UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action
No. 1:25-cv-3452-DDD-STV

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

INTRODUCTION 1

BACKGROUND 5

A. The Federal Patent System 5

B. Colorado's Price-Control Scheme 6

C. Amgen's Patent-Protected Drug Enbrel 9

D. The Board Declares Enbrel Unaffordable Based in Part on Its Patent Status and Selects It for Establishment of an Upper Payment Limit 11

E. Amgen's First Lawsuit Is Dismissed as Premature 13

F. The Board Establishes an Upper Payment Limit for Enbrel 14

LEGAL STANDARD 17

ARGUMENT 18

I. Amgen's standing is now clear 18

II. Amgen is likely to succeed on the merits of its claims 24

A. Colorado's price cap is preempted by the federal patent laws 25

B. Colorado's regime lacks meaningful standards and thus violates due process 30

III. Amgen will suffer irreparable harm absent a preliminary injunction 35

IV. The balance of equities and public interest strongly favor Amgen 37

CONCLUSION 38

RULE 7.1(a) CERTIFICATION 40

CERTIFICATE OF SERVICE 41

TABLE OF AUTHORITIES

Cases

Amgen Inc. v. Mizner,
No. 1:24-cv-810 (D. Colo. Mar. 28, 2025), ECF 49 ..... *passim*

Bella Health & Wellness v. Weiser,
699 F. Supp. 3d 1189 (D. Colo. 2023) 17, 37

Beltronics USA, Inc. v. Midwest Inventory Distrib., LLC,
562 F.3d 1067 (10th Cir. 2009) 17, 35, 38

Biotech. Indus. Org. v. District of Columbia (*BIO I*),
496 F.3d 1362 (Fed. Cir. 2007) ..... *passim*

Biotech Indus. Org. v. District of Columbia (*BIO II*),
505 F.3d 1343 (Fed. Cir. 2007) 27

Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,
489 U.S. 141 (1989) 3, 6, 25

Carpenters Indus. Council v. Zinke,
854 F.3d 1 (D.C. Cir. 2017) 20

Chamber of Com. v. Edmondson,
594 F.3d 742 (10th Cir. 2010) 5, 35, 38

Dep't of Com. v. New York,
588 U.S. 752 (2019) 20

Diamond Alt. Energy, LLC v. EPA,
606 U.S. 100 (2025) ..... *passim*

Duquesne Light Co. v. Barasch,
488 U.S. 299 (1989) 34

Energy Future Coal. v. EPA,
793 F.3d 141 (D.C. Cir. 2015) 18

English v. Gen. Elec. Co.,
496 U.S. 72 (1990) 25

Fed. Power Comm'n v. Hope Nat. Gas Co.,
320 U.S. 591 (1944) 34

Greater Yellowstone Coal. v. Flowers,
321 F.3d 1250 (10th Cir. 2003) 35

Guar. Nat'l Ins. Co. v. Gates,
916 F.2d 508 (9th Cir. 1990) 34, 35

Helferich Patent Licensing, LLC v. N.Y. Times, Co.,
778 F.3d 1293 (Fed. Cir. 2015) 29

Hobbs ex rel. Hobbs v. Zenderman,
579 F.3d 1171 (10th Cir. 2009) 31, 33

Immunex Corp. v. Samsung Bioepis Co.,
No. 2:19-cv-11755 (D.N.J. Nov. 3, 2021), ECF 128 10

Immunex Corp. v. Sandoz Inc.,
964 F.3d 1049 (Fed. Cir. 2020) 10

Immunex Corp. v. Sandoz Inc.,
No. 2:16-cv-1118 (D.N.J. Oct. 8, 2019), ECF 719 10

Impression Prods., Inc. v. Lexmark Int'l, Inc.,
581 U.S. 360 (2017) 30

In re C.W. Mining Co.,
625 F.3d 1240 (10th Cir. 2010) 31

Kim v. Kettell,
694 F. Supp. 3d 1379 (D. Colo. 2023 25

King Instruments Corp. v. Perego,
65 F.3d 941 (Fed. Cir. 1995) 6, 26, 28

LaChance v. Erickson,
522 U.S. 262 (1998) 31

Mathews v. Eldridge,
424 U.S. 319 (1976) 31

Mich. Bell Tel. Co. v. Engler,
257 F.3d 587 (6th Cir. 2001) 34, 35

Nat'l Infusion Ctr. Ass'n v. Becerra (*NICA*),
116 F.4th 488 (5th Cir. 2024) 20

Nken v. Holder,
556 U.S. 418 (2009) 17

Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.,
299 U.S. 183 (1936) 31

Saleh v. Titan Corp.,
580 F.3d 1 (D.C. Cir. 2009) 28

Salomon & Ludwin, LLC v. Winters,
150 F.4th 268 (4th Cir. 2025) 37

Sanofi-Synthelabo v. Apotex, Inc.,
470 F.3d 1368 (Fed. Cir. 2006) 25, 26

Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.,
240 F.3d 832 (9th Cir. 2001) 37

Susan B. Anthony List v. Driehaus (*SBA*),
573 U.S. 149 (2014) 18

Tenoco Oil Co. v. Dep't of Consumer Affairs,
876 F.2d 1013 (1st Cir. 1989) 34

Teva Pharms., USA, Inc. v. Weiser,
709 F. Supp. 3d 1366 (D. Colo. 2023) 22

Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.,
342 F.3d 1298 (Fed. Cir. 2003) 25

Vermont v. MPHJ Tech. Invs., LLC,
803 F.3d 635 (Fed. Cir. 2015) 25

White v. Roughton,
530 F.2d 750 (7th Cir. 1976) 31

Constitutional Provisions

U.S. Const. art I, § 8, cl. 8 ..... 3, 25

U.S. Const. amend. XIV, § 1 30

Statutes

21 U.S.C. § 355(j) 6

35 U.S.C. § 156 6

42 U.S.C. § 262(k) 6

42 U.S.C. § 1320f *et seq.* 15

42 U.S.C. § 1320f-2 24

Colo. Rev. Stat. § 10-16-1401 ..... 1, 7

Colo. Rev. Stat. § 10-16-1402 7

Colo. Rev. Stat. § 10-16-1403 7

Colo. Rev. Stat. § 10-16-1406 ..... 8, 22, 32

Colo. Rev. Stat. § 10-16-1407 ..... 9, 15, 22, 33

Colo. Rev. Stat. § 10-16-1408 22

Colo. Rev. Stat. § 10-16-1412 ..... 17, 19, 22, 37

Colo. Rev. Stat. §§ 10-16-1401 to 10-16-1416 1

Regulations

3 Colo. Code Regs. § 702-9:3.1 ..... 8, 32

3 Colo. Code Regs. § 702-9:4.1 9

Other Authorities

Amgen,
2024 Sustainability Highlights Report,
available at https://www.amgen.com/responsibility/
2024-sustainability-highlights-report 11

Amgen Safety Net Found.,
About (2025), https://www.amgensafetynetfoundation.com/about.html 11

Joint Mot. to Establish Briefing Schedule,
Amgen Inc. v. Mizner, No. 1:24-cv-810 (D. Colo. May 16, 2024), ECF 18 13

Reply in Supp. of Cross-Mot. for Summ. J.,
Amgen Inc. v. Mizner, No. 1:24-cv-810 (D. Colo. Oct. 4, 2024), ECF 42 30

Corrected Resp. Br.,
Amgen Inc. v. Mizner, No. 25-1641 (Fed. Cir. Aug. 28, 2025), ECF 23 24

Colo. PDAB & Advisory Council (2025),
https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board 11

Colo. PDAB,
2023 Affordability Review Report: Trikafta (Dec. 15, 2023),
available at https://doi.colorado.gov/sites/doi/files/documents/PUBLIC_Trikafta%20Affordability%20Review%20Final%20Report.pdf 32

ENBREL® (etanercept),
Support & Resources (2024), http://www.enbrel.com/support 11

H.R. Rep. No. 98-857, pt. 1 (1984) 6

Hearing on S.B. 21-175 Before H. Comm. on Health & Ins., 73d Sess. (Colo. 2021),
available at https://tinyurl.com/3tas6ddc 7, 22

Shepherd, Joanna,
Deterring Innovation: New York v. Actavis *and the Duty to Subsidize Competitors' Market Entry*, 17 Minn. J.L. Sci. & Tech. 663 (2016) 26

INTRODUCTION

Pursuant to Civil Rule 65(a), Plaintiffs Amgen Inc., Immunex Corporation, and Amgen Manufacturing Limited LLC (collectively "Amgen") respectfully move this Court for a preliminary injunction enjoining Defendants from enforcing Colo. Rev. Stat. §§ 10-16-1401 to 10-16-1416 with respect to Amgen's patented drug ENBREL®.

On October 3, 2025, the Colorado Prescription Drug Affordability Review Board established an unlawful price cap on Enbrel that is more than 70% below the market price. The Board took this action despite controlling precedent, which holds that the federal patent laws preempt state laws that seek to "restrain" what a state considers "excessive prices" for patented drugs, "in effect diminishing the reward to patentees in order to provide greater benefit to [in-state] drug consumers." *Biotech. Indus. Org. v. District of Columbia* (*BIO I*), 496 F.3d 1362, 1372–74 (Fed. Cir. 2007).

The Board did not hide its disagreement with federal patent policy. It lamented that Enbrel is patent-protected until 2029 and that "such intellectual property rights can be associated with increased drug prices." Compl. Ex. C at C-9; Compl. Ex. D at C-11. Board members acknowledged that they chose to impose a price cap on Enbrel instead of its therapeutic alternatives because the alternatives had recently gone off-patent and become subject to "competition [that] lowers the price." Compl. Ex. E at 33:24–34:2. And the Board's Chair admitted that the Board capped Enbrel's price because, in its view, Amgen "has had more than enough time to recoup the investment they made on … the development of that drug." Compl. Ex. J at 82:2–4.

This is not the first time Amgen has sued over the Board's efforts to cap Enbrel's price. In March 2024, after the Board declared Enbrel "unaffordable for Colorado consumers" and selected Enbrel for establishment of an upper payment limit ("UPL"), Amgen sought relief. Judge Wang dismissed Amgen's complaint for lack of standing, holding that "[u]nless and until a UPL is set for Enbrel and at a price lower than [the market price], … Amgen's alleged future injuries are hypothetical at best." Mem. Op. & Order at 17, *Amgen Inc. v. Mizner*, No. 1:24-cv-810 (D. Colo. Mar. 28, 2025), ECF 49 ("Summ. J. Order"). The conditions Judge Wang said would be necessary for Amgen to have standing have now been fulfilled: The Board established a UPL for Enbrel, and it set the UPL far below Enbrel's market price. Accordingly, any doubt as to Amgen's standing has been resolved.

In her earlier ruling, Judge Wang accepted the State's position that the UPL would not apply "directly" to Amgen's own sales of Enbrel to wholesalers and would apply only to "downstream" sales, such as a wholesaler's sale to a pharmacy or hospital. Summ. J. Order at 12–14. That does not diminish Amgen's standing. Amgen has standing as an "object of regulation" because even if the price cap does not directly regulate Amgen's *sales*, it directly targets Amgen's *product*. *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 114–15 (2025). Moreover, when a "downstream" regulation will predictably cause "upstream economic injuries to others in the [supply] chain, such as … manufacturers," the manufacturers have standing. *Id.* at 116–17 (cleaned up). Both "commonsense economic principles" and "record evidence" demonstrate that

if wholesalers are forced to *sell* Enbrel for less to downstream purchasers, they will in turn *buy* Enbrel for less from Amgen. *See id.* at 116–18.

Amgen is entitled to a preliminary injunction because it is likely to prevail on its patent-preemption and due-process claims and the remaining preliminary injunction factors are satisfied.[1]

First, Amgen is likely to prevail on its claim that the federal patent laws preempt Colorado's price cap. The Constitution vests in Congress, not the states, the power to encourage innovation and creativity by protecting intellectual property rights. U.S. Const. art I, § 8, cl. 8. Exercising that power, Congress has designed the patent system to strike "a careful balance" between "the need to promote innovation" by letting innovators set their own prices during the patent term and the benefits of greater affordability that flow from competition after the term expires. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). As applied to Enbrel, Colorado's price-control regime disrupts that finely tuned system by allowing the Board to strip away the economic rewards and incentives that Congress sought to provide to patent holders. The Federal Circuit—whose case law is controlling on issues of patent preemption—has already resolved this issue, holding that a state may not impose price controls on patented drugs because allowing states to "re-balance the [federal] statutory framework of rewards and incentives" by limiting "the

[1] Amgen is also likely to prevail on its Commerce Clause claim, but it is not seeking preliminary relief based on that claim.

pecuniary rewards stemming from the patent right" would be "contrary to the goals established by Congress in the patent laws." *BIO I*, 496 F.3d at 1372–74.

Second, Amgen is likely to prevail on its claim that Colorado's scheme violates Amgen's due-process rights. The statute does not provide any meaningful standards for the Board to apply either when determining whether a drug is "unaffordable for Colorado consumers" or when setting a UPL. Without standards to constrain the Board's decisionmaking, Amgen has been deprived of the *sine qua non* of due process—the opportunity to be heard at a meaningful time and in a meaningful manner. The statute also violates the more specific due-process principles that apply to administrative price-control schemes, which courts have required to include standards and procedures to guard against arbitrary or discriminatory price-setting and to ensure that affected parties can earn a reasonable return on their investments. Colorado's scheme lacks those essential safeguards and has left Amgen subject to the uncontrolled whims of the Board.

The other requirements for preliminary relief are also met. Not only will the UPL negatively impact Amgen's revenue when it formally takes effect on January 1, 2027, it will also impose substantial, unrecoverable costs on Amgen well before that date. For example, Amgen must update its internal systems to prepare to comply with the UPL and negotiate terms with its contracting partners that account for the UPL. Critical contracts for 2027 will be negotiated early in 2026, and the UPL will affect Amgen's bargaining position, potentially jeopardizing Enbrel's place on health plans'

prescription drug formularies. Amgen also must determine whether it will continue to sell Enbrel in Colorado once the UPL takes effect, a decision Colorado law requires it to make by no later than July 5, 2026. All these costs are "irreparable" because they "cannot later be recovered [due to] sovereign immunity," *Chamber of Com. v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010).

Finally, the balance of equities favors Amgen because Colorado "does not have an interest in enforcing a law that is likely constitutionally infirm," and "the public interest will perforce be served by enjoining the enforcement of the invalid provisions of state law." *Id.* at 771 (cleaned up). Moreover, due to insurance and Amgen's generous payment-assistance programs, there is no evidence that the UPL will meaningfully improve patient access to Enbrel.

Amgen respectfully requests that the Court issue a preliminary injunction barring Defendants from enforcing a price cap for Enbrel.

BACKGROUND

A. The Federal Patent System

Prescription drugs are vital to public health. But conducting cutting-edge research to develop new drugs, navigating the lengthy and uncertain clinical trial and FDA approval processes, and bringing the drugs to patients entails tremendous cost and risk. To reward and incentivize such risk-taking and investment, Congress has long relied on the Constitution's express grant of authority to create a uniform federal patent system.

Under the patent system Congress designed, "the fundamental purpose of the patent grant" is to "create[] an incentive for innovation" by providing "economic rewards during the period of exclusivity." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) (cleaned up). Once the patent period expires, others may enter the market and compete with the patent holder, driving down the product's costs. Congress has struck "a careful balance" between "the need to promote innovation" by letting innovators set their own prices during the patent term and the greater affordability that flows from competition after the term expires. *Bonito Boats*, 489 U.S. at 146.

Congress has paid special attention to fine-tuning this balance for pharmaceutical patents. Recognizing the enormous costs and complexity associated with developing new drugs, Congress passed the 1984 Hatch-Waxman Act, extending patent terms for pharmaceutical inventions to "create a significant, new incentive" that "would result in increased expenditures for research and development." H.R. Rep. No. 98-857, pt. 1, at 18 (1984); *see* 35 U.S.C. § 156. At the same time, Congress has promoted affordability by creating streamlined pathways for competing drugs (generics and biosimilars) to obtain FDA approval—while specifying that such competition can occur only *after* any applicable patents on the innovator drug have expired. *See* 21 U.S.C. § 355(j); 42 U.S.C. § 262(k).

B. Colorado's Price-Control Scheme

Not content with Congress's balance between affordability and innovation,

Colorado has sought to strike its own balance. To "protect Colorado consumers from excessive prescription drug costs," Colo. Rev. Stat. § 10-16-1403(1), Colorado's price-control scheme targets the economic rewards that are the engine of the federal patent system. As a leading sponsor of the legislation explained, "[t]he reason we did this is because we wanted to impact the entities in Colorado that are purchasing these drugs and give them the support they need to get better pricing from the industry." *Hearing on S.B. 21-175 Before H. Comm. on Health & Ins.*, 73d Sess. at 7:22:00–7:22:30 (Colo. 2021) ("S.B. 21-175 Hr'g"), *available at* https://tinyurl.com/3tas6ddc (statement of Rep. Kennedy). Colorado thus seeks to shift the balance set by Congress toward lower prices for in-state consumers and away from incentives for innovation that benefit the entire nation.

In 2021, Colorado created a five-member Prescription Drug Affordability Review Board and charged it with "[e]stablish[ing] upper payment limits for [selected] prescription drugs." Colo. Rev. Stat. §§ 10-16-1402(3), -1403(1). An upper payment limit is defined as "the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the prescription drug." *Id.* § 10-16-1401(23). On its face, this upper payment limit would apply to sales by manufacturers to wholesalers—that is, Amgen's own sales—but the State has taken the position that the price applies only to "downstream" transactions, such as sales by wholesalers to pharmacies, providers, or consumers. Summ. J. Order at 12–14.

As an initial step toward establishing UPLs, the Board must create a list of prescription drugs eligible for an "affordability review." *Id.* § 10-16-1406(1). Whether a drug is eligible depends on the list price charged by the drug's manufacturer, known as the "wholesale acquisition cost" or "WAC." *Id.*; *see* 3 Colo. Code Regs. § 702-9:3.1(C). The Board then decides which eligible drugs to select for an affordability review. In making that determination, the Board considers, among other factors, whether a drug is subject to competition from any "therapeutically equivalent prescription drugs." Colo. Rev. Stat. § 10-16-1406(2); *see* 3 Colo. Code Regs. § 702-9:3.1(D).

Once a drug is selected for an affordability review, the Board must "determine whether use of the prescription drug" is "unaffordable for Colorado consumers." Colo. Rev. Stat. § 10-16-1406(3). The statute does not define what it means for a drug to be "unaffordable." Instead, it gives the Board sweeping discretion to make that determination after considering a long list of factors, the first of which is the manufacturer's list price. *Id.* § 10-16-1406(4). The Board may also consider "information relating to the manufacturer's selection of" that list price, including the manufacturer's "[p]rojected revenue" and whether the drug is subject to "[m]arket competition." *Id.* § 10-16-1406(6). The Board has issued a regulation listing additional factors it may consider, including "estimated manufacturer net-sales or net-cost amounts." 3 Colo. Code Regs. § 702-9:3.1(E)(2)(j). Neither the statute nor the regulation indicates what facts would weigh for or against a finding of unaffordability

or how much weight any particular factor should receive.

Once the Board determines that a drug is unaffordable, it can establish an upper payment limit for the drug. Colo. Rev. Stat. § 10-16-1407(1)(a). The Board is supposed to "determine by rule the methodology for establishing an upper payment limit," while ensuring that the methodology complies with certain general statutory guidelines. Colo. Rev. Stat. § 10-16-1407(2). The Board's regulation, however, merely parrots those general guidelines and does not specify a methodology. *See* 3 Colo. Code Regs. § 702-9:4.1(C)(2). The regulation does note that the Board may consider various "price and cost metrics," starting again with the manufacturer's list price. *Id.* But neither the statute nor the regulation sets forth any coherent methodology to guide or limit the Board's discretion when setting an upper payment limit.

C. Amgen's Patent-Protected Drug Enbrel

Enbrel is a groundbreaking injectable medicine used to treat various autoimmune diseases, such as rheumatoid and psoriatic arthritis. Compl. ¶ 48. Enbrel can help patients reduce joint pain, avoid permanent joint damage, and dramatically improve physical function and overall quality of life. *Id.* Enbrel is manufactured by Plaintiffs Immunex Corporation and Amgen Manufacturing, Limited, both of which are wholly owned subsidiaries of Plaintiff Amgen Inc.

Enbrel is covered by several United States patents, including two that limit competing biosimilar products from entering the market until 2029. *See* Compl. Ex. D at 25, C-11, C-13. The Federal Circuit upheld the validity of those patents when they

were challenged. *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1068 (Fed. Cir. 2020), *cert. denied*, 141 S. Ct. 2623 (2021). As a result of that litigation, a federal court has entered two separate permanent injunctions barring competitors from entering the market until April 24, 2029. *See Immunex Corp. v. Sandoz Inc.*, No. 2:16-cv-1118 (D.N.J. Oct. 8, 2019), ECF 719; *Immunex Corp. v. Samsung Bioepis Co.*, No. 2:19-cv-11755 (D.N.J. Nov. 3, 2021), ECF 128.

Amgen sells Enbrel to wholesalers and distributors, who in turn sell the drug to other downstream purchasers, such as pharmacies and hospitals. Declaration of Patrick Costello ("Costello Decl.") ¶ 4. The price Amgen charges wholesalers is known as the manufacturer's list price or wholesale acquisition cost ("WAC"). *Id.* When wholesalers sell Enbrel to downstream purchasers, they do not add a markup; instead, they sell at WAC or a price lower than WAC. *Id.* ¶ 5. If a wholesaler is required to provide a discount or other price reduction, Amgen is contractually obligated to reimburse the wholesaler for the discount through a special payment known as a "chargeback." *Id.* ¶¶ 6–7. All of this is consistent with standard practice in the pharmaceutical industry. *Id.*

Amgen offers programs that support patients who may have difficulty affording medicine. For example, for more than 20 years Amgen has sponsored a nonprofit patient assistance program that helps eligible patients in the United States gain access to qualifying Amgen medicines. In 2024 alone, the program provided $2.5

billion worth of drugs to eligible uninsured or underinsured patients at no cost.[2] Amgen also offers an Enbrel Co-Pay Program to help eligible patients with commercial insurance reduce their out-of-pocket costs for Enbrel, allowing patients to pay as little as $0 out-of-pocket for each dose.[3]

D. The Board Declares Enbrel Unaffordable Based in Part on Its Patent Status and Selects It for Establishment of an Upper Payment Limit

In June 2023, the Board approved the final list of 604 drugs eligible for affordability reviews based on the list prices set by their manufacturers. Several weeks later, the Board selected five drugs, including Enbrel, for affordability reviews. According to the Board, all of the selected drugs were brand-name drugs covered by unexpired patents.[4]

On February 9, 2024, the Board published its draft affordability review report for Enbrel. Compl. Ex. C. On February 16, the Board declared that Enbrel is "unaffordable for Colorado consumers." Compl. Ex. E at 103–05. On February 23, the

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[2] Amgen Safety Net Found., *About* (2025), https://www.amgensafetynetfoundation.com/about.html; Amgen, 2024 Sustainability Highlights Report, at 8, *available at* https://www.amgen.com/responsibility/2024-sustainability-highlights-report.

[3] ENBREL® (etanercept), *Support & Resources* (2024), http://www.enbrel.com/support.

[4] The other drugs selected were Cosentyx, Genvoya, Stelara, and Trikafta. Each was determined by the Board to be covered by at least one unexpired patent, as the Board acknowledged in its reports. *See* Colo. PDAB & Advisory Council (2025), https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board (reports can be found by navigating to "Public Resources," then "2023/2024 Affordability Review Activities").

Board voted to adopt the final affordability review report for Enbrel and to "select[] Enbrel for establishment of an upper payment limit." Compl. Ex. F at 36–37. The Board published the final version of its Enbrel affordability review report on March 21, 2024. *See* Compl. Ex. D.

While the Board's report followed no discernable methodology, it made clear that Enbrel's patent protection was a major factor in the Board's decision. It noted that Enbrel is protected by "patents that prevent the introduction of biosimilar products" until 2029 and that "such intellectual property rights can be associated with increased drug prices." Compl. Ex. D at 25, C-11; *see also id.* at C-13 ("Amgen has protected Enbrel through litigation of its patents in U.S. courts. … As a result, despite there being two approved biosimilars for Enbrel, both biosimilars are not allowed to enter the market until at least 2029."). The report drew a contrast with "[t]wo of Enbrel's therapeutic alternatives, Humira and Remicade," which the Board observed had recently gone off-patent (*i.e.*, their patents had expired) and become subject to competition that resulted in "price reduction." *Id.* at 25.

The Board's deliberations reflected this same goal of countering the price effect of Amgen's patent rights. During the Board's discussion about whether to declare Enbrel unaffordable, the Chair noted that even though Humira had historically been more expensive than Enbrel, the Board had chosen to review Enbrel because Humira had recently gone off-patent and become subject to biosimilar competition, whereas Enbrel was still patent-protected:

> BOARDMEMBER CATHERINE HARSHBARGER: … I think in the graphs that we saw in our report, Humira cost-wise isn't cheaper, I guess is the way I'd put it; it's very expensive as well.
>
> BOARDMEMBER AMY GUTIERREZ: Back in 2022, Cathy, yes. But … whenever something goes biosimilar … that competition lowers the price. … [W]ith [Humira] … the biosimilars didn't become available until 2023.
>
> CHAIR GAIL MIZNER: And as you may recall, we actually decided not to do an affordability review on Humira because of those biosimilars that had become available.
>
> BOARDMEMBER CATHERINE HARSHBARGER: Right, right, okay.

Compl. Ex. E at 33:17–34:11. The Board's treatment of Enbrel in contrast to its treatment of off-patent drugs leaves no doubt that Enbrel was targeted because of its patent protection.

E. Amgen's First Lawsuit Is Dismissed as Premature

On March 22, 2024, Amgen brought suit challenging Colorado's price-setting scheme. The parties agreed that Amgen's claims "raise[d] legal questions that [could] be properly resolved through dispositive motions, without the need for discovery or trial." Joint Mot. to Establish Briefing Schedule at 2, *Amgen Inc. v. Mizner*, No. 1:24-cv-810 (D. Colo. May 16, 2024), ECF 18. The parties accordingly filed cross-motions for summary judgment.

On March 28, 2025, Judge Wang dismissed Amgen's complaint without prejudice for lack of subject-matter jurisdiction. Summ. J. Order at 19. Judge Wang first held that "Amgen is not subject to direct regulation under the Act" because she

accepted Defendants' argument that "a UPL does not directly apply to a wholesaler's purchase from a manufacturer" and "applies directly only to downstream transactions," such as "a consumer's purchase from a pharmacy or provider, reimbursements by certain insurance payers, and pharmacies' and providers' purchases" from wholesalers. *Id.* at 12–14. She then held that "Amgen's asserted future injury" from a UPL was "simply too speculative to be 'concrete' and 'imminent'" at that juncture. *Id.* at 14. Judge Wang emphasized that "no UPL for Enbrel has been set and it is unclear when and if such a UPL will be set." *Id.* at 16. She thus reasoned that "[u]nless and until a UPL is set for Enbrel and at a price lower than WAC, … Amgen's alleged future injuries are hypothetical at best." *Id.* at 17. Amgen appealed that decision to the Federal Circuit. *See* No. 25-1641 (docketed Apr. 14, 2025).[5]

F. The Board Establishes an Upper Payment Limit for Enbrel

While Amgen's appeal was pending, the Board moved forward to establish a price cap for Enbrel. The Board held public rulemaking hearings on May 23, July 11, August 22, and October 3, 2025.

The Board did not disclose a proposed UPL amount for Enbrel until its third rulemaking hearing on August 22, 2025, when it voted to amend the proposed UPL rule (which until that point had included a blank space where the specific price cap would go) to set the UPL for Enbrel at $583.89 per unit. The Board stated that this

[5] In light of the Board's adoption of the final UPL rule and Amgen's filing of this action, Amgen proposed that the parties stipulate to dismiss the appeal without prejudice. Defendants have not yet responded to that proposal.

price was equivalent to the so-called "maximum fair price" ("MFP") imposed under the federal Inflation Reduction Act, 42 U.S.C. § 1320f *et seq.*, for sales of Enbrel that are covered by Medicare. Compl. Ex. I at 68:13–69:21. The Board Chair acknowledged that the MFP was nearly 70% lower than Enbrel's then-current National Average Drug Acquisition Cost, a pricing benchmark that is intended to reflect prices paid by retail pharmacies. *Id.* at 18:4–19. The price is also more than 70% below Enbrel's wholesale acquisition cost. Costello Decl. ¶ 9.[6]

The Board's uncritical reliance on the federal MFP for Medicare sales as its sole basis for determining the state upper payment limit reflected the lack of any meaningful statutory standards to guide the Board's price-setting discretion, as well as the Board's disregard of its statutory responsibility to "determine by rule the methodology for establishing an upper payment limit." Colo. Rev. Stat. § 10-16-1407(2). The Board never claimed to have performed *any* analysis to determine that the MFP would be an appropriate UPL for Colorado. One Board member admitted that the Board was in effect abdicating its own responsibility for determining an

[6] The IRA provisions authorizing the Centers for Medicare and Medicaid Services to impose an MFP for Enbrel and other drugs are the subject of ongoing litigation, including a constitutional challenge brought by Pharmaceutical Research and Manufacturers of America, of which Amgen is a member. *See Nat'l Infusion Ctr. Ass'n v. Kennedy*, No. 25-50661 (5th Cir.). For present purposes, the salient point is that the Enbrel MFP is a *federal* price that applies exclusively to sales covered by Medicare. The MFP does not apply to Enbrel dispensed to privately insured patients, and nothing in the Inflation Reduction Act authorizes *states* to interfere with federal patent rights by imposing the MFP or any other price cap on in-state sales of patented drugs.

appropriate price: "I know a lot of people are concerned. How are you going to come up with that price? What is the calculation? Where's the research? Well, in this instance, it was already done at that level" (referring to the federal MFP for Medicare sales). Compl. Ex. I at 41:16–20.

The Board held its fourth and final rulemaking hearing on October 3, 2025. At that hearing, the Board amended the proposed rule to set the UPL at $600.00 per unit, a change that members described as "using the MFP, but just rounding up" to provide "wiggle room" in case the MFP "gets adjusted." Compl. Ex. J at 37–38, 47–48. During the public comment period, in response to a commenter who suggested that imposing a UPL would reduce incentives for drug companies to invest in developing and deploying innovative medicines, the Board Chair stated: "Enbrel was approved over 25 years ago, and so the company has had more than enough time to recoup the investment they made on … the development of that drug." *Id.* at 82:1–4.

At the conclusion of the October 3 hearing, the Board voted to adopt a final rule setting the upper payment limit for Enbrel at $600.00 per unit. The UPL will take effect on January 1, 2027. Board members described this as a "drop dead date" and made clear that it would not be extended. Compl. Ex. J at 56. They also acknowledged that Amgen and other supply chain actors would have to incur compliance costs well in advance of that date, stating that the date was selected to provide "more runway to … get everything discussed and coordinated" and "give adequate time for the necessary adjustments," including providing time for

"pharmacies and others … to talk to their manufacturers … to make it clear that they can't pay more than this Upper Payment Limit." *Id.* at 51–52.

Now that the Board has established a UPL for Enbrel, Colorado law forbids Amgen from withdrawing Enbrel "from sale or distribution within" Colorado unless it provides at least 180 days' advance notice to the Attorney General. Colo. Rev. Stat. § 10-16-1412. Failure to provide the required notice triggers a penalty of up to half a million dollars. *Id.* Accordingly, if Amgen does not wish to sell Enbrel at the extraordinarily low price dictated by the Board beginning January 1, 2027, it must notify the Attorney General no later than July 5, 2026.

LEGAL STANDARD

To obtain a preliminary injunction, Amgen must show that "(1) it is substantially likely to succeed on the merits; (2) it will suffer irreparable injury if the injunction is denied; (3) its threatened injury outweighs the injury the opposing party will suffer under the injunction; and (4) the injunction would not be adverse to the public interest." *Beltronics USA, Inc. v. Midwest Inventory Distrib., LLC,* 562 F.3d 1067, 1070 (10th Cir. 2009). "The third and fourth preliminary-injunction factors 'merge' when the government is the party opposing the injunction." *Bella Health & Wellness v. Weiser*, 699 F. Supp. 3d 1189, 1202 (D. Colo. 2023) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

ARGUMENT

I. Amgen's standing is now clear.

Judge Wang previously held that "[u]nless and until a UPL is set for Enbrel and at a price lower than WAC, … Amgen's alleged future injuries are hypothetical at best." Summ. J. Order at 17. Now that the Board has set a UPL that is far below WAC, Amgen has standing. Standing requires (1) a "threatened injury" that is "certainly impending" or has a "substantial risk" of occurring; (2) a "causal connection" between the injury and the statute; and (3) a "likelihood" that the injury "will be redressed by a favorable decision." *Susan B. Anthony List v. Driehaus* (*SBA*), 573 U.S. 149, 158 (2014) (cleaned up). Amgen's standing is clear for at least two independently sufficient reasons.

First, Amgen is an "object" of the government action at issue, so there is "little question" that Amgen has standing. *Diamond*, 606 U.S. at 114 (cleaned up). Whether or not the UPL applies directly to *Amgen's sales*, it applies specifically to *Amgen's product* (and *only* Amgen's product).

The Supreme Court recently recognized the "force" of the argument that "when a regulation targets the provider of a product … by limiting another entity's use of that product," the provider should be "considered an object of the … regulation[]." *Id.* at 114–16; *see also Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015) (Kavanaugh, J.) (concluding that biofuel producers were objects of regulation "technically directed" at vehicle manufacturers because the regulation concerned the

producers' product). The Court stated that if the government regulates downstream sales of hot dogs, aluminum bats, or books, then hot dog manufacturers, aluminum bat manufacturers, and book publishers could reasonably be considered "objects of the regulation," even if their own upstream sales are not directly regulated. *Diamond*, 606 U.S. at 114–15. And it stated that gasoline producers could similarly be considered an "object of … California regulations" that restricted the use of gasoline by imposing fuel-efficiency requirements on automakers. *Id.*

It is even more obvious that Amgen is an object of regulation here than it was for the gasoline producers in *Diamond* or the product manufacturers in the Court's hypotheticals. Here, the UPL will target Amgen's *specific* product (Enbrel) rather than a category of products produced by many manufacturers (like gasoline or hot dogs), and the UPL was established based on extensive consideration of Amgen's intellectual property rights and prices. It strains credulity to claim that Amgen is not an object of a government action that identifies Amgen's patented drug by name, sets a maximum price for that specific drug, and forbids Amgen from withdrawing that drug from Colorado without notifying the state six months in advance, *see* Colo. Rev. Stat. § 10-16-1412.

Second, even if Amgen were not an object of the Board's actions, it would still have standing because the price cap the Board has set for Amgen's product—which is significantly less than the current market price—will cause Amgen financial harm. As in *Diamond*, Amgen's standing is demonstrated both by "commonsense economic

principles" and by "record evidence confirm[ing] what common sense tells us." 606 U.S. at 116–18.

To start, "commonsense economic principles" make clear that if wholesalers are forced to *sell* Enbrel for less, they will in turn *buy* it for less. No evidentiary record is needed to establish this fundamental principle. A theory of standing may rely on "the predictable effect of Government action on the decisions of third parties," *Dep't of Com. v. New York*, 588 U.S. 752, 768 (2019), and "[w]hen third party behavior is predictable, commonsense inferences may be drawn," *Diamond*, 606 U.S. at 116. Courts evaluating such inferences should assume that "profit-seeking business[es]" are "guided by basic economic rationality." *Nat'l Infusion Ctr. Ass'n v. Becerra* (*NICA*), 116 F.4th 488, 500 (5th Cir. 2024); *see also, e.g.*, *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 6 (D.C. Cir. 2017) (holding that "[c]ommon sense and basic economics" established plaintiff's standing). Colorado has never identified any reason why economically rational wholesalers would purchase units of Enbrel from Amgen for far less than they can legally resell those units.

While no more should be needed, to make matters crystal clear, Amgen has submitted evidence confirming that it will bear the cost of a downstream price cap. The declaration of Patrick Costello, Amgen's Associate Vice President, explains that if wholesalers must sell Enbrel to pharmacies and providers at the UPL, those wholesalers will not purchase Enbrel from Amgen at WAC unless Amgen reimburses them for the difference in price. Costello Decl. ¶¶ 12–15. Amgen's contracts with its

wholesalers and standard industry practice require Amgen to provide such reimbursement, which it normally does in the form of chargebacks that reduce the net price paid by the wholesaler. *Id.* ¶¶ 6–7, 13. Without such reimbursement, the wholesaler would lose money on each sale of Enbrel that is subject to the UPL. *Id.* ¶ 14. Buying high and selling low is not a viable business model in any industry, and certainly not for pharmaceutical wholesalers, which operate on extremely thin margins and generally do not have the capacity to absorb uncompensated discounts. *Id.* ¶ 7. The declarations of senior employees at the three largest wholesalers in the country—Cardinal Health, Cencora, and McKesson—confirm that if the wholesalers are expected to offer Enbrel to customers at the UPL, they will expect to receive either an upfront discount or post-sale chargeback from Amgen in order for distribution to be economically tenable for the wholesalers. Declaration of Natalie Adams ¶¶ 7–8; Declaration of Christopher Reed ¶ 6; Declaration of Jeanine Singer ¶¶ 6–9.

This case thus presents "the familiar circumstance where government regulation" of one business is "likely to cause injuries to other linked businesses," which is sufficient to give the linked businesses standing. *Diamond*, 606 U.S. at 116 (cleaned up). Any suggestion by Colorado that Amgen's injuries from the Enbrel UPL are "too attenuated to confer standing" should meet with the same response this Court gave when Colorado tried a similar argument in another case: "Far from 'pure conjecture,' it appears imminent and inevitable that the law will impact [Amgen] in the way [it] allege[s] is a constitutional violation." *Teva Pharms., USA, Inc. v. Weiser*,

709 F. Supp. 3d 1366, 1375 (D. Colo. 2023), *aff'd*, No. 24-1035, 2025 WL 2555552 (10th Cir. Sep. 5, 2025).

None of this can come as a surprise to Colorado, which fully intends an upper payment limit to function as a cap on what a drug's manufacturer can charge for that drug. As a leading sponsor of Colorado's law explained, manufacturers will bear the cost of a UPL because wholesalers "will sell [the drug] to pharmacies or hospitals … at that lower price and then they will be made whole on the back-end by the pharmaceutical manufacturer." S.B. 21-175 Hr'g at 7:22:00–7:23:30 (statement of Rep. Kennedy).

The text of Colorado's law is replete with evidence of the state's intent to regulate manufacturers' prices. The manufacturer's list price for a drug is the sole determinant of whether the drug is eligible for an affordability review, and it is the first factor the Board considers when determining whether the drug is unaffordable. Colo. Rev. Stat. § 10-16-1406(1), (4)(a). When the Board establishes an upper payment limit for a drug, it must "[i]nquire of manufacturers" whether they are "able to make the … drug available for sale in the state" notwithstanding the UPL. *Id.* § 10-16-1407. An entire section of the statute is devoted to specifying the manufacturer's obligations if it must stop selling the drug in Colorado, and imposing draconian penalties on manufacturers that do so without giving the Attorney General sufficient notice. *Id.* § 10-16-1412; *see also id.* § 10-16-1408(4) (addressing situations where "a manufacturer refuses to make the drug available as a result of an upper payment

limit"). These provisions all reflect the legislature's expectation that a UPL would limit the net price charged by manufacturers. By contrast, the law includes no similar provisions regarding wholesalers or other downstream actors and does not impose any requirements on those parties before the UPL's effective date.

The Board, too, has acknowledged that a UPL will constrain manufacturers' prices. For example, one member noted that wholesalers "buy everything at one price [*i.e.*, the WAC] and then they submit documentation after the fact to get those chargebacks [from the manufacturer] so that they get the accurate net price for their sales." Compl. Ex. G at 56:14–17. Similarly, a wholesaler representative on the Board-appointed Advisory Council explained that if a wholesaler is required to sell a drug to "the downstream customer, the pharmacy, the hospital, nursing home, et cetera" at a price below WAC, then "the manufacturer would make the wholesaler whole on a chargeback basis" to "make sure that [the wholesaler is] not buying at a higher cost [and] selling it at this lower cost." *Id.* at 59–60. Another Board member thus recognized that "pharmacies and others" would need to "talk to their manufacturers … to make it clear that they can't pay more than this Upper Payment Limit." Compl. Ex. J at 51–52.

Consistent with this universal understanding of how a UPL will affect manufacturers, the Board stated that it was using its UPL authority to target *Amgen's* patented product because *Amgen's* "intellectual property rights" have led to "increased drug prices." *See* p. 12, *supra*. And the Board set the UPL based on the

federal MFP for Medicare sales, which is a price cap that applies directly to *Amgen* as the drug's "manufacturer." *See* 42 U.S.C. § 1320f-2(a)(1). The Board has never expressed any concern about the prices charged by wholesalers as distinct from the prices charged by Amgen, and it has never questioned whether a price cap on Enbrel will affect Enbrel's manufacturer.

Judge Wang's decision dismissing Amgen's previous lawsuit does not mean Amgen lacks standing now. Judge Wang stated that "[u]nless and until a UPL is set for Enbrel and at a price lower than WAC, … Amgen's alleged future injuries are hypothetical at best." Summ. J. Order at 17. That hypothetical is now a reality. In response to Amgen's appeal of Judge Wang's decision, Colorado stated: "To the extent subsequent events have bolstered Amgen's standing arguments, it has a readily available remedy: filing a new case." Corrected Resp. Br. at 44, *Amgen Inc. v. Mizner*, No. 25-1641 (Fed. Cir. Aug. 28, 2025), ECF 23. Amgen has now filed this case, and the Court should proceed to the merits of Amgen's claims.

II. Amgen is likely to succeed on the merits of its claims.

Amgen clears the likelihood-of-success bar. Colorado's imposition of a price cap on Amgen's patented drug interferes with the incentives for innovation provided by the federal patent laws and is thus preempted under binding precedent. Colorado's price-control regime is also unconstitutional because it lacks the meaningful standards required by the Due Process Clause.

A. Colorado's price cap is preempted by the federal patent laws.

State law is preempted "where it regulates conduct in a field that Congress intended the federal government to occupy exclusively" or where it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) (cleaned up). When a state law is challenged as preempted by the federal patent laws, the case is deemed to arise under the patent laws, so Federal Circuit precedent is controlling. *See BIO I*, 496 F.3d at 1369; *Vermont v. MPHJ Tech. Invs., LLC*, 803 F.3d 635, 643–47 (Fed. Cir. 2015); *Kim v. Kettell*, 694 F. Supp. 3d 1379, 1395 (D. Colo. 2023).

As Supreme Court and Federal Circuit precedent make clear, state efforts to regulate the price of patented drugs implicate both field and conflict preemption. The Constitution vests authority over patent policy in Congress, not the states. U.S. Const. art I, § 8, cl. 8. "The patent statute's careful balance between public right and private monopoly to promote certain creative activity is a scheme of federal regulation … so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Bonito Boats*, 489 U.S. at 167 (cleaned up). And state price controls obstruct the "fundamental purpose" of Congress's grant of exclusive patent rights, which is to incentivize innovation by allowing manufacturers to set their own prices during the patent term. *BIO I*, 496 F.3d at 1372 (quoting *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006)); *see also Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 342 F.3d 1298, 1305–06 (Fed. Cir. 2003)

("Through the federal patent laws, Congress has balanced innovation incentives against promoting free competition, and state laws upsetting that balance are preempted.").

The "pecuniary rewards stemming from the patent right" are especially critical in the pharmaceutical sector, where they are needed to encourage drug companies "to continue costly development efforts." *BIO I*, 496 F.3d at 1372 (quoting *Sanofi-Synthelabo*, 470 F.3d at 1383). The process of developing new drugs is time-consuming, uncertain, and expensive. On average, bringing a single new drug to market takes 10 to 15 years and costs more than $2 billion, and only about 1 in 5,000 potential new drugs obtains approval and reaches patients. Compl. ¶ 32 nn.1–3 (citing sources). Of the medicines approved for patient use, only about 20% ever generate enough revenue to cover their own development costs. Joanna Shepherd, *Deterring Innovation:* New York v. Actavis *and the Duty to Subsidize Competitors' Market Entry*, 17 Minn. J.L. Sci. & Tech. 663, 665 (2016). "The economic rewards during the period of exclusivity are the carrot" that incentivizes companies to run this gauntlet, and "[u]pon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace." *BIO I*, 496 F.3d at 1372 (quoting *King Instruments*, 65 F.3d at 950).

In *BIO*, the Federal Circuit confronted a statute that would have reduced the size of the carrot by limiting the prices of patented prescription drugs sold in the District of Columbia. The court held that federal patent law preempted the District's

attempt to "restrain" what it considered "excessive prices" for patented drugs, "in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers." *Id.* at 1374. "By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent"—the District had "chosen to re-balance the [federal] statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* The statute thus conflicted with "federal patent law's balance of objectives as established by Congress" and was therefore preempted. *Id.*; *see also Biotech Indus. Org. v. District of Columbia* (*BIO II*), 505 F.3d 1343, 1345 (Fed. Cir. 2007) (Gajarsa, J., concurring in denial of reh'g en banc) (explaining that there was a "direct conflict between the D.C. Act and the objects and purposes of the federal patent laws" and "the D.C. Act could also be considered preempted by 'field preemption' because it impermissibly establish[ed] new patent policy").

Colorado's price-control law should meet the same fate. Like the law struck down in *BIO*, Colorado's statute, as applied by the Board to Enbrel, seeks to restrain what the State considers "excessive prices" for patented drugs, thereby "diminishing the reward to patentees" in order to benefit Colorado consumers. *BIO I*, 496 F.3d at 1374. Congress, however, has already tailored federal law to achieve what it considers "the best balance" between the competing interests in rewarding innovation and promoting affordability. *Id.* at 1373. Colorado's attempt to reweigh those competing interests invades the field of federal patent policy and "is contrary to the goals

established by Congress in the patent laws." *Id.* at 1374. The Board Chair's assertion that it is appropriate to cap Enbrel's price because Amgen "has had more than enough time to recoup [its] investment," Compl. Ex. J at 82:2–4, even though Enbrel remains patent-protected under federal law, exemplifies the Board's rejection of "the framework of rewards and incentives" established in the patent laws. By replacing the "dictates of the marketplace," *King Instruments*, 65 F.3d at 950, with the dictates of the Board, Colorado's approach would reduce the "size of the carrot" Congress provided and upset the balance Congress struck between innovation and affordability. But "[t]he underlying determination about the proper balance between investors' profit and consumer access to medication … is exclusively one for Congress." *BIO I*, 496 F.3d at 1374.

The conflict with federal law is especially stark here because the Board has deliberately targeted Enbrel based on its patent protection. To be sure, the application of Colorado's price-control scheme to regulate the price of patented drugs would trigger preemption even without that targeting, because "generally applicable state laws may conflict with and frustrate the purposes of a federal scheme just as much as a targeted state law." *Saleh v. Titan Corp.,* 580 F.3d 1, 12 n.8 (D.C. Cir. 2009). But the Board's focus on patented products makes the interference with federal objectives even clearer. The Board "decided not to do an affordability review" for a drug that was historically more expensive than Enbrel because that drug, unlike Enbrel, had recently gone off-patent. *See* pp. 12–13, *supra*. And the Board's report

emphasized Amgen's patent rights and their role in limiting biosimilar competition until 2029. *See* p. 12, *supra*. The Board stated it found consideration of Amgen's patents "helpful" because "intellectual property rights can be associated with increased drug prices." Compl. Ex. D at C-11. Although not necessary for preemption, the Board's focus on using state law to counteract the effect of Amgen's federal patent rights on the price of Enbrel confirms that Colorado is seeking to "re-balance" the federal patent laws' "framework of rewards and incentives insofar as it relates to inventive new drugs." *BIO I*, 496 F.3d at 1374.

In response to Amgen's previous lawsuit, Colorado argued that because Amgen's sale of Enbrel to its wholesaler is deemed to "exhaust" Amgen's patent rights, the patent laws do not prevent Colorado from restricting the price of Enbrel in subsequent, downstream transactions. But the doctrine of patent exhaustion is irrelevant to preemption—it is simply a defense to a patent-infringement suit. *See Helferich Patent Licensing, LLC v. N.Y. Times, Co.*, 778 F.3d 1293, 1301 (Fed. Cir. 2015). Unlike preemption doctrine, which addresses the relationship between the federal government and the states, patent exhaustion addresses the relationship between the seller of a patented product and the product's subsequent purchasers. When courts say that a sale of a patented product "exhausts" the patent right, they mean only that "[t]he purchaser and all subsequent owners are free to use or resell the product just like any other item of personal property, without fear of an infringement lawsuit." *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360,

366 (2017). They do not mean that *states* are free to undercut the economic rewards flowing to the patent owner without fear of a *preemption* lawsuit.

As Colorado has acknowledged, the patent exhaustion doctrine is premised on the notion that "the purpose of the patent law is fulfilled *when the patentee has received his reward for the use of his invention*." Reply in Supp. of Cross-Mot. for Summ. J. at 11, *Amgen Inc. v. Mizner*, No. 1:24-cv-810 (D. Colo. Oct. 4, 2024), ECF 42 (emphasis added) (quoting *Impression Prods.*, 581 U.S. at 371). But Colorado's price-control scheme will *prevent* Amgen from receiving that due "reward" by forcing Amgen to reduce the net price it charges wholesalers for Enbrel. By Colorado's logic, a state could nullify Amgen's patent rights by imposing a near-zero price cap, yet still escape preemption by having the price cap fall nominally on downstream sales. That cannot be correct. Colorado's position would be an invitation for states to siphon away "the pecuniary rewards stemming from the patent right," *BIO I*, 496 F.3d at 1372, rendering the Federal Circuit's precedent a dead letter.

B. Colorado's regime lacks meaningful standards and thus violates due process.

Colorado's delegation of virtually unfettered price-setting power to the Board is also unconstitutional because it lacks the procedural safeguards necessary to comport with basic requirements of due process. The Due Process Clause prohibits the government from depriving a person of "life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. Amgen has a protected property interest in Enbrel. And it is "well-settled" that "the right of the owner of property to fix the

price at which he will sell it is an inherent attribute of the property itself" and "within the protection of" due process. *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). Yet neither Colorado's statute nor the Board's regulation establishes any standard to constrain the Board's discretion either in determining whether a drug is "unaffordable" or in setting a UPL. This lack of ascertainable standards violates due process by denying manufacturers a meaningful opportunity to be heard and failing to protect them against arbitrary, confiscatory, or discriminatory deprivations.

"The core of due process is the right to notice and a *meaningful opportunity* to be heard." *In re C.W. Mining Co.*, 625 F.3d 1240, 1244–45 (10th Cir. 2010) (quoting *LaChance v. Erickson*, 522 U.S. 262, 266 (1998)); *see Mathews v. Eldridge,* 424 U.S. 319, 333 (1976). For a hearing to be meaningful, the law must set "ascertainable limit[s]" on the agency's discretion. *Hobbs ex rel. Hobbs v. Zenderman*, 579 F.3d 1171, 1185–86 (10th Cir. 2009); *see White v. Roughton*, 530 F.2d 750, 753–54 (7th Cir. 1976) (per curiam) ("The requirements of due process include a determination of the issues according to articulated standards."). Such standards are necessary to allow affected parties to present arguments targeted to the applicable standards, and to ensure that the public can hold government officials accountable for arbitrary or unlawful decisions. The lack of standards "deprives any hearing … of its meaning and value." *White*, 530 F.2d at 754.

Colorado's price-control regime violates due process because the Board's

decisionmaking is not governed by any ascertainable standards. The central question the Board must answer is whether a given drug is "unaffordable for Colorado consumers." Colo. Rev. Stat. § 10-16-1406(3). Yet the statute does not define that term or meaningfully limit the Board's discretion to deem particular drugs "unaffordable." The Board need only "consider" a multitude of factors "to the extent practicable," and it can name "any other factors" it wants in regulations. Colo. Rev. Stat. § 10-16-1406(4); 3 Colo. Code Regs. § 702-9:3.1(E). Most of the factors are exceedingly vague, and neither the statute nor the regulation explains how to assess or weigh those factors. *See* pp. 8–9, *supra*. As a result, the Board's decisionmaking is effectively a black box.

This lack of standards is powerfully illustrated by the Board's unexplained and contradictory determination that Enbrel, with an average annual per-patient cost of $46,772 and average annual out-of-pocket cost of $3,980, is unaffordable, while Trikafta, with an average annual per-patient cost of $234,439 and average annual out-of-pocket cost of nearly $9,000, is affordable.[7] One useful benchmark for whether a law affords due process is whether it is possible for affected parties to understand why they are being treated differently from others who are subject to the same law. Amgen, however, has no idea why the Board deemed Enbrel unaffordable but deemed Trikafta affordable, and the state has refused to provide any explanation.

[7] *Compare* Compl. Ex. D at 2 *with* Colo. PDAB, 2023 Affordability Review Report: Trikafta, at 2–3 (Dec. 15, 2023), *available at* https://doi.colorado.gov/sites/doi/files/documents/PUBLIC_Trikafta%20Affordability%20Review%20Final%20Report.pdf.

The Board's discretion in setting an "upper payment limit" for a drug it has deemed unaffordable is similarly standardless. The statute does not impose any meaningful constraint on the Board's power to dictate prices—there is no price floor, nor even any standard of reasonableness or fairness. Colo. Rev. Stat. § 10-16-1407(2). The Board is required only to "consider" or "review" certain factors before choosing a price—but how those factors should affect the Board's decision, if at all, is left unsaid. *See* p. 9, *supra*. The Board's decision to uncritically adopt the federal MFP for Enbrel as the UPL, without performing any independent analysis of whether the MFP comports with Colorado law or whether it represents a fair and reasonable price for Enbrel, confirms that the Board is exercising standardless discretion. Indeed, one Board member openly acknowledged that the Board relied on the MFP so it would not have to do any "research" or "calculation[s]" of its own in order to "come up with that price." Compl. Ex. I at 41:14–18.

In short, throughout the administrative process, Amgen has been subject to the whims of the Board, with no comprehensible statutory standard to constrain the Board's discretion. This scheme violates Amgen's general "due process right to be free from" determinations unconstrained by "any publicly-available standard." *Hobbs*, 579 F.3d at 1185.

Colorado's regime also violates the more specific due-process principles that apply to administrative price-control regimes. Courts have long held that to satisfy due process, a statute that authorizes an agency to set prices must contain both

substantive standards and procedural mechanisms sufficient to "ensure a fair and reasonable rate of return on investment." *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587, 594 (6th Cir. 2001); *see also Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990). A constitutional price must not only allow the seller to recoup its costs; it must also include "compensat[ion] … for the risk assumed." *Mich. Bell*, 257 F.3d at 593 (quoting *Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 605 (1944)); *see Tenoco Oil Co. v. Dep't of Consumer Affairs*, 876 F.2d 1013, 1020 (1st Cir. 1989) (rates that do not allow a "fair return on investment" are "'confiscatory'" (quoting *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989)). It is not enough that an agency might happen to select a constitutional price; courts strike down price-control statutes if they "d[o] not guarantee the constitutionally-required fair and reasonable rate of return," *Mich. Bell*, 257 F.3d at 595–96, or do not "provide[] any mechanism to guarantee a constitutionally required fair and reasonable return," *Guaranty*, 916 F.2d at 512–15.

Colorado's price-control scheme fails to provide these minimum constitutional safeguards. Neither the statute nor the regulations require that prices set by the Board be sufficient to allow a fair and reasonable return on drug manufacturers' investments. In fact, a fair rate of return is not even listed among the many factors the Board is required to *consider* when determining whether a drug is "unaffordable" and fixing an upper payment limit. And despite the Board Chair's remark that Amgen "has had more than enough time to recoup [its] investment," Compl. Ex. J at 82:2–4,

the Board performed no analysis of that issue and made no determination regarding whether the UPL it set for Enbrel would provide Amgen with a fair rate of return on its investments. Because the statute lacks "any mechanism to guarantee a constitutionally required fair and reasonable return," it violates due process. *Guaranty*, 916 F.2d at 512; *accord Mich. Bell*, 257 F.3d at 595–96.

III. Amgen will suffer irreparable harm absent a preliminary injunction.

Amgen also meets the next element of the preliminary injunction test: that "it will suffer irreparable injury if the injunction is denied." *Beltronics,* 562 F.3d at 1070. The "irreparable harm requirement is met if a plaintiff demonstrates a *significant risk* that he or she will experience harm that cannot be compensated after the fact by monetary damages." *Greater Yellowstone Coal. v. Flowers*, 321 F.3d 1250, 1258 (10th Cir. 2003) (cleaned up). In a suit against state officials, *all* losses are irreparable because sovereign immunity prevents the plaintiff from recovering damages. *Edmondson*, 594 F.3d at 770–71.

Amgen clears that bar. As detailed above, the UPL will cause Amgen to suffer substantial lost revenue when it takes effect on January 1, 2027. It is undisputed that the UPL will cap the price of Enbrel at a steep discount to current market prices—indeed, that is the point.

That is not all: As the Board acknowledged, the UPL will begin imposing costs on Amgen well in advance of its effective date. In setting the effective date, Board members acknowledged that it was necessary to provide a lengthy "runway" for

Amgen and other supply-chain actors "to get everything discussed and coordinated" and make "the necessary adjustments," including providing time for pharmacies to "talk to their manufacturers … to make it clear that they can't pay more than [the UPL]" and for "wholesalers to make the changes they need … on their systems." Compl. Ex. J at 51–52. On this point, the Board was correct. Amgen cannot snap its fingers on December 31, 2026, and begin complying with the UPL the next day. It will likely take at least twelve months for Amgen to update its payment systems to implement Colorado's price cap. *See* Costello Decl. ¶ 18.

Amgen also must account for the price cap in contract negotiations that must take place far in advance of the UPL's effective date. For example, Amgen enters into annual contracts with pharmacy benefit managers ("PBMs")—entities that administer prescription drug benefits for health benefit plans—to ensure that Enbrel will be included as a covered drug on the PBMs' formularies. Declaration of Adam Grennan ¶ 7. Discussions about these contracts have already begun, and based on past practice, the formal bidding cycle for 2027 contracts with major PBMs will take place in the first quarter of 2026, with the PBMs finalizing their 2027 formulary decisions by approximately May 2026. *Id.* ¶¶ 7–10. Absent preliminary injunctive relief, Amgen will have to assume that Enbrel will be subject to the UPL in 2027, which will undermine Amgen's ability to bargain for formulary position. *Id.* ¶¶ 10–11. At a minimum, uncertainty about the UPL will greatly complicate Amgen's contract negotiations and decisions, imposing substantial costs on Amgen's business.

Id. ¶ 12. Amgen also has multi-year contracts with PBMs that extend into 2027, which must be renegotiated well in advance of the UPL's effective date. *Id.* ¶ 13.

Moreover, even before its effective date, the UPL will cause broader market disruption that will injure Amgen's consumer goodwill and business relationships nationwide. For example, customers outside of Colorado who are not subject to the UPL may object to being charged higher prices than customers in Colorado. *See* Costello Decl. ¶ 16. This disruption will cause Amgen to suffer "lost goodwill, lost customer trust and damage to reputation," all of which independently constitute irreparable harm. *Salomon & Ludwin, LLC v. Winters*, 150 F.4th 268, 278 n.7 (4th Cir. 2025); *see also, e.g.*, *Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 841 (9th Cir. 2001).

As explained above, Colorado law also forbids Amgen from withdrawing Enbrel "from sale or distribution within" Colorado without providing 180 days' advance notice to the Attorney General. Colo. Rev. Stat. § 10-16-1412. That means Amgen must decide whether it will sell Enbrel at the UPL at least 180 days before the effective date, *i.e.*, by no later than July 5, 2026. Amgen will be irreparably harmed if it does not have clarity about the law well in advance of that date so that it can make an informed decision.

IV. The balance of equities and public interest strongly favor Amgen.

The last two preliminary-injunction factors, which "merge" because "the government is the party opposing the injunction," *Bella Health*, 699 F. Supp. 3d at

1202 (cleaned up), also favor Amgen: Amgen's "threatened injury outweighs the injury the opposing party will suffer under the injunction," and "the injunction would not be adverse to the public interest." *Beltronics,* 562 F.3d at 1070. Where, as here, a party is "likely to succeed on the merits" of a claim that state law is "preempted," these factors favor entry of a preliminary injunction because the state "does not have an interest in enforcing a law that is likely constitutionally infirm" and "the public interest will perforce be served by enjoining the enforcement of the invalid provisions of state law." *Edmondson*, 594 F.3d at 750, 771 (cleaned up).

While the unlawfulness of Colorado's price cap is sufficient to dispose of the public-interest factor, it also bears emphasis that the price cap would not improve patients' access to Enbrel. As Amgen and patient advocates explained in unrebutted testimony to the Board, the UPL will not provide any direct benefit to patients because, due to a combination of insurance and Amgen's generous patient assistance programs, there is no evidence that any Colorado patient is currently required to pay more than the UPL out-of-pocket for Enbrel. The Board did not claim otherwise, and it made no finding that the UPL would make Enbrel more affordable *for patients*.

CONCLUSION

Amgen respectfully requests that the Court grant Amgen's motion and preliminarily enjoin Defendants from enforcing an upper payment limit for Enbrel.

Dated: November 21, 2025

Respectfully submitted,

/s/ Paul Alessio Mezzina

Ashley C. Parrish
(D.C. Bar No. 464683)
Paul Alessio Mezzina
(D.C. Bar No. 999325)
Kelly Nicole Reeves
(D.C. Bar No. 471923)
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Counsel for Plaintiffs

RULE 7.1(a) CERTIFICATION

I hereby certify that I conferred with counsel for Defendants as to the relief sought in this motion, and counsel for Defendants indicated that they oppose the requested relief.

On October 30, 2025, shortly after filing the complaint in this action, I notified defendants' counsel via email that Amgen anticipated filing a motion for preliminary injunction and proposed meeting to discuss a mutually agreeable briefing schedule and next steps. On November 5, I met with defendants' counsel via video teleconference and reiterated the need for an expedited schedule and a prompt resolution of the issues. Following that meeting, defense counsel asked for additional time to confer with their clients. A follow-up meeting was scheduled for November 10 but was canceled unilaterally by defendants. A second follow-up meeting was scheduled for November 13, but defendants canceled that meeting as well and did not propose a new meeting time. Accordingly, on November 17, I advised defendants' counsel via email that Amgen would move for a preliminary injunction on November 19.

On November 19, defendants via email offered for the first time to "stay enforcement of the Enbrel Upper Payment Limit pending a judgment before the US District Court for the District of Colorado in case no. 25-cv-3452." Defendants stated, "This offer is contingent on Amgen not filing a motion for preliminary injunction." I responded via email that defendants' proposal would not provide adequate relief

because substantial time is needed for Amgen and others to prepare to comply with the UPL, as the Board acknowledged when it set the effective date for the UPL rule approximately 15 months after the date of its adoption. I asked if defendants would agree to stay enforcement of the UPL for 15 months after a judgment in this Court to ensure that Amgen would not be prejudiced by any delay and that there would be sufficient time for Amgen to come into compliance in the event the UPL is upheld.

On November 20, defendants via email rejected Amgen's proposal and asked that Amgen include the following statement as Defendants' position on this motion: "Defendants oppose and, given their willingness to stay enforcement of the Enbrel upper payment limit pending an order from this District Court, believe this motion unnecessary and moot."

/s/ Paul Alessio Mezzina
Paul Alessio Mezzina

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2025, I electronically filed the foregoing Motion for Preliminary Injunction with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all attorneys of record.

/s/ Paul Alessio Mezzina
Paul Alessio Mezzina

Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action
No. 1:25-cv-3452

DECLARATION OF PATRICK COSTELLO

I, Patrick Costello, declare as follows:

1. I am over the age of eighteen, and I am competent to provide this declaration.

2. I have worked for Amgen since 2007, holding roles of increasing responsibility in Amgen's finance, marketing, and value and access organizations. Since 2007, I have held the following roles: Accounting Manager (2007 to 2008); Finance Manager (2008 to 2011); Finance Sr. Manager (2011 to 2016); Finance Director (2016 to 2019); Marketing Director (2019 to 2020); Contracts and Pricing Director (2021); Executive Director, United States Value and Access (2021 to June 2024). Since June 2024 I have been in my current role, Associate Vice President,

United States Value and Access.

3. My professional experiences and leadership roles at Amgen have given me significant knowledge about how the pharmaceutical supply chain works, including standard industry practice for the pricing and distribution of prescription drugs. I am also well acquainted with Amgen's pricing and distribution practices for Enbrel, including with respect to wholesalers, pharmacies, and health care providers.

STANDARD INDUSTRY PRACTICE

4. As a general matter, pharmaceutical manufacturers sell drugs to wholesalers and other distributors ("direct customers"), which in turn sell the drugs to other downstream purchasers, such as pharmacies and hospitals ("indirect purchasers"). The price at which manufacturers sell their drugs to wholesalers is typically referred to as the "Wholesale Acquisition Cost" or "WAC." The WAC is a national list price that does not reflect any reductions, including the (often substantial) rebates demanded of manufacturers by pharmacy benefit managers (PBMs), or discounts applicable to pharmacies, hospitals, and other entities that purchase drugs from wholesalers.

5. Wholesalers typically sell drugs to indirect purchasers at WAC or at a price lower than WAC. Wholesalers' profit margins generally come from discounts they obtain from the manufacturer for prompt payment and/or from administrative or service fees they charge to the manufacturer for managing distribution of its drugs.

6. Wholesalers are at times required to provide discounts or other price

reductions at the point of purchase (e.g., when a drug is sold by the wholesaler to an indirect purchaser, it may include a discount indicated by the manufacturer). The wholesalers then seek reimbursement from the manufacturer for such discounts. This standard practice is known in the industry as a "chargeback."

7. As a general matter, Amgen is contractually obligated to reimburse wholesalers for certain discounts, deductions, rebates, and/or allowances the wholesalers provide to indirect customers (e.g., discounts to 340B covered entities or other government purchasers, or Amgen's contracted discounts to commercial indirect customers, such as hospitals and pharmacies). Accordingly, Amgen utilizes chargebacks to credit wholesalers for the amount of such discounts for drugs the wholesalers sell to indirect customers. Without that reimbursement, wholesalers would lose money. Buying high and selling low is unprofitable in any industry, but it is especially so with respect to pharmaceutical wholesalers, which operate on extremely thin margins and generally do not have the capacity to absorb uncompensated discounts.

THE COLORADO LEGISLATION AND THE ENBREL UPPER PAYMENT LIMIT

8. I am aware of the legislation Colorado enacted in 2021 creating a new Prescription Drug Affordability Review Board with the power to impose price controls, termed "upper payment limits," on sales of prescription drugs dispensed or distributed in Colorado.

9. I am also aware that the Board has adopted a final rule imposing an

upper payment limit of $600.00 per 50 milligram/milliliter unit on Amgen's drug Enbrel, with an effective date of January 1, 2027. This amount is more than 70 percent below Enbrel's current WAC of $2,039.40 per 50 milligram/milliliter unit.

10. I understand that the statute defines an upper payment limit as "the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the prescription drug," Colo. Rev. Stat. § 10-16-1401(23).

11. Amgen's sales of Enbrel are financial transactions concerning the purchase of or reimbursement for a prescription drug. I understand, however, that Colorado has claimed in prior litigation that an upper payment limit would apply to sales made by Amgen's wholesalers and distributors but not to sales made by Amgen itself.

THE EFFECTS OF THE UPPER PAYMENT LIMIT ON AMGEN

12. Even assuming that the upper payment limit applies only to "downstream" transactions (such as wholesalers' sales to pharmacies, specialty pharmacies, and hospitals), it will predictably operate as an effective cap on the net price Amgen can charge wholesalers. (Specialty pharmacies provide specialized or more complex pharmacy services, including shipments of certain medications for chronic and other serious conditions directly to patients. They often provide additional services that help ensure patients can access their medication.)

13. First, based on my experience in the industry, and as a matter of basic

economics and common sense, if the upper payment limit is imposed on wholesalers' sales of Enbrel, there is no realistic chance that wholesalers will absorb the discount required to comply with the upper payment limit without passing the cost on to Amgen. Indeed, Amgen is contractually required to reimburse wholesalers for such legally required discounts.

14. Second, as described above, Amgen cannot reasonably expect wholesalers to purchase products at WAC, without any discount or reimbursement from Amgen, if Colorado dictates that wholesalers must sell the products for less than WAC (as it will if the upper payment limit takes effect as scheduled). Like any other rational economic actor, wholesalers will not agree to purchase a product for more than what they can lawfully recover from reselling that product. Otherwise, the wholesalers would lose money on each sale. The upper payment limit will thus function as a cap on Amgen's net price for affected units of Enbrel.

15. Third, if for some reason Amgen and a wholesaler are unable to come to an agreement regarding how to compensate the wholesaler for the cost of complying with the upper payment limit for Enbrel, Amgen will still be negatively impacted. Amgen will lose revenue due to the loss of sales, as the wholesaler will choose to purchase alternative products not subject to an upper payment limit. And whether or not an agreement is ultimately reached, Amgen will incur administrative costs negotiating with its wholesalers over these issues.

16. Fourth, besides forcing Amgen to lower its net price for affected units of

Enbrel, Colorado's upper payment limit may also disrupt the broader market for Enbrel and damage Amgen's business relationships, reputation, and goodwill. For example, indirect purchasers outside of Colorado (to whom the upper payment limit does not apply) may object to being charged higher prices than indirect purchasers in Colorado. Amgen will incur additional costs negotiating with such customers and dealing with these and other broader market effects of the upper payment limit.

17. I am therefore certain that Amgen will incur costs as a result of the imposition of the upper payment limit on "downstream" sales of Enbrel. There is no scenario in which the upper payment limit for Enbrel will not negatively affect Amgen. Irrespective of where in the supply chain the upper payment limit on Enbrel is applied, it will disrupt the market for Enbrel and reduce the amount of revenue Amgen can obtain from sales of Enbrel.

18. While the Board set the upper payment limit to take effect January 1, 2027, Amgen will begin incurring costs well in advance of that date. For example, Amgen will need to incur costs to modify its payment systems to ensure that transactions affected by the upper payment limit are identified and that the upper payment limit is accounted for. Planning and implementing these changes will likely take at least twelve months. Amgen will also need to incur costs to address this issue with its wholesalers and specialty pharmacies. And Amgen will need to address objections raised by indirect purchasers in other states.

19. What is more, none of this is likely to benefit patients. To the contrary, because the upper payment limit would force market participants to operate under economically irrational conditions, the ultimate effect is more likely to restrict patient access than enhance it.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 18th day of November 2025.

By: 
Patrick Costello

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO

AMGEN, INC.;
IMMUNEX CORPORATION; and
AMGEN MANUFACTURING LIMITED LLC,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board;
SAMI DIAB, MD, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
AMARYLIS GUTIERREZ, PharmD, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
CATHERINE HARSHBARGER, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
JAMES JUSTIN VANDENBERG, PharmD, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
MICHAEL CONWAY, in his official capacity as Commissioner of the Colorado Division of Insurance; and
PHILIP WEISER, in his official capacity as Attorney General of the State of Colorado,

Defendants.

Case No. 25-cv-3452

DECLARATION OF NATALIE ADAMS

I, Natalie Adams, am over 18 years of age and hereby declare as follows:

1. I am competent to provide this declaration. I have worked for Cardinal

Health, Inc. ("Cardinal Health") since 2000. Currently, I am the Vice President of Strategic Sourcing and have overall responsibility for Cardinal Health's contracts and business relationships with pharmaceutical manufacturers.

2. My professional experiences and leadership roles at Cardinal Health have given me significant knowledge about how the pharmaceutical supply chain operates, including standard industry practice for the pricing and distribution of prescription drugs.

I. Background

3. As a wholesale pharmaceutical distributor, Cardinal Health plays a critical role in ensuring the safe, efficient, and reliable delivery of healthcare products every day from manufacturers to pharmacies, hospitals, and other licensed healthcare providers. Cardinal Health works across the entire healthcare spectrum, delivering daily to more than 35,000 locations, with products sourced from approximately 2,000 different organizations.

4. As a general matter, pharmaceutical manufacturers sell drugs to wholesalers and other distributors, like Cardinal Health, which in turn sell the drugs to hospitals, pharmacies, and other licensed healthcare providers. The price at which manufacturers sell their drugs to wholesale distributors is typically referred to as the Wholesale Acquisition Cost ("WAC"). Wholesale distributors do not set or control the WAC. The WAC is a national list price that does not reflect any reductions, including any rebates or discounts, applicable to entities that

purchase these drugs from wholesale distributors (e.g., pharmacies). Cardinal Health receives certain discounts from manufacturers (e.g., prompt pay discounts) and typically sells pharmaceuticals to its customers at WAC or at a price lower than WAC.

5. Wholesale distributors are at times required to provide discounts or other price reductions at the point of purchase (e.g., when a purchaser or its agent has negotiated a price directly with the manufacturer). In those instances, a wholesale distributor seeks reimbursement from the manufacturer for such discounts. This standard industry practice is known as a "chargeback."

6. Manufacturers are typically obligated to reimburse wholesalers for the difference between WAC and the contracted cost to which the wholesalers' customers are entitled, either statutorily (e.g., discounts to government purchasers, discounts under certain government programs like 340B), or through pricing agreements negotiated by the wholesalers' customers or their agents with manufacturers. Manufacturers typically utilize chargebacks to credit wholesalers for the amount of such discounts. If manufacturers do not provide these chargebacks, wholesalers would lose money by purchasing the drugs from manufacturers at WAC and selling to their customers at prices lower than WAC.

II. Colorado Legislation

7. I am aware of the legislation that Colorado enacted in 2021 creating a new Prescription Drug Affordability Review Board that can impose price controls,

termed "upper payment limits," on sales of prescription drugs dispensed or distributed in Colorado. I also understand that the statute defines an upper payment limit as "the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the prescription drug." Colo. Rev. Stat. § 10-16-1401(23). I am aware that the upper payment limit in Colorado for the drug Enbrel becomes effective January 1, 2027.

8. Based on my experience, it would not be economically feasible for a wholesale distributor to purchase a drug at WAC but then be required to sell it to customers in Colorado at the upper payment limit. If that were to occur, a wholesale distributor would need to be reimbursed from the manufacturer for that difference.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: November 19, 2025

Respectfully submitted,

Natalie Adams

Natalie Adams
Vice President, Strategic Sourcing
Cardinal Health, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO

Amgen Inc. *et al*.,

Plaintiffs,

v.

Gail Mizner, MD, in her official Capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al*.,

Defendants.

DECLARATION OF CHRISTOPHER REED

Case No. 1:25-cv-3452

DECLARATION OF CHRISTOPHER REED

I, Christopher Reed, am over 18 years of age and hereby declare as follows:

1. I oversee distribution operations at Cencora, Inc. and provide this declaration based on my own personal knowledge.

2. Wholesale distributors in the pharmaceutical industry ensure the safe, efficient, and reliable delivery of millions of healthcare products every day from manufacturers to pharmacies, hospitals, and other healthcare providers.

3. In general, wholesale distributors purchase pharmaceutical products from manufacturers at a price known as Wholesale Acquisition Cost ("WAC").

4. In general, wholesale distributors sell pharmaceutical products to customers at a price that is at or close to WAC.

5. In certain situations, wholesale distributors provide discounts to customers that reflect negotiated pricing between such customers and manufacturers. In such

instances, wholesale distributors submit what is known as chargebacks to manufacturers in order for the distributors to be made whole on the discounts being passed through to customers.

6. To the extent legislation dictates that wholesalers are required to sell a manufacturer's drug at substantially less than WAC, wholesalers such as Cencora would expect that manufacturer to provide a chargeback or other financial accommodation in order to make it economically viable for wholesalers to sell such product.

Further affiant sayeth not.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on November 18, 2025.

Reed, Christopher (a107264) Digitally signed by Reed, Christopher (a107264) Date: 2025.11.18 10:19:17 -05'00'

Christopher Reed, Vice President

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action
No. 1:25-cv-3452

DECLARATION OF JEANINE SINGER

I, Jeanine Singer, am over 18 years of age and hereby declare as follows:

1. I am the Senior Vice President, National and Key Accounts & Field Sales at McKesson Corporation and provide this declaration based on my own personal knowledge.

2. Wholesale distributors in the pharmaceutical industry play a critical role in ensuring the safe, efficient, and reliable delivery of healthcare products from manufacturers to pharmacies, hospitals, and other healthcare providers. Distributors provide sophisticated services, including thermally controlled packaging and transport, electronic data reporting, advanced analytics, administrative third-party contract management, exception management systems, quality controls, and inventory logistics.

3. Distributors serve pharmacies, hospitals, clinics, long-term care facilities, and other patient-facing organizations through a network of distribution centers geographically dispersed across the nation. These distribution centers and the systems they support provide consistent just-in-time delivery to their service areas so that providers can reliably deliver high quality care to patients.

4. McKesson serves pharmacies, hospitals, and other healthcare providers in Colorado, including through a distribution center in Colorado.

5. Brand manufacturers sell their drugs to McKesson at a price referred to as the Wholesale Acquisition Cost or "WAC." McKesson does not set or control the WAC for drug products. Instead, manufacturers set the WAC for drug products on a national basis.

6. McKesson typically sells brand drugs at or below WAC. Manufacturers pay fees to McKesson as compensation for the distribution services McKesson provides. McKesson also typically receives an upfront discount from manufacturers for promptly paying manufacturer invoices. The operating profit margin across McKesson's U.S. Pharmaceutical segment is typically around 1%.

7. In the instances when McKesson is required by manufacturers to sell brand drugs to customers at heavily discounted prices (for example, under the federal 340B Drug Pricing Program), McKesson typically gets reimbursement from the manufacturer for such discounts. This standard practice is known in the industry as a "chargeback." Without that reimbursement from the manufacturer, wholesalers would actually lose money distributing the drug products and it would not be

economically feasible to continue providing distribution services while sustaining such significant losses.

8. I am generally aware of the legislation in Colorado, which created a new Prescription Drug Affordability Board with the power to impose "upper payment limits" on sales of prescription drugs distributed in Colorado. I am also aware that the Board has selected Amgen's drug Enbrel to have an upper payment limit of less than half of the current WAC beginning January 1, 2027.

9. If this law goes into effect, McKesson's customers would expect their acquisition price to be significantly lower to reflect the lower reimbursement they would get via the upper payment limit set for Enbrel. If McKesson is expected to offer the heavily discounted price to its customers, McKesson would further expect to receive either an upfront discount or post-sale chargeback from Amgen for Enbrel sales into Colorado in order for distribution to be economically tenable for McKesson.

Further affiant sayeth not.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on 11/14/25.

Jeanine Singer

Date: 11/14/25

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action
No. 1:25-cv-3452

DECLARATION OF ADAM GRENNAN

I, Adam Grennan, declare as follows:

1. I am over the age of eighteen, and I am competent to provide this declaration.

2. I have worked for Amgen since 2007, holding roles of increasing responsibility in Amgen's sales, account management, and access organizations. Since 2007, I have held the following roles: Biopharmaceutical Sales Representative (2007 to 2012); District Manager - Oncology (2012 to 2015); Corporate Account Manager (2015 to 2016); National Accounts Sr. Manager (2016 to 2017); National Accounts Director (2017 to 2020); Executive Director and General Manager, US Market Access (2020 to 2024); Executive Director, Contracting & Pricing Strategy:

Inflammation (2024 to April 2025). Since April 2025 I have been in my current role, Associate Vice President, Head US Market Access.

3. My professional experiences and leadership roles at Amgen have given me significant knowledge about Amgen's contract negotiation practices for its drug ENBREL®, including for contracts with pharmacy benefit managers ("PBMs"), entities that administer prescription drug benefits for health benefit plans and other organizations. In my current role, I oversee the process through which Amgen enters into contracts with PBMs for coverage of Amgen's drugs, including Enbrel.

4. I am aware of the legislation Colorado enacted in 2021 creating a new Prescription Drug Affordability Review Board with the power to impose price controls, termed "upper payment limits," on sales of prescription drugs dispensed or distributed in Colorado.

5. I am also aware that the Board has adopted a final rule imposing an upper payment limit of $600.00 per 50 milligram/milliliter unit on Enbrel, with an effective date of January 1, 2027.

6. While the Board set the upper payment limit to take effect January 1, 2027, Amgen will begin incurring costs well in advance of that date.

7. For example, Amgen enters into contracts with PBMs on an at least an annual basis (if not more frequently) to ensure that Enbrel is included on the PBMs' formularies (lists of covered drugs). Discussions between Amgen and PBMs regarding these contracts for 2027 have already begun.

8. [redacted]

9. Based on past practice and industry norms, the formal bidding cycle for 2027 contracts with major PBMs (such as CVS Caremark, Express Scripts, and OptumRx) will take place from approximately January through March 2026, and the PBMs will likely finalize their formulary decisions by approximately May 2026.

10. If Amgen must assume that Enbrel will be subject to Colorado's UPL starting in 2027, Amgen thus will have to factor that into its bids for these contracts starting in the first quarter of 2026.

11. [redacted]

12. At a minimum, uncertainty about the UPL will greatly complicate Amgen's contract negotiations and decisions and make it difficult for Amgen to evaluate potential contract terms with PBMs, imposing substantial costs on Amgen's

business.

13. In addition, Amgen has certain contracts with PBMs that extend into 2027, but which do not currently account for the UPL. If the UPL remains in place, those contracts will have to be renegotiated well in advance of the UPL's effective date.

14. The information in paragraphs 8 and 11 of this Declaration is confidential, competitively sensitive business information. Amgen's competitive standing and its position in future contract negotiations would be harmed if the information in those two paragraphs were made public, and redacting those paragraphs in full is necessary to adequately protect Amgen against this harm.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 18th day of November 2025.

By: _____
Adam Grennan