgment should be granted.

³⁹ Currently, 24 states have passed laws on drug pricing transparency and 10 states have codified affordability review processes. See State Laws Passed to Lower Prescription Drug Costs: 2017-2024 (2024), available at <https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2024/>.

⁴⁰ See Kaiser Family Foundation (KFF), Public Opinion on Prescription Drugs and Their Prices (2023), available at <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/> and National Public Radio, Poll: Americans Support Government Action To Curb Prescription Drug Prices (2019), available at <https://www.npr.org/sections/health-shots/2019/03/01/699086303/poll-americans-support-government-action-to-curb-prescription-drug-prices>.

DATED at Denver, Colorado this 16th day of August, 2014.

Respectfully submitted,

/s/Annamarie Martínez
Annamarie Martínez, 48494
Counsel for *Amici Curiae*
Litigation Director
Colorado Center on Law and Policy
789 N. Sherman St., Suite 300
Denver, CO 80203
e: amartinez@copolicy.org
t: 303-573-5669 x314

CERTIFICATE OF SERVICE

I hereby certify that on this August 16, 2024, I electronically filed the foregoing Brief of *Amici Curiae* in Support of Defendant, with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to attorneys of record.

/s/Annamarie Martínez
Annamarie Martinez
Counsel for *Amici Curiae*