IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

AMGEN, INC., *et al.*,

Plaintiffs,

Civil Action No. 1:25-cv-03452-DDD-STV

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 AND COLORADO CONSUMER HEALTH INITATIVE IN SUPPORT OF DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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IDENTIES AND STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are nonprofit advocacy organizations that work on behalf of Colorado consumers, patients, and communities affected by poverty, health-care costs, and barriers to accessing necessary care. Amici share a strong interest in this case because Plaintiffs' challenge threatens Colorado's ability to address excessive prescription-drug costs through a transparent, evidence-based, and public regulatory process.

The Colorado Prescription Drug Affordability Board ("PDAB") was created to address a concrete and growing problem: Coloradans are too often forced to choose between filling necessary prescriptions and paying for basic needs such as food, rent, transportation, and utilities. The Board's affordability review process is designed to evaluate those burdens, consider the impact of high drug costs on patients and the health-care system, and determine whether upper payment limits are necessary to protect access to needed medications. Amici have participated in and supported that process because prescription-drug affordability is central to health, economic security, and consumer protection.

Amici bring a perspective distinct from the parties. As nonprofit organizations that advocate for consumers and low-income Coloradans, amici can address the public-health, anti-poverty, consumer-protection, and health-equity implications of the requested preliminary injunction. Amici also have direct experience with Colorado's prescription-drug affordability work, including the implementation of the PDAB, public comment, stakeholder engagement, legislative advocacy, and consumer education.

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[1] Counsel for *Amici* have consulted with counsel for all parties, there are no objections to 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. No other person or entity, other than *amici*, their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

Here is a general description of each amicus curiae and its particular interest in this case:

Colorado Center on Law and Policy

The Colorado Center on Law and Policy ("CCLP"), established in 1998, is a nonprofit organization dedicated to eradicating poverty across Colorado. CCLP works to advance economic security through research, policy development, legislative advocacy, administrative advocacy, litigation, and amicus participation. Its work focuses on four main areas: food, housing, income, and health.

Healthcare access and affordability are central to CCLP's mission. CCLP advocates at the legislature, in rulemaking, and in the courts to promote equitable access to medical services and to reduce barriers that prevent low-income Coloradans from obtaining necessary care. A major priority for CCLP is ensuring that all Coloradans can access lifesaving and life-improving medications needed to manage chronic conditions and other health-care needs. No Coloradan should be forced to choose between affording a necessary prescription and meeting basic needs.

CCLP supported the creation of the PDAB and has actively participated as a stakeholder in its implementation. CCLP has advocated 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.

Colorado Consumer Health Initiative

The Colorado Consumer Health Initiative ("CCHI"), established in 2000, is a nonprofit, consumer-oriented, membership-based health advocacy organization that works to ensure all Coloradans have equitable access to high-quality, affordable health care. CCHI advances the consumer voice to improve access to health care statewide, with a focus on equity, access, affordability, and quality.

In 2021, CCHI championed the original Prescription Drug Affordability Board legislation, SB21-175, as part of a broad and diverse coalition of community partners and organizations responding to growing concerns about prescription-drug costs from Colorado patients, health-care providers, small businesses, and other stakeholders across the state. Since passage of the PDAB legislation, CCHI has remained deeply engaged in the Board's implementation and in prescription-drug affordability work more broadly.

CCHI staff have attended nearly all Board and Advisory Council meetings over the past five years, submitted more than twenty comments for the Board's consideration, testified twice during Enbrel's upper-payment-limit process, and engaged numerous consumers in the Board's work. CCHI has also participated in three subsequent legislative efforts related to the Board, prioritized legislator education around the PDAB's work, and helped inform the public about key milestones through media engagement.

Amici submit this brief because a ruling for Plaintiffs would have consequences beyond this case. It could restrict Colorado's ability to craft and implement policies that help residents access affordable prescription drugs, including medications necessary to live with dignity, manage chronic conditions, and avoid preventable health deterioration. Amici respectfully seek to assist the Court by offering a consumer-centered, health-equity, and anti-poverty perspective on the public interests at stake. Because the public interest is not served by disabling Colorado from using a careful, public, and evidence-based process to address prescription-drug costs that place necessary medication out of reach for the people who need it most.

INTRODUCTION

Colorado's Prescription Drug Affordability Act, (C.R.S. § 10-16-1401 *et seq.*), is a public-health and consumer-protection measure designed to improve access to necessary prescription drugs by addressing market dysfunction and excessive costs. This case does not present a dispute over private commercial expectations alone but concerns Colorado's ability to protect residents from drug costs that threaten access to medically necessary care, deepen poverty, and force families to choose between medication and other basic needs.

The Enbrel Affordability Review Summary Report considered Colorado All Payer Claims Database information, patient and caregiver surveys, and literature documenting barriers to access. (Enbrel Report).[2] The report reflects that Coloradans struggle to afford Enbrel, a medication used to treat rheumatoid arthritis and other serious conditions.[3] Those affordability barriers fall especially hard on low-income households and communities already facing health inequities. Plaintiffs nevertheless seek the extraordinary remedy of a preliminary injunction to stop Colorado from enforcing a democratically enacted affordability law.

SUMMARY OF ARGUMENT

Amgen cannot meet its burden to obtain preliminary relief. The Act is an exercise of Colorado's longstanding police power to protect public health, safety, and welfare. Federal patent law grants a right to exclude competitors; it does not confer immunity from state regulation affecting the economics of a patented product. Colorado's Act does not determine patentability, shorten patent

[2] PDAB, 2023 Affordability Review Report: Enbrel (Feb. 23, 2024), https://drive.google.com/drive/folders/1xdHNz_KHSB5uL6o2DDSqcKOZbCsmRXq2?usp=drive_lin
[3] *Id.*, 25.

terms, authorize infringement, or create patent-like rights. It regulates affordability in Colorado's health-care market.

Plaintiffs' due process challenge also fails. They have not identified a protected property interest in any particular reimbursement level or financial return on Enbrel. Even assuming due process applies, economic regulation is reviewed deferentially, and Colorado's Act is not standardless. The Board may set an upper payment limit only after an affordability review; it must act through statutory criteria, rulemaking, methodology, required factors, administrative process, and judicial review.

Finally, the equities and public interest weigh against an injunction. The report documents real harms from unaffordable prescriptions: skipped medication, worsened health, medical debt, and tradeoffs with basic necessities. Plaintiffs' private economic objection does not outweigh Colorado's interest in protecting residents from excessive drug costs and preserving access to necessary medication.

ARGUMENT

I. Amgen Is Not Likely to Succeed on the Merits

Because Amgen seeks the extraordinary remedy of a preliminary injunction, it bears the burden of showing a likelihood of success on the merits. It cannot meet that burden.

a. Colorado's Act Falls Within the State's Longstanding Police Power to Protect Public Health, Safety, and Welfare

Colorado's Act sits at the core of the State's police power. It is not a state patent law. Rather, it is a public-health and consumer-protection law directed at a concrete affordability crisis: the cost of prescription drugs necessary to treat illness, prevent deterioration, and sustain life.

The Supreme Court has long recognized that States possess broad authority to enact reasonable laws protecting public health, safety, and welfare. *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905). In *Munn v. Illinois*, the Court upheld rate regulation against a due-process challenge, explaining that when private property is "affected with a public interest," it may be subject to public regulation. 94 U.S. 113, 130 (1876). In *Nebbia v. New York*, the Court upheld milk-price regulation, emphasizing the State's authority "to promote the general welfare" where ordinary supply-and-demand forces cannot be expected to correct the problem. 291 U.S. 502, 518, 524 (1934). That authority is especially strong in matters of health and safety, which are "primarily, and historically, a matter of local concern." *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 719 (1985). States have "great latitude" to protect "the lives, limbs, health, comfort, and quiet of all persons." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). The police power extends beyond immediate physical danger; public safety and public health "illustrate the scope of the power" but "do not delimit it." *Berman v. Parker*, 348 U.S. 26, 32 (1954).

Patent law does not erase that authority. In *Webber v. Virginia*, the Court explained that "Congress never intended that the patent laws should displace the police powers of the States," including powers "by which the health, good order, peace, and general welfare of the community are promoted." 103 U.S. 344, 347 (1880). A patent grants a right to exclude competitors; it does not create immunity from state laws governing the sale, use, or affordability of products within the State's borders.

Colorado's Act is an exercise of that traditional authority. The General Assembly declared that "in exercise of its police powers and responsibility for the public health, safety, and general welfare of Colorado residents," the State must act to reduce excessive prescription-drug costs and protect Coloradans who cannot afford necessary medication. S.B. 21-175, § 1(2), 73d Gen. Assemb., 1st Reg.

Sess. (Colo. 2021). The Act directs the Board to establish upper payment limit methodology "to protect consumers from the excessive cost of prescription drugs and ensure they can access prescription drugs necessary for their health." C.R.S. § 10-16-1407(2). This is health-and-welfare not patent regulation.

b. Federal Patent Law Does Not Give Amgen Immunity from Generally Applicable State Health-Care Affordability Regulation.

Federal patent law grants Amgen a right to exclude others from making, using, offering for sale, selling, or importing the patented invention. 35 U.S.C. § 154(a)(1). It does not grant a right to be free from all state regulation affecting the economics of a patented product nor does it confer an unrestricted entitlement to any particular reimbursement level, pricing structure, or return from Colorado consumers, payors, or public programs.

Colorado's Act does not determine patentability, shorten a patent term, authorize infringement, or create patent-like rights. It regulates affordability in Colorado's health-care market through statutory criteria and administrative process. Because neither the Patent Act nor Hatch-Waxman expressly preempts state drug-affordability laws, Amgen must satisfy the high bar for implied preemption. But implied preemption is not a license for courts to invalidate state laws merely because they affect the economics of a federally protected product. The Supreme Court has warned against a "freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011). And where a State regulates in areas traditionally occupied by the States—public health, consumer protection, and economic welfare—preemption should not be inferred absent clear congressional intent. See *Arizona v. United States*, 567 U.S. 387, 400 (2012); *Hillman v. Maretta*, 569 U.S. 483, 490–91 (2013).

Amgen's reliance on *BIO* is misplaced. That case involved a District of Columbia law that singled out patented drugs and used foreign patent-system benchmarks to determine whether a manufacturer's price was excessive. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007). Colorado's Act does neither. It does not use patent status as the trigger for regulation, attempt to rebalance patent incentives, or regulate the rewards federal law provides for innovation.

"[t]he Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases." *Nebbia*, 291 U.S. at 527–28. Amgen's theory would convert a federal right to exclude competitors into immunity from generally applicable state health-care affordability regulation. Federal patent law does not require that result.

c. The Act Provides Meaningful Standards and Procedural Safeguards Consistent with Due Process.

Plaintiffs' due process challenge fails at the threshold because they have not identified a protected property interest in any particular reimbursement level, pricing structure, or return in Enbrel. Procedural due process applies only where the State deprives a person of a protected liberty or property interest. Property interests 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 v. Roth*, 408 U.S. 564, 577 (1972). A protected property interest requires more than an "abstract need or desire" or "unilateral expectation"; it requires a "legitimate claim of entitlement." Id.

Plaintiffs cannot show a legitimate claim of entitlement to Enbrel's existing reimbursement rates or to any particular payment level by Colorado consumers, payors, or public programs. Patent law may protect Amgen's right to exclude competitors for a defined period, but it does not create a due process entitlement to sell a drug at any price it might choose. The Third Circuit recently rejected a similar theory in litigation challenging the Medicare Drug Price Negotiation Program, explaining that

federal patent laws "do not confer a right to sell at a particular price." *AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 127 F.4th 491, 502–03 (3d Cir. 2025).

Even assuming due process applies, Colorado's Act is economic regulation subject to deferential review. Economic regulation satisfies due process if it is not "unreasonable, arbitrary or capricious" and if the means selected bear a "real and substantial relation" to the legislative objective. *Nebbia v. New York*, 291 U.S. 525, 527–28 (1934). Price regulation offends due process only where it is "arbitrary, discriminatory, or demonstrably irrelevant to the policy the Legislature is free to adopt." Id. at 539.

The Act clears that standard. Plaintiffs describe the Act as lacking "ascertainable standards," but the Board may establish an upper payment limit only after conducting an affordability review and determining that a prescription drug is unaffordable for Colorado consumers. C.R.S. § 10-16-1407(1)(a). The statute limits the number of drugs the Board may consider each year, requires the Board to adopt a methodology by rule, and directs that methodology toward protecting consumers from excessive drug costs while ensuring access to drugs necessary for health. C.R.S. § 10-16-1407(1)(a)(I), (2). It further identifies factors the Board must consider, including costs related to administering and dispensing the drug, distribution costs to Colorado consumers, drug-shortage status, and other relevant costs. Id. It also prohibits valuation methods that discount the value of life based on age or disability. *Id.*

Plaintiffs' "standardless discretion" argument mistakes expert judgment for constitutional defect. Due process does not require the legislature to reduce complex economic regulation to a single formula. The prescription-drug market involves manufacturers, wholesalers, pharmacy benefit managers, insurers, pharmacies, public programs, and patients; affordability cannot be assessed through one variable alone. Colorado, therefore, did what legislatures routinely do in complex

regulatory fields: it identified the public purpose, set eligibility criteria, required rulemaking, specified factors to consider, preserved administrative process, and subjected final agency action to judicial review. C.R.S. §§ 10-16-1407, 24-4-106. This is structured administrative decision-making and not standardless discretion.

Nor does the Board's consideration of the Medicare Maximum Fair Price for Enbrel make the scheme arbitrary. Congress created the Medicare Drug Price Negotiation Program through the Inflation Reduction Act, directing CMS to negotiate prices for selected high-cost drugs beginning in 2026. 42 U.S.C. § 1320f(a). For Enbrel, that federal process included consideration of patents and exclusivities, along with other mandatory factors, and involved exchanges of offers and counteroffers between CMS and Amgen prior to a series of meetings between the parties. The Board's consideration of a federal benchmark produced through a drug-specific negotiation process involving the same manufacturer and same drug was rational, particularly where Colorado's upper payment limit was set slightly above the Medicare MFP.

Plaintiffs' argument also mischaracterizes the role of patent status. The process did not begin with patent status, and the Act does not punish patent protection. It begins with affordability and access. To the extent patents or exclusivities are relevant, they are relevant as part of a broader market analysis, including whether meaningful competition exists for a specific drug. Considering market competition when assessing affordability is ordinary economic regulation, not patent regulation.

Plaintiffs' "fair and reasonable return" argument does not change the analysis. Even in traditional rate-regulation contexts, due process does not require a regulator to preserve a company's preferred profit level, investment expectations, or pricing strategy. It requires that regulation not be confiscatory, arbitrary, or disconnected from a legitimate public purpose. See *Nebbia v. New York*, 291 U.S. 502, 525, 539 (1934); *Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 602–05 (1944);

Duquesne Light Co. v. Barasch, 488 U.S. 299, 310, 314–16 (1989). Plaintiffs have not shown a constitutional entitlement to any particular Enbrel reimbursement rate, nor have they shown that Colorado's process is confiscatory or irrational. Disagreement with the outcome of an affordability process does not establish a likelihood of success on a facial due-process challenge.

II. The Balance of Equities and Public Interest Favor Preserving Colorado's Public-Health Protections and Coloradans' Access to Affordable, Lifesaving Drugs.

The remaining equitable factors confirm why preliminary relief is inappropriate. The public interest does not favor enjoining a law designed to protect Coloradans from the health and economic consequences of unaffordable prescription drugs. The General Assembly found that excessive prescription-drug costs prevent residents from obtaining necessary medications, endanger health, threaten well-being, and contribute to unsustainable increases in health-care costs and health-insurance premiums. For low-income Coloradans, excessive drug costs can mean choosing between medication and rent, food, utilities, transportation, or other necessities.

A recent survey of Colorado residents found that approximately 304,000 Coloradans have a somewhat difficult or very difficult time affording their prescriptions.[4] Among respondents who identified cost as a reason for not filling a prescription, 40% reported that their health condition worsened as a result.[5] The Enbrel-specific record demonstrates nearly 53% of Colorado respondents reported that the medication's cost caused them to cut costs in other areas of life; 21% reported that out-of-pocket costs caused them to accrue medical debt; and 71% reported that cost affected their access to the drug.[6]

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

5 Id.

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

These harms extend beyond individual households. Delayed treatment, rationed medication, and avoidable health deterioration can increase reliance on emergency care, public insurance programs, public benefits, and other state and local services. Colorado has a strong public interest in preventing those harms before they occur.

That interest is particularly weighty where the drug at issue treats serious and chronic conditions and patients lack meaningful consumer choice. Patients who need Enbrel are not ordinary consumers in an ordinary marketplace. Reporting on Enbrel's patent estate has described at least 68 granted patents around the drug and noted that biosimilar competition may be delayed in the United States until 2029, even though FDA-approved biosimilars have existed for years. The same reporting noted that Enbrel had already generated more than $70 billion in cumulative revenue and could approach $100 billion before lower-cost competition enters the U.S. market. These facts underscore why Colorado could rationally consider market competition as part of an affordability analysis: where patent barriers delay alternatives, patients cannot rely on ordinary market forces to discipline price.[7]

The equities also favor enforcement because excessive prescription-drug costs fall unevenly. The General Assembly recognized that high drug costs disproportionately harm Coloradans with low incomes. Enbrel report further reflects that members of historically marginalized racial and ethnic groups are more likely to be diagnosed with conditions Enbrel treats. For Amici, and the communities it serves, affordability is therefore not merely a consumer-pricing issue; it is an access-to-justice, anti-poverty, and health-equity issue.

Against these concrete public harms, Amgen asserts a private economic interest in avoiding the operation of a generally applicable affordability law. That interest should be weighed in context of

[7] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

the broader economic record. Recent analysis found that the ten largest drug manufacturers earned approximately $131 billion in net profits in 2025 while spending approximately $84 billion on shareholder compensation and $109 billion on research and development; Amgen alone reported approximately $8 billion in net profits, $7 billion in R&D spending, and $5 billion in shareholder compensation.[8] The same analysis reported that R&D spending increased after the Inflation Reduction Act and that most top manufacturers projected revenue growth in 2026, the first year negotiated Medicare prices take effect.[9] Enjoining the Act would interfere with Colorado's responsibility to protect the health, safety, and welfare of its residents and delay protections designed to make necessary medications more accessible and affordable.

CONCLUSION

For the foregoing reasons, and for the reasons set forth in Defendants' briefs, this Court should deny Plaintiffs' Motion for Preliminary Injunction.

DATED at Denver, Colorado this 5th day of May 2026.

Respectfully submitted,

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[8] https://www.protectourcare.org/greed-watch-drug-company-profits-skyrocket-as-trump-cuts-back-room-deals-that-screw-over-working-families/
[9] Id.

RULE 7.1 CERTIFICATION

I hereby certify that the foregoing motion complies with the type-volume limitation set forth in Judge Domenico's Practice Standard III(A)(1).

/s/ Annamarie Martínez
Annamarie Martínez, 48494
Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on this May 5, 2026, 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 Martínez
Counsel for Amici Curiae