

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

AMGEN INC., IMMUNEX CORPORATION,
AMGEN MANUFACTURING, LIMITED,
Plaintiffs-Appellants,

v.

GAIL MIZNER, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, SAMI DIAB, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board, AMARYLIS GUTIERREZ, 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, 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, PHILIP WEISER, in his official capacity as Attorney General of the State of Colorado,
Defendants-Appellees.

On Appeal from the United States District Court for the District of Colorado, No. 1:24-cv-00810-NYW-SBP, Hon. Nina Y. Wang

OPENING BRIEF FOR PLAINTIFFS-APPELLANTS

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June 13, 2025

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel for Appellant certifies the following:

1. The full names of the parties represented by me:
Amgen Inc., Immunex Corp., Amgen Manufacturing, Ltd. (n/k/a Amgen Manufacturing Limited LLC).
2. The names of the real parties in interest represented by me:
N/A.
3. Parent corporations and publicly held companies that own 10% or more of stock in the party:

The full name of Immunex Corp.'s parent corporation is Amgen Inc.

The full names of Amgen Manufacturing, Ltd. (n/k/a Amgen Manufacturing Limited LLC)'s parent corporations and all publicly held companies that own 10% or more stock in the entities are Amgen International Holdings Inc., Onyx Pharmaceuticals, Inc., and Amgen Inc.
4. The names of all firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:
 - King & Spalding LLP
 - Brian A. Bohnenkamp
 - Kelly Nicole Reeves
 - Clifford Stricklin

4. Are there any cases known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal:

No.

5. The organizational victims and bankruptcy cases applicable to this appeal:

N/A.

Date: June 13, 2025

/s/ Paul Alessio Mezzina
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TABLE OF CONTENTS

TABLE OF AUTHORITIES	v
STATEMENT OF RELATED CASES	xii
INTRODUCTION	1
JURISDICTION	5
STATEMENT OF THE ISSUE	6
STATEMENT OF THE CASE	6
A. The Federal Patent System	6
B. Colorado’s Drug Price-Control Regime	8
C. Amgen’s Patent-Protected Drug Enbrel	12
D. The Board’s Decision to Cap Enbrel’s Price.....	15
E. The District Court Proceedings	17
F. The Board’s Continuing Proceedings Against Enbrel.....	21
STANDARD OF REVIEW.....	23
SUMMARY OF ARGUMENT	23
ARGUMENT	27
I. Colorado’s price-control statute is preempted under this Court’s controlling precedent.....	27
II. The district court refused to reach the merits by applying the wrong standard for Article III standing	33
III. The district court erred in holding that Amgen failed to establish Article III standing.....	40
A. It is all but certain that the Board will set a price cap for Enbrel.....	41

B.	It is all but certain that the price cap will be below Enbrel’s current price	45
C.	It is entirely certain that the price cap will cause financial harm to Amgen	46
1.	Common sense and basic economics demonstrate that a price cap on a drug will harm the drug’s manufacturer	47
2.	Unrebutted record evidence confirms that a price cap on Enbrel will harm Amgen	50
3.	Colorado recognizes that drug manufacturers will bear the cost of price caps on their drugs	55
	CONCLUSION	59
	CERTIFICATE OF COMPLIANCE	
	ADDENDUM	

TABLE OF AUTHORITIES

Cases

<i>Adidas AG v. Nike, Inc.</i> , 963 F.3d 1355 (Fed. Cir. 2020)	34
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<i>Apple Inc. v. Vidal</i> , 63 F.4th 1 (Fed. Cir. 2023).....	5, 34, 36, 39
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<i>Armitage v. United States</i> , 991 F.2d 746 (Fed. Cir. 1993)	51
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<i>Biotech. Indus. Org. v. District of Columbia (BIO)</i> , 496 F.3d 1362 (Fed. Cir. 2007)	<i>passim</i>
<i>Biotech. Indus. Org. v. District of Columbia</i> , 505 F.3d 1343 (Fed. Cir. 2007)	31, 32
<i>Bonito Boats, Inc. v. Thunder Craft Boats, Inc.</i> , 489 U.S. 141 (1989)	7, 28
<i>Canadian Lumber Trade All. v. United States</i> , 517 F.3d 1319 (Fed. Cir. 2008)	5, 47, 49
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<i>Competitive Enter. Inst. v. FCC</i> , 970 F.3d 372 (D.C. Cir. 2020)	53, 54, 55

<i>Davis v. FEC</i> , 554 U.S. 724 (2008)	54
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<i>English v. Gen. Elec. Co.</i> , 496 U.S. 72 (1990)	28
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<i>Immunex Corp. v. Sandoz Inc.</i> , 964 F.3d 1049 (Fed. Cir. 2020)	13
<i>Intell. Tech LLC v. Zebra Techs. Corp.</i> , 101 F.4th 807 (Fed. Cir. 2024)	23
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<i>Middle S. Energy, Inc. v. Ark. Pub. Serv. Comm’n</i> , 772 F.2d 404 (8th Cir. 1985).....	33
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<i>New Jersey v. EPA</i> , 989 F.3d 1038 (D.C. Cir. 2021).....	54
<i>Pause Tech. LLC v. TiVo Inc.</i> , 401 F.3d 1290 (Fed. Cir. 2005)	23
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<i>Scahill v. District of Columbia</i> , 271 F. Supp. 3d 216 (D.D.C. 2017).....	40
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Constitutional Provisions	
U.S. Const. art. I, § 8, cl. 8	6
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28 U.S.C. § 1331	5
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42 U.S.C. § 1395w-3a(c)(6)(B)	10
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D.C. Code § 28-4553 30

Regulations

3 Colo. Code Regs. § 702-9:3.1..... 10, 11

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STATEMENT OF RELATED CASES

No other appeal in or from the same civil action in the district court was previously before this or any other appellate court. Counsel is unaware of any case pending in this or any other tribunal that will directly affect or be directly affected by this Court's decision in the pending appeal.

INTRODUCTION

This appeal involves a straightforward question of Article III standing: whether the manufacturer of a patented drug has standing to challenge an impending price cap on that drug. The answer to that question could hardly be more intuitive. Yet as this case illustrates, “[c]ourts sometimes make standing law more complicated than it needs to be.” *Thole v. U.S. Bank N.A.*, 590 U.S. 538, 547 (2020).

The district court held that Amgen lacks standing to challenge Colorado’s effort to impose unconstitutional price controls on Amgen’s patented drug Enbrel®—an effort that has already resulted in a declaration that Enbrel is “unaffordable,” a formal vote to select Enbrel for imposition of a price cap, and ongoing regulatory proceedings to determine the amount of the price cap (proceedings that Amgen contends are preempted). It did so despite uncontroverted record evidence establishing that the State’s price controls will cause Amgen financial harm. This Court should reverse that anomalous holding and direct the district court to promptly resolve Amgen’s constitutional claims on the merits.

Federal law preempts states from imposing price controls on patented drugs. As this Court has explained, Congress sought to incentivize innovation by providing patent holders with exclusive rights that allow them to earn enhanced profits during the life of the patent. For a state to limit “the pecuniary rewards stemming from the patent right” in the name of making patented drugs more affordable is thus “contrary to the goals established by Congress in the patent laws.” *Biotech. Indus. Org. v. District of Columbia (BIO)*, 496 F.3d 1362, 1372–74 (Fed. Cir. 2007) (striking down D.C.’s price-control scheme for patented drugs).

In defiance of this settled principle, Colorado’s new Prescription Drug Affordability Review Board has formally voted to declare that Amgen’s patented drug Enbrel is “unaffordable for Colorado consumers”—due in large part to Amgen’s “patents that prevent the introduction of biosimilar products”—and to “select[] Enbrel for establishment of an upper payment limit.” Appx586, Appx608, Appx1276. Based on those votes, the Board is currently holding hearings for the express purpose of determining what Enbrel’s upper payment limit should be.

After the Board voted to select Enbrel for establishment of a price cap, Amgen brought suit challenging Colorado's unconstitutional attempt to regulate Enbrel's price. In response, the State tried to distinguish *BIO* by asserting that Colorado's price cap would not apply directly to sales by Amgen, but would instead apply one step "downstream," to sales by Amgen's wholesalers and distributors.

But even accepting that dubious premise (which is contrary to the plain language of the statute), it makes no difference. For one thing, the price cap is still being imposed *on Amgen's drug*. For another, as Amgen explained and supported with evidence that the State did not try to rebut, the structure of pharmaceutical pricing and the terms of Amgen's contracts with its wholesalers make it "certain" that the cost of a downstream price cap will fall on Amgen itself, depriving it of the financial rewards Congress intended it to receive. Appx1447. And this is precisely what the Colorado legislature intended: A leading sponsor of the price-control legislation explained that wholesalers required to "sell [the drug] to pharmacies or hospitals" at a price dictated by the State "will be made whole on the back-end by the pharmaceutical manufacturer." *Hearing on S.B. 21-175 Before H. Comm. on Health &*

Ins., 73d Sess., at 7:22:00–7:23:30 (Colo. 2021) (“S.B. 21-175 Hr’g”) (statement of Rep. Kennedy), *available at* <https://tinyurl.com/3tas6ddc>.

This dispute is ripe for resolution now. Colorado has made clear that it intends to regulate the price of patented drugs, and it has already commenced a preempted regulatory price-setting process that is imposing significant costs and uncertainty on Amgen and other drug manufacturers. Yet the district court held that Amgen’s injuries from an impending price cap on its patented drug are “too speculative” to support Article III standing. Appx14. The court reasoned that the cost of a price cap *might* be borne entirely by Amgen’s wholesalers and distributors, disregarding Amgen’s unrebutted evidence that there was “no realistic chance” this could happen. Appx1446. The court added that the Board *might* change its mind and decide not to impose any price cap on Enbrel (even though the Board had already voted to select Enbrel for a price cap and the State offered no reason why it might reconsider) and that the price cap *might* not be lower than Enbrel’s current price (even though the entire purpose of a price cap is to reduce the current, supposedly “unaffordable” price).

Allowing such remote theoretical possibilities to defeat Amgen’s standing contravenes fundamental constitutional principles. “Injury-in-fact is not Mount Everest.” *Canadian Lumber Trade All. v. United States*, 517 F.3d 1319, 1333 (Fed. Cir. 2008) (cleaned up). As the Supreme Court and this Court have held, standing requires a plaintiff to demonstrate only a “substantial risk” of future harm, not an absolute certainty. *Apple Inc. v. Vidal*, 63 F.4th 1, 16–17 (Fed. Cir. 2023) (quoting *Susan B. Anthony List v. Driehaus (SBA)*, 573 U.S. 149, 158 (2014)). Amgen far exceeded that standard by showing that it was already experiencing ongoing harm from Colorado’s preempted regulatory process, that Colorado is all but certain to impose a price cap on Amgen’s patented drug at the end of that process, and that such a price cap will inevitably cause Amgen harm. Yet the district court allowed Colorado to insulate its unconstitutional scheme from timely review. This Court should reverse.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331. On March 28, 2025, the district court entered an order and final judgment granting Defendants’ motion for summary judgment and dismissing

Amgen’s complaint without prejudice for lack of standing. Amgen filed a timely notice of appeal on April 8, 2025. Appx1599–1600. This Court has jurisdiction under 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUE

Whether the district court erred in holding that Amgen lacks standing to challenge Colorado’s attempt to impose preempted, unconstitutional price controls on Amgen’s patented drug.

STATEMENT OF THE CASE

A. The Federal Patent System

Congress has long relied on the federal patent system to reward and incentivize the risk-taking and investment necessary “[t]o promote the Progress of Science and useful Arts.” U.S. Const. art. I, § 8, cl. 8. A federal patent confers “the right to exclude others from making, using, offering for sale, or selling the invention” for a limited period of time. 35 U.S.C. § 154(a)(1).

As this Court has explained, “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). By specifying the duration of exclusivity periods and other patent rules, 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 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).

Congress has paid special attention to fine-tuning that balance for pharmaceutical patents. Recognizing the enormous costs and complexity associated with discovering and 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 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).

This system has worked as Congress intended, providing significant benefits to the American people. Thanks to the incentives provided by federal patent law, the United States is a leader in

pharmaceutical innovation; American pharmaceutical companies have invested hundreds of billions of dollars in research and development, leading to the introduction of countless lifesaving and life-improving medicines; and generic competition after patent expiration has helped to broaden access and increase affordability.¹

B. Colorado’s Drug Price-Control Regime

Not content with Congress’s chosen balance between affordability and innovation, Colorado has sought to strike its own balance. To “protect Colorado consumers from excessive prescription drug costs,” Colorado’s price-control scheme targets the economic rewards that are the engine of the federal patent system. Colo. Rev. Stat. § 10-16-1403(1). As a leading sponsor of the legislation explained, “[t]he reason we did this is because

¹ See, e.g., Cong. Budget Off., Research & Development in the Pharmaceutical Industry, at 1 (Apr. 2021), *available at* <https://www.cbo.gov/publication/57025> (the pharmaceutical industry devoted \$83 billion to R&D in 2019, about 10 times what the industry spent per year in the 1980s); Wendy H. Schacht & John R. Thomas, Cong. Rsch. Serv., No. RL30756, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 (“The Hatch-Waxman Act”), at 30–31 (Jan. 10, 2005), *available at* <https://www.everycrsreport.com/reports/RL30756.html> (the decades after Hatch-Waxman saw dramatic increases in both pharmaceutical industry R&D spending on innovative new drugs and the availability of generic drugs after patent expiration).

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.” S.B. 21-175 Hr’g at 7:22:00–7:23:30 (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.

To that end, 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 (or “UPL”) 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).

As an initial step toward establishing UPLs, the Board must identify a list of prescription drugs that are eligible for an “affordability review.” *Id.* § 10-16-1406(1). Whether a drug is eligible depends entirely on the list price charged by the drug’s manufacturer—known as the wholesale acquisition cost or “WAC”—and how that price has changed

over time. *Id.*; *see also* 3 Colo. Code Regs. § 702-9:3.1(C).² No other factors are relevant to eligibility. The Board then decides which eligible drugs to select for an affordability review. In making that determination, the Board must consider, 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 and non-exhaustive list of factors, the first of which is the manufacturer’s list price for the drug. *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

² Congress defined “wholesale acquisition cost” as “the manufacturer’s list price for the drug or biologic[] to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price.” 42 U.S.C. § 1395w-3a(c)(6)(B). Colorado’s price-control statute borrows that federal definition. *See* Colo. Rev. Stat. § 10-16-1401(24).

whether the drug is subject to “[m]arket competition.” *Id.* § 10-16-1406(6). The Board has issued a regulation listing additional factors it will 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 indicate 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 for Colorado consumers, it can then 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. *Id.* § 10-16-1407(2). The Board’s regulation, however, merely parrots those 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 (but without any guidance as to what the Board should do with that information). *Id.* § 702-9:4.1(C)(2)(a).

Colorado’s statute expressly recognizes that capping a drug’s price will affect the drug’s manufacturer. Whenever the Board establishes an

upper payment limit for a drug, it must “[i]nquire of manufacturers of the prescription drug as to whether each such manufacturer is able to make the prescription drug available for sale in the state” notwithstanding the price cap. Colo. Rev. Stat. § 10-16-1407(10). An entire section of the statute specifies a manufacturer’s obligations if the manufacturer must stop selling its price-controlled drug in Colorado (and imposes draconian penalties on manufacturers that do not comply). *See id.* § 10-16-1412. And the statute provides expedited review of access determinations regarding “a prescription drug that is unavailable ... because a manufacturer refuses to make the drug available as a result of an upper payment limit.” *Id.* § 10-16-1408(4). These provisions are consistent with the legislature’s expectation that drug manufacturers would bear the cost of price caps established by the Board. *See* S.B. 21-175 Hr’g at 7:22:00–7:23:30 (statement of Rep. Kennedy).

C. Amgen’s Patent-Protected Drug Enbrel

Enbrel is a groundbreaking injectable medicine used to treat various autoimmune diseases, such as rheumatoid arthritis and psoriatic arthritis. Appx2, Appx54. Enbrel can help patients reduce joint pain,

avoid permanent joint damage, and dramatically improve their physical function and overall quality of life. Appx54.

Enbrel is covered by several United States patents, including two that limit competing biosimilar products from entering the market until 2029 at the earliest. Appx2. This Court has upheld the validity of those patents. *See Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1053 (Fed. Cir. 2020).

Plaintiff-Appellant Immunex Corporation is the manufacturer of Enbrel and the exclusive licensee of commercial rights in those patents. Appx42, Appx55. Immunex has granted Plaintiff-Appellant Amgen Manufacturing, Limited (“AML”) an exclusive sublicense to the patents to manufacture and sell Enbrel, and AML has invested heavily to ensure a safe and reliable supply of Enbrel. Appx42, Appx55. Both Immunex and AML are subsidiaries of Plaintiff-Appellant Amgen Inc. Appx42. For simplicity, this brief refers to Plaintiffs-Appellants collectively as “Amgen.”

Amgen sells Enbrel to wholesalers and distributors, who in turn sell the drug to other downstream purchasers, such as pharmacies and hospitals. Appx1443. The price Amgen charges wholesalers is known as

the manufacturer's list price or wholesale acquisition cost. Appx1443. When wholesalers sell Enbrel to downstream purchasers, they do not add a markup; instead, they sell at WAC or a price lower than WAC. Appx1444. If a wholesaler is required to provide a discount or other price reduction below WAC, Amgen reimburses the wholesaler for the discount through a special payment known as a "chargeback." Appx1444. All of this is consistent with standard practice in the pharmaceutical industry. Appx1443–1445.

While Amgen's patents allow it to charge higher prices for innovative drugs like Enbrel during the life of those patents, Amgen offers programs that support patients who may have difficulty affording medicine. For example, for more than 20 years Amgen has sponsored the Amgen Safety Net Foundation, a nonprofit patient assistance program that helps eligible patients in the United States gain access to qualifying Amgen medicines. In 2024 alone, the Foundation provided \$2.5 billion worth of drugs to eligible uninsured or underinsured patients at no cost.³

³ See 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>.

D. The Board's Decision to Cap Enbrel's Price

In June 2023, the Board approved a list of 604 drugs that were eligible for affordability reviews based on the list prices set by their manufacturers. Appx6. Several weeks later, the Board selected five of those drugs, including Enbrel, for affordability reviews. Appx6. 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. Appx81. On February 16, 2024, the Board declared that Enbrel is “unaffordable for Colorado consumers.” Appx1248; *see* Appx6. A week after that, on February 23, 2024, the Board voted to “select[] Enbrel for establishment of an upper payment limit.” Appx1276. The Board published the final version of its Enbrel affordability review report on March 21, 2024. Appx583, Appx1184.

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 for those drugs (which are available at Colo. Dep't of Regul. Agencies, *Colorado Prescription Drug Affordability Review Board & Advisory Council* (2025), <https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board> (click on “Previous PDAB Activities,” then “Affordability Reviews”)).

The Board's written report made clear that Enbrel's patent protection was a major factor in the Board's decision to regulate Enbrel's price. 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." Appx608, Appx642; *see also* Appx644 (the Board stating: "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 biosimilar competition that resulted in "price reduction." Appx608.

The Board's deliberations reflected this same concern with countering the price effect of Amgen's patent rights. During the discussion about whether to declare Enbrel unaffordable, the Chair reminded the Board that even though Humira had historically been more expensive than Enbrel, the Board had chosen to review Enbrel rather than Humira because Humira had recently gone off-patent and become

subject to biosimilar competition, whereas Enbrel was still patent-protected. The following exchange occurred:

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.

Appx1230–1231.

E. The District Court Proceedings

On March 22, 2024—the day after the Board published its final affordability review report for Enbrel—Amgen filed this action seeking declaratory and injunctive relief with respect to the constitutionality of Colorado's price-control scheme. Appx7. Amgen pointed out that under this Court's *BIO* precedent, federal patent law preempts Colorado from imposing price controls on patented drugs like Enbrel. Appx60–63.

Amgen also alleged that Colorado's scheme violates due process, interferes with federal healthcare programs, and violates the Commerce Clause. Appx63–70. The parties agreed that Amgen's claims raised legal questions that could be resolved on summary judgment without the need for discovery or trial, and the Court allowed the case to be resolved on that basis. Appx1118.

The parties filed cross-motions for summary judgment. In its motion, the State asserted for the first time that even though the price-control statute purports to govern “any financial transaction” involving the drug, Colo. Rev. Stat. § 10-16-1401(23), a price cap on Enbrel would not apply to Amgen's sales but only to “downstream” sales, including sales by Amgen's wholesalers. Appx1306–1308. On that basis, the State argued that Amgen lacked standing because it would not be “directly injured by the Board's work.” Appx1306. It also argued that the case was not ripe “as the Board has not, and may never, set a UPL.” Appx1306.

In response, Amgen pointed out that the Board had already formally declared Enbrel unaffordable and voted to select it for imposition of an upper payment limit, and the State had not offered any reason why the Board would reverse course. Amgen further explained

that it was certain to bear the cost of even a downstream price cap. Appx1414–1418. Amgen noted that it obviously has an interest in not having its patented product subjected to state-imposed price controls, and that common sense and basic economics indicate that a price cap on a manufacturer’s product is bound to injure the manufacturer.

But Amgen did not stop there—it also submitted a sworn declaration from Patrick Costello, Amgen’s Associate Vice President, United States Value and Access. He explained that when wholesalers are required to provide discounts to downstream purchasers (as Colorado’s price cap would force them to do), Amgen is contractually obligated to reimburse the wholesaler for the discount by providing a chargeback. Appx1443–1445. As Mr. Costello pointed out, this is standard industry practice and reflects the economic reality that wholesalers operate on extremely thin margins and lack the capacity to absorb uncompensated discounts. Appx1444. Mr. Costello thus averred that even if a price cap applied only to downstream transactions, it would be “certain” to have “predictable and negative effects” on Amgen, and there was “no scenario in which an upper payment limit for Enbrel would not negatively affect Amgen.” Appx1446–1447. Colorado did not submit any evidence to rebut

the Costello declaration, and the record before the district court was thus undisputed on these points.

The district court heard argument on October 22, 2024, and issued its decision on March 28, 2025, dismissing Amgen’s complaint without prejudice. Appx19. The court held that Amgen had failed to establish standing for three reasons. *First*, it accepted the State’s conclusory assertion that the Board could theoretically decide not to impose any price cap on Enbrel. Appx17. *Second*, raising a possibility that not even the State had put forward, the court speculated that the Board might impose a price cap but set it above Amgen’s current list price (*i.e.*, the price the Board considered when it declared Enbrel unaffordable) so that the price cap would have no practical effect. Appx17. *Third*, the court hypothesized that even if the Board did “establish a below-list-price UPL for Enbrel,” Amgen’s wholesalers might react by absorbing *all* of the associated costs, sparing Amgen from any injury. Appx17–18. The court did not address Mr. Costello’s sworn testimony that “Amgen is contractually required to reimburse wholesalers for such legally required discounts” and that in any event, the wholesalers “operate on extremely

thin margins and generally do not have the capacity to absorb uncompensated discounts.” Appx1444–1446.

F. The Board’s Continuing Proceedings Against Enbrel

As soon as the district court issued its decision, the Board moved forward with its proceedings against Enbrel (which it had repeatedly postponed while the summary-judgment motions were pending, *see* Appx1587–1588, Appx1590–1591, Appx1593, Appx1596–1597).

A few days after the decision, the Board published a cost-benefit analysis of its proposal to establish an upper payment limit for Enbrel. *See* Colo. Dep’t of Regul. Agencies, Cost-Benefit Analysis (Apr. 1, 2025) (“Cost-Benefit Analysis”), *available at* https://www.dora.state.co.us/pls/real/SB121_Web.Show_Rule?p_rule_id=10523. Belying the State’s suggestion that the Board might decide not to impose any price cap, the Board characterized a UPL as having significant benefits and only “minimal” costs, while it described the alternative of not establishing a UPL as having only costs and no benefits. *Id.* § 5. It warned that “[i]f [a UPL] isn’t adopted, prescription drug supply chain entities would likely continue operating as usual and the unsustainable high costs of prescription drugs would continue to grow.” *Id.*

The Board held its first rulemaking hearing to establish a price cap for Enbrel on May 23, 2025. A video recording of the hearing is available on the Board’s website. At the hearing, the Board did not discuss the option of not establishing any UPL for Enbrel. Nor did the Board seriously consider the possibility raised by the district court of setting a UPL above the current manufacturer list price; indeed, at one point a Board staff member noted that she would “recommend not setting a UPL above WAC” because “that wouldn’t do anything,” prompting laughter from the Board Chair.⁵

The Board has scheduled additional Enbrel rulemaking hearings to take place on July 11 and August 22, 2025. The Board will have up to 180 days after the last public hearing to issue a rule adopting a price cap for Enbrel. Colo. Rev. Stat. § 24-4-103(4)(d). The price cap’s effective date must be at least six months after the adoption of the rule. *Id.* § 10-16-1407(5).

⁵ See May 23, 2025 PDAB Meeting at 1:58:30–40, available at <https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board> (click on “2025 PDAB/PDAAC Meeting Links & Recordings”).

STANDARD OF REVIEW

“Article III standing determinations are reviewed de novo.” *Intell. Tech LLC v. Zebra Techs. Corp.*, 101 F.4th 807, 813 (Fed. Cir.), *cert. denied*, 145 S. Ct. 568 (2024). On “matters relating to this [C]ourt’s jurisdiction,” including questions of standing, this Court “appl[ies] Federal Circuit law, not that of the regional circuit from which the case arose.” *BIO*, 496 F.3d at 1369 (quoting *Pause Tech. LLC v. TiVo Inc.*, 401 F.3d 1290, 1292 (Fed. Cir. 2005)).

SUMMARY OF ARGUMENT

Despite this Court’s precedent holding that state price controls on patented drugs are preempted by federal law, Colorado is poised to impose a price cap on Amgen’s patented drug Enbrel. Amgen has demonstrated far more than a substantial risk that the impending price cap will cause Amgen financial harm. The district court accordingly erred in holding that Amgen lacked Article III standing and refusing to reach the merits of Amgen’s claims.

I. Colorado’s attempt to impose price controls on patented drugs is unconstitutional under this Court’s controlling precedent. As this Court has long recognized, Congress designed the federal patent system to

incentivize innovation through the enhanced economic rewards that accrue to a patent holder during the life of a patent. Those incentives are especially important in the pharmaceutical field, where Congress has sought to address the high cost of research and development through legislation such as the Hatch-Waxman Act. Like the District of Columbia law in *BIO*, Colorado's law invades the preempted field of federal patent policy and undermines the fundamental objectives of the federal patent system by striking directly at the financial incentives that patent protection is intended to provide. Accordingly, the ongoing process by which Colorado seeks to regulate Enbrel's price is itself preempted.

II. To avoid reaching the merits of Amgen's constitutional claim, the district court misapplied well-established principles of Article III standing, which require a plaintiff to establish only that it faces a "substantial risk" of harm. The district court failed to mention (let alone apply) that standard. Instead, it ignored the cost and uncertainty resulting from Colorado's preempted regulatory process and dismissed Amgen's risk of injury from the impending price cap, which was confirmed by un rebutted record evidence, as "hypothetical." It justified that conclusion by invoking remote theoretical possibilities with no

evidence to support them, such as the idea that the Board could turn on a dime and reverse its decision to impose a price cap (or just as implausibly, set the price cap higher than the price the Board considered when it declared Enbrel unaffordable). The court also appeared to suggest that a heightened standard for standing applies when the plaintiff is not a direct object of the challenged regulation. But a manufacturer *is* the direct object of a price cap that targets its product, and in any event, the same “substantial risk” test applies regardless of whether the plaintiff is the direct object of regulation.

III. The district court gave three reasons for dismissing Amgen’s injury as speculative, each of which underscores the court’s failure to apply the proper standard.

A. First, the district court suggested that the Board might have a change of heart and not impose any price cap on Enbrel. But the State has not explained why it should be permitted to subject Amgen to ongoing regulatory proceedings, with the cost and disruption they inevitably cause, for a purpose that is plainly preempted under federal law. Moreover, the Board has already declared Enbrel unaffordable after months of review culminating in a 500-page report, voted to select Enbrel

for imposition of an upper payment limit, and commenced proceedings to set the amount of that limit. The State has never identified any reason why the Board would abandon its efforts to cap the price of a drug it considers unaffordable, and the mere theoretical possibility that the Board could change its mind cannot defeat review.

B. Second, the district court suggested that the Board might set the upper payment limit at or above Enbrel’s current list price. But such conjecture cannot defeat Amgen’s standing—especially since it is implausible that the Board would declare Enbrel unaffordable, decide that a price cap is warranted, and go through a lengthy regulatory process to establish a price cap, only to set the cap at a level that does not actually affect the price. The State did not even raise this idea, and the district court should not have treated it as a genuine possibility.

C. Third, the district court suggested that even if an upper payment limit is set below current prices, it may not affect Amgen because, under Colorado’s late-breaking interpretation of the statute that the court accepted, a UPL applies only to downstream sales (such as those made by wholesalers), not to sales by manufacturers. Even assuming that interpretation is correct, however, it is crystal clear that

a price cap on Amgen’s drug will harm Amgen. As a matter of common sense, basic economics, and unrebutted record evidence, there is no basis for assuming that Amgen’s wholesalers will be able or willing to absorb all of the costs of a UPL. Mr. Costello’s declaration explains why the wholesalers cannot and will not absorb those costs and points out that Amgen will be required—by both the terms of its existing contracts and the practical realities of the industry—to bear those costs itself. Moreover, the price-control statute expressly anticipates that manufacturers will incur costs as a result of a UPL, one of its leading sponsors acknowledged as much during legislative deliberations, and the Board’s proceedings have focused on manufacturer list prices. This Court should reject the State’s remarkable contention that a drug’s manufacturer has no skin in the game when the Board sets a price cap for that drug.

ARGUMENT

I. Colorado’s price-control statute is preempted under this Court’s controlling precedent.

Colorado’s counterintuitive insistence that a drug manufacturer lacks standing to challenge the State’s imposition of a price cap *on that manufacturer’s own drug* reflects the challenges the State faces in

defending its law on the merits. Colorado’s attempt to impose price controls on patented drugs is preempted under a straightforward application of this Court’s precedent.

It is well established that 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) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). State efforts to regulate the price of patented drugs implicate both field and conflict preemption. “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 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). And state price controls obstruct the “fundamental purpose” of Congress’s grant of exclusive patent rights, which is to incentivize innovation by allowing manufacturers of patented products to set their

own prices during the patent term. *BIO*, 496 F.3d at 1372 (quoting *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006)).

Such financial incentives for innovation are especially critical in the pharmaceutical sector, where they are needed to encourage drug companies “to continue costly development efforts.” *Id.* (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 10–15 years and costs more than \$2 billion, and only about 1 in 5,000 potential new drugs obtains approval and reaches patients.⁶ Of the medicines approved for patient use, only about 20% ever generate enough revenue to cover their own development costs.⁷ “The economic rewards during the period of exclusivity are the carrot”

⁶ See GAO, No. GAO-20-215SP, *Artificial Intelligence in Health Care*, at 34 (Dec. 2019), available at <https://www.gao.gov/assets/gao-20-215sp.pdf>; Stephen Ezell, Info. Tech. & Innovation Found., *Ensuring U.S. Biopharmaceutical Competitiveness*, at 29–30 (July 2020), available at <https://www2.itif.org/2020-biopharma-competitiveness.pdf>; Paul Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 *Computational & Structural Biotech. J.* 4538, 4547 (2021), <https://doi.org/10.1016/j.csbj.2021.08.011>.

⁷ 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).

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*, 496 F.3d at 1372 (quoting *King Instruments*, 65 F.3d at 950).

In *BIO*, this Court confronted a District of Columbia statute that would have reduced the “size of the carrot,” *id.* (quoting *King Instruments*, 65 F.3d at 950), by limiting the prices of patented prescription drugs. Although the D.C. law did “not directly regulate manufacturers’ wholesale prices,” *id.* at 1371, it imposed liability on manufacturers if their conduct “result[ed] in the prescription drug being sold in the District for an excessive price,” *id.* at 1365 (quoting D.C. Code § 28-4553).

The Court held that federal 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*, 505 F.3d 1343, 1345 (Fed. Cir. 2007) (Gajarsa, J., concurring in denial of reh’g en banc) (noting 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 establishes new patent policy”).

Colorado’s price-control law should meet the same fate. Like the law this Court struck down in *BIO*, Colorado’s statute 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*, 496 F.3d at 1374. Congress, however, has already tailored federal patent 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 preempted field of federal patent policy and “is contrary to the goals established by Congress in the patent laws.” *Id.* at 1374. “The underlying determination about the proper balance between

innovators' profit and consumer access to medication ... is exclusively one for Congress." *Id.*

Moreover, because Colorado is preempted from regulating the price of patented drugs, Colorado's ongoing regulatory "process" aimed at regulating the prices of Enbrel and other patented drugs "itself is preempted ... regardless of what the outcome" of that process might be. *NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 342–44 (3d Cir. 2001); see *Biotech. Indus. Org.*, 505 F.3d at 1345 (Gajarsa, J., concurring in denial of reh'g en banc) (a state's "attempt to change federal patent policy within" that state is both field- and conflict-preempted (cleaned up)). Amgen should not have to submit to that preempted, unconstitutional process and await its final outcome before challenging it. See, e.g., *Sayles Hydro Assocs. v. Maughan*, 985 F.2d 451, 453–54 (9th Cir. 1993) (preemption challenge to state permitting process was ripe because "[t]he hardship is the process itself," which "may impose cost and uncertainty"); *Middle S. Energy, Inc. v. Ark. Pub. Serv. Comm'n*, 772 F.2d 404, 413 (8th Cir. 1985) (similar).

II. The district court refused to reach the merits by applying the wrong standard for Article III standing.

Faced with a clear violation of this Court’s precedent, the district court avoided reaching the merits by misapplying settled law. The court required Amgen to demonstrate to a certainty that it will be harmed by a price cap imposed at the end of Colorado’s ongoing regulatory price-setting process, ignoring the injurious cost and uncertainty that result from the preempted process itself and the “substantial risk” standard that the Supreme Court and this Court use to evaluate standing based on the prospect of future harm.

As an initial matter, “focus[ing] on the possible ultimate result of the state regulatory process”—*i.e.*, whether the Board will follow through on its stated intent to impose a price cap—overlooks that the “process itself can be the preempted burden.” *NE Hub Partners*, 239 F.3d at 342–44; *see also, e.g., Sayles Hydro Assocs.*, 985 F.2d at 453–54 (preemption challenge to state permitting process was ripe because “[t]he hardship is the process itself,” which “may impose cost and uncertainty”); *Middle S. Energy*, 772 F.2d at 413 (similar). The Board’s proceedings aimed at regulating Enbrel’s price are preempted regardless of their ultimate outcome. Yet the district court did not consider the concrete harms

Amgen is already suffering (and will continue to suffer) because it is forced to incur substantial costs to defend its interests in a preempted state price-setting process and to deal with the regulatory uncertainty that process creates.

With respect to future harm, the Supreme Court has made clear that Article III standing in a pre-enforcement challenge requires only a “substantial risk” of harm, not an absolute certainty. *SBA*, 573 U.S. at 158 (quotation marks omitted). This Court, too, has held that “[a]n allegation of future injury may suffice if the threatened injury is certainly impending, *or there is a substantial risk that the harm will occur.*” *Apple*, 63 F.4th at 16 (emphasis added) (quoting *SBA*, 573 U.S. at 159). For example, this Court has consistently applied that standard to evaluate the standing of a party facing a threat of patent infringement litigation. A party in that position need only demonstrate a “substantial risk” of an infringement suit—not a certainty or even a specific threat. *See, e.g., Gen. Elec. Co. v. Raytheon Techs. Corp.*, 983 F.3d 1334, 1341–42 (Fed. Cir. 2020); *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1357 (Fed. Cir. 2020); *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1005 (Fed. Cir. 2018).

Similarly, in *BIO*, this Court found standing based on a “realistic danger” of injury to manufacturers. 496 F.3d at 1370 (quotation marks omitted). The Court held that D.C.’s price-control law posed a sufficient likelihood of harm to manufacturers even though the law “d[id] not directly regulate” manufacturers’ prices, no price cap had been imposed, no existing price had been deemed “excessive” (or unaffordable), and no proceedings had been instituted to enforce the law against any manufacturer. *Id.* at 1370–71 (quotation marks omitted). It was enough that manufacturers had a “well-founded fear that the law [would] be enforced against them.” *Id.* at 1370 (quotation marks omitted).

Here, the district court did not even mention the “substantial risk” standard, let alone apply that standard faithfully. Instead, the court effectively required a literal certainty of future harm. The court repeatedly invoked the formulation that threatened injury must be “*certainly* impending.” Appx15 (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013)); *see also* Appx18. But it never acknowledged the mountain of more recent precedent recognizing that a “substantial risk” is sufficient. *See, e.g., SBA*, 573 U.S. at 158; *Apple*, 63 F.4th at 16. The court thus treated *any* possibility that Amgen would be spared from

harm—no matter how remote, theoretical, or even fanciful—as sufficient to defeat Amgen’s standing.

For instance, the court declared 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.” Appx17. Of course, any future injury is by definition “hypothetical” in the sense that it has not actually happened yet. But when courts say that an Article III injury cannot be “hypothetical,” they mean it cannot be “*merely* hypothetical”—*i.e.*, merely possible, as opposed to reasonably likely. *Sierra Club v. Franklin Cnty. Power of Ill., LLC*, 546 F.3d 918, 926 (7th Cir. 2008) (emphasis added); *see also, e.g., Arcia v. Fla. Sec’y of State*, 772 F.3d 1335, 1341 (11th Cir. 2014) (finding standing based on a “realistic probability” of harm because “[w]hile the threatened future injury cannot be *merely* hypothetical or conjectural, probabilistic harm is enough” (emphasis added)); *MainStreet Org. of Realtors v. Calumet City*, 505 F.3d 742, 744 (7th Cir. 2007) (“[S]tanding in the Article III sense does not require a certainty or even a very high probability that the plaintiff is complaining about a real injury, suffered or threatened”).

Here, there is obviously much more than a “merely hypothetical” possibility that the Board will impose a price cap on Enbrel that is below the current list price. The Board has already declared Enbrel “unaffordable” and voted to “select[] Enbrel for establishment of an upper payment limit.” Appx586, Appx1276. It has given every indication that it will follow through. And while the Board could, in theory, suddenly reverse course, the State has never offered any reason why it would do so. Nor is there any reason to think the Board will set the price cap at a level that doesn’t actually affect Enbrel’s price, a possibility the State never even raised. To the contrary, there is an overwhelming likelihood (and much more than a “substantial risk”) that the Board will do what it has “publicly announced its commitment” to do, *Franklin Cnty. Power*, 546 F.3d at 926, and impose a price cap that requires a reduction in Enbrel’s current (and supposedly unaffordable) price.

Without ever acknowledging the “substantial risk” standard, the district court appeared to suggest that Amgen should be held to a higher standard because the Enbrel price cap will only apply to downstream sales and, therefore, the court regarded Amgen as not a direct object of regulation under the price-control statute. *See, e.g.*, Appx17 (“Amgen fails

to cite any authority for the proposition that an unregulated plaintiff can establish standing based on hypothetical government action.”). That suggestion is wrong for two independent reasons.⁸

First, Amgen *is* a direct object of regulation because the price cap will regulate the price of *Amgen’s product*. As the D.C. Circuit observed (in an opinion by then-Judge Kavanaugh), a hot-dog manufacturer is properly considered an “object” of a regulation that “makes it harder for concession stands to sell hot dogs,” and a sugar manufacturer is an “object” of a regulation that “makes it harder for soda manufacturers to use sugar,” even though neither regulation applies directly to the manufacturer. *Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015) (quotation marks omitted) (holding that biofuel producers were “object[s]” of a regulation “technically directed” at vehicle manufacturers because the regulation concerned the biofuel producers’ product

⁸ Colorado’s law states that an upper payment limit applies to “any financial transaction” involving the drug, Colo. Rev. Stat. § 10-16-1401(23), which on its face would include sales by manufacturers. The district court nonetheless accepted the State’s position that a UPL will apply only to sales by wholesalers and other downstream distributors. Appx13–14. Because Amgen has standing regardless, Amgen assumes for purposes of this appeal that the State will not apply the UPL to Amgen’s own sales of Enbrel, but will apply it to sales by Amgen’s wholesalers and distributors.

(quotation marks omitted)). That conclusion is even more obvious here, where Colorado is seeking to regulate not a class of products (like hot dogs, sugar, or biofuels), but a particular drug from a single manufacturer.

Second, neither the Supreme Court nor this Court has ever limited the “substantial risk” test to directly regulated plaintiffs. Whether the effect on the plaintiff is direct or indirect, the standard remains the same: A plaintiff who “alleges future injury from a regulation that does not directly regulate the party itself” can demonstrate standing by showing “a substantial risk that the harm will occur.” *Nat’l Infusion Ctr. Ass’n v. Becerra (NICA)*, 116 F.4th 488, 497 (5th Cir. 2024) (quoting *Dep’t of Com. v. New York*, 588 U.S. 752, 767 (2019)); *see also, e.g., Apple*, 63 F.3d at 16–17 (applying “substantial risk” standard to claim that Director’s new instructions to Patent Trial and Appeal Board would cause it to deny more of plaintiff’s IPR petitions); *Stilwell v. Off. of Thrift Supervision*, 569 F.3d 514, 518 (D.C. Cir. 2009) (holding that investor challenging a rule that “directly regulate[d] ... subsidiaries, not investors,” had to “show a ‘substantial probability’ of injury as a result of the rule” (cleaned up)); *Scahill v. District of Columbia*, 271 F. Supp. 3d 216, 227–31 (D.D.C.

2017) (“Where not directly regulated by a challenged government regulation, a plaintiff must show that there is a ‘substantial probability’ that he will be harmed as a result of the rule”), *aff’d*, 909 F.3d 1177 (D.C. Cir. 2018).

In sum, Amgen is properly considered a direct object of Colorado’s effort to impose a price cap *on Amgen’s patented drug*, even if the price cap would only apply to downstream sales of the drug. But even if it were appropriate to consider Amgen an “unregulated party,” Appx14, that still would not justify the district court’s failure to apply the well-established “substantial risk” standard, and the court’s failure to do so was legal error.

III. The district court erred in holding that Amgen failed to establish Article III standing.

Applying the correct standard, there can be no serious question that Amgen demonstrated at least a substantial risk of injury from Colorado’s effort to cap the price of Enbrel. The district court identified three reasons why Amgen supposedly lacks standing: (1) the Board might decide not to impose a price cap on Enbrel after all; (2) the Board might set the price cap at or above Enbrel’s current list price; and (3) a price cap below the list price might not injure Amgen because Amgen’s wholesalers might

absorb the entire financial loss resulting from the price cap, leaving Amgen unscathed. Appx17.

Even setting aside the ongoing harm to Amgen from the State's preempted regulatory process, none of the district court's reasons holds up to scrutiny. *First*, there is every reason to expect that the Board will follow through on its decision to impose a price control on Enbrel. *Second*, it is fanciful to imagine that the Board will choose to set the price cap at a level that would have no effect on prices. And *third*, the suggestion that a price cap on Amgen's drug will not hurt Amgen not only defies common sense and basic economics, but also ignores unrebutted record evidence confirming that Amgen will be injured.

A. It is all but certain that the Board will set a price cap for Enbrel.

The district court had no reason to doubt that the Board will set an upper payment limit for Enbrel. The *raison d'être* of Colorado's statutory scheme is to impose upper payment limits on drugs that the Board determines are "unaffordable." The Act's stated purpose is to "protect Colorado consumers from excessive prescription drug costs." Colo. Rev. Stat. § 10-16-1403(1). To fulfill that mandate, the Act commands that the Board "*shall* ... [p]erform affordability reviews of prescription drugs" and

“*shall* ... [e]stablish upper payment limits for prescription drugs.” *Id.* (emphasis added).

Here, the Board has been deliberately and methodically marching toward imposing an upper payment limit on Enbrel. The Board undertook a monthslong proceeding to declare Enbrel unaffordable, published a 500-page report detailing its assessment, and then formally voted to “select[] Enbrel for establishment of an upper payment limit.” Appx1276. The State has never identified any reason why the Board, having come this far, would suddenly reverse course and abandon its plans to cap Enbrel’s price. As Amgen pointed out below (citing authorities the district court ignored), an agency “*always* retains the power to revise” its decisions, so the mere “possibility” that the agency might have a change of heart cannot defeat review. *Am. Petroleum Inst. v. EPA*, 906 F.2d 729, 739–40 (D.C. Cir. 1990) (per curiam); accord 13B Wright & Miller, *Federal Practice and Procedure* § 3532.6 (3d ed.) (“[A]ny agency attempt to defeat review by the bare assertion that the agency position may some day change should be summarily rejected.”). A mere possibility is all the State has offered here, asserting that the Board

could, in theory, change its mind about the need for a price cap, while offering no reason to think the Board might actually do so.

BIO is again instructive. This Court held that the plaintiffs in *BIO* had standing to challenge D.C.’s price-control scheme, even though D.C.’s efforts to enforce that scheme were not nearly as far along as Colorado’s are here. As explained above, the D.C. law in *BIO* prohibited “excessive” prices, but no existing price had been deemed excessive and no proceedings had been instituted against any manufacturer. 496 F.3d at 1370–71. Here, by contrast, the Board has already declared Enbrel unaffordable and has begun holding hearings (which were postponed while the action was pending before the district court) to determine an appropriate price cap.

Moreover, while the record before the district court is more than sufficient to demonstrate the near-certainty of a price cap, the Board’s recent public (and thus judicially noticeable) proceedings confirm its intent. The Board’s cost-benefit analysis portrays an upper payment limit on Enbrel as an unqualified good with sizeable benefits and minimal costs. The Board states that capping Enbrel’s price will “[r]educ[e] prescription drug costs” without *any* “adverse effect on consumers” or “on

the economy, private markets, small businesses, job creation, [or] economic competitiveness.” Cost-Benefit Analysis §§ 2, 4. It states that “direct and indirect costs will be minimal” and refuses even to acknowledge the costs to drug manufacturers and the costs flowing from diminished incentives for innovation. *Id.* § 4. The Board concludes its analysis by warning that “[i]f [a price cap] isn’t adopted ... the unsustainable high costs of prescription drugs would continue to grow.” *Id.* § 5. Consistent with that one-sided analysis, the Board’s deliberations at the May 23 hearing included significant discussion regarding the *amount* of the price cap, but none at all regarding *whether* to impose a price cap.

Why would the Board—which was created for the sole purpose of regulating prices of supposedly unaffordable drugs, has already found Enbrel unaffordable and voted to select it for imposition of a price cap, and sees price controls as an unmitigated good—decline to impose a price cap on Enbrel? The State has offered no answer to that question. There is far more than a substantial risk that the State will impose a price cap, and the theoretical possibility that it might not do so cannot defeat Amgen’s standing.

B. It is all but certain that the price cap will be below Enbrel's current price.

The district court also dismissed Amgen's standing as "speculative" on the ground that, in theory, the Board could set an upper payment limit for Enbrel that is equal to or higher than Enbrel's current list price. Appx16–17. It is hard to understand why the district court took this possibility seriously. The State had not even raised it, and for good reason: The idea that the Board would go to the trouble of declaring a drug unaffordable and holding multiple rulemaking hearings to establish a price cap, only to select a cap that would have no effect on current prices, makes no sense and is implausible on its face. Indeed, at the first rulemaking hearing, the prospect of setting a UPL above the current list price was rightly treated as a joke because it "wouldn't do anything." See p. 21, *supra*. The Board's cost-benefit analysis likewise assumes that a UPL will be below WAC and does not seriously entertain setting a UPL at or above WAC. Such a far-fetched possibility cannot defeat Amgen's standing under the "substantial risk" standard.

Moreover, even assuming *arguendo* that the Board might set a price cap at or above the current list price, such a cap would still injure Amgen by preventing it from setting the price going forward based on "the

dictates of the marketplace.” *BIO*, 496 F.3d at 1372 (quoting *King Instruments*, 65 F.3d at 950); *see id.* at 1371 (even if D.C.’s price-control law did not cause manufacturers to change their pricing structure, “the need to monitor and consider that structure in light of the Act will necessarily impose upon them actual administrative costs”).

C. It is entirely certain that the price cap will cause financial harm to Amgen.

That a manufacturer has a concrete interest in opposing a price control on its product is so self-evident that it should go without saying. Even assuming that an upper payment limit will not apply to Amgen’s direct sales, there is no dispute that it will apply to sales made by Amgen’s wholesalers and distributors. The district court doubted that such a “downstream” price cap would reduce Amgen’s profits and considered it “speculative” that wholesalers forced to sell Enbrel at a lower price would “demand[] that Amgen absorb any costs associated with” the price cap. Appx14, Appx17. But it defies both common sense and undisputed record evidence to suggest that wholesalers will absorb all the costs themselves, without any of the financial burden of the price cap falling on Amgen. That suggestion also flies in the face of the

Colorado statute and its legislative history, which contemplate that the burden of an upper payment limit will fall on manufacturers.

1. Common sense and basic economics demonstrate that a price cap on a drug will harm the drug's manufacturer.

It is well established that standing can be based on “[c]ommon sense and basic economics.” *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 6 (D.C. Cir. 2017); *see Canadian Lumber*, 517 F.3d at 1333 (holding that plaintiff “could fairly employ economic logic” to establish its standing); *NICA*, 116 F.4th at 500 (evaluating standing on the assumption that “third-party decisions ... are guided by basic economic rationality”). That includes the “familiar circumstance[]” in which regulation of downstream businesses causes “upstream economic injuries to others in the chain, such as ... manufacturers.” *FDA v. All. for Hippocratic Med. (AHM)*, 602 U.S. 367, 384–86 (2024); *see, e.g., Energy Future Coal.*, 793 F.3d at 144 (biofuel producers had standing to challenge regulation of vehicle manufacturers); *Wedges/Ledges of Cal., Inc. v. City of Phoenix*, 24 F.3d 56, 61 (9th Cir. 1994) (“[A] provider of goods or services has standing to challenge government regulations that directly affect its customers and restrict its market.”).

Here, common sense makes clear that limiting the price wholesalers can charge for a drug will impose costs on the manufacturer that sells the drug to those wholesalers by reducing what wholesalers are willing to pay (or, at a bare minimum, by affecting the manufacturers' negotiations with the wholesalers). If Colorado sought to limit how much distributors can charge for Coca-Cola, no one would think that the Coca-Cola Company had no stake in the matter. Everyone would recognize that if distributors are forced to *sell* for less, they will in turn *buy* for less. See *NICA*, 116 F.4th at 500 (“[P]redicting a profit-seeking business’s response to changing economic incentives simply requires determining the direction in which the incentives are changing.”).

The district court objected that “[n]othing in the record defines what the amorphous concepts of ‘basic economics and common sense’ entail.” Appx15. But one does not need an evidentiary record to establish that something is common sense—that is what makes it *common* sense. See *Carpenters Indus. Council*, 854 F.3d at 6; *NICA*, 116 F.4th at 500. Judges are “not required to exhibit a naiveté from which ordinary citizens are free.” *Dep’t of Com.*, 588 U.S. at 785 (quoting *United States v. Stanchich*, 550 F.2d 1294, 1300 (2d Cir. 1977) (Friendly, J.)). Basic

economics and common sense are tools that courts are supposed to *apply* to the record, not precepts that they must be able to *derive* from the record.

To the extent the State contends that ordinary economic logic does not apply here, it should bear the burden of coming forward with some evidence that the relationship between drug manufacturers and wholesalers is so unusual that a price cap on the wholesalers will have no effect on the manufacturers that sell to them. *See Canadian Lumber*, 517 F.3d at 1333 n.17 (defendants could “attempt to rebut [plaintiff’s] arguments from economic logic” by presenting contrary evidence). But the State has never offered any explanation for how that could possibly be true. Instead, it has gestured vaguely at the “complexities” of the pharmaceutical market in general. *E.g.*, Appx1491. This hand-waving about “complexity,” which the district court echoed without citing any record evidence, *see* Appx16, is a distraction. Regardless of whether the market for prescription drugs *in general* may be complex, there is no reason to think that the *particular aspect* of the market at issue here—

whether wholesalers will pay less for a drug that they must sell for less—is anything but straightforward.⁹

2. Unrebutted record evidence confirms that a price cap on Enbrel will harm Amgen.

In any event, the district court did not need to rely on basic economics or common sense alone in this case, because Amgen also presented unrebutted evidence that it would bear the cost of a downstream price cap on Enbrel. Mr. Costello’s declaration explained in detail why this is so, and the State offered no contrary evidence. *See* Appx1442–1447.

As Mr. Costello explained, Amgen has no choice but to reimburse its wholesalers for any discounts they are required to provide below the list price, which it typically does through special payments known as

⁹ The district court relied on Amgen’s CEO’s statement that certain other, unrelated aspects of the pharmaceutical market exhibit “counterintuitive pricing behavior.” Appx16. But that comment, which the court took out of context, was about the pressures on manufacturers to increase their list prices in order to provide greater downstream rebates to pharmacy benefit managers. To the extent it is relevant here at all, that dynamic reinforces Amgen’s point that changes in the supply chain downstream affect manufacturers upstream. The State offered no evidence or argument that such “counterintuitive” behavior would apply to the aspect of the market at issue here or that it would make Amgen’s wholesalers willing to buy Enbrel from Amgen at a price higher than the price at which they are allowed to sell it.

“chargebacks.” Appx1444–1446. Amgen is obligated to do so both by the terms of its existing contracts with wholesalers and by industry standards that reflect fundamental market realities. *See* Appx1446. Pharmaceutical wholesalers “operate on extremely thin margins,” sell drugs at or below the manufacturer’s list price, and “generally do not have the capacity to absorb uncompensated discounts” below the list price. Appx1444–1445. And like “any other rational economic actor,” these wholesalers “will not agree to purchase a product for more than what they can lawfully recover from reselling that product.” Appx1446. Accordingly, if Amgen refused to reimburse wholesalers that are forced to sell Enbrel below list price, the wholesalers would stop buying Enbrel, and Amgen would lose sales. Appx1446–1447.

Colorado did not object to Mr. Costello’s declaration and presented no contrary evidence, even though Amgen’s presentation of “unrebutted” evidence shifted “the burden of avoiding entry of summary judgment” on standing to the State. *Armitage v. United States*, 991 F.2d 746, 751 (Fed. Cir. 1993). And while “[a]ttorney argument is no substitute for evidence,” *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 424 F.3d 1276, 1284 (Fed. Cir.

2005), Colorado’s counsel did not even make any arguments attempting to explain why Mr. Costello’s account is wrong.

Yet the district court disregarded Amgen’s evidence, positing without any basis that wholesalers might not “demand[] that Amgen absorb any costs” of a price cap. Appx17. To the extent the court was relying again on the “complexity of the supply chain and the various rebates, reimbursements, chargebacks and discounts that are exchanged,” Appx16, Mr. Costello specifically addressed those features of the supply chain and explained why they *support* Amgen’s standing. The court simply ignored Mr. Costello’s explanation and dismissed his well-grounded testimony as “conclusory.” Appx17. Again, while some aspects of the pharmaceutical market may be complicated, the effect of a UPL on Amgen is simple and straightforward, and the record on this point is entirely one-sided.

To the extent the district court dismissed Mr. Costello’s explanation as “speculative” simply because it involved a multi-step causal chain, Appx16–17, “[t]his wrongly equates injury ‘fairly traceable’ to the defendant with injury as to which the defendant’s actions are the very last step in the chain of causation.” *Bennett v. Spear*, 520 U.S. 154, 168–

69 (1997); *see also Competitive Enter. Inst. v. FCC*, 970 F.3d 372, 384–85 (D.C. Cir. 2020) (collecting cases where standing was based on a multi-step causal chain). And the causal chain here is neither long nor complex. As discussed above, the Board is all but certain to impose a UPL and to set it below the current list price, so those “conditions precedent” to Amgen’s injury, Appx16, are of minimal significance. And as Mr. Costello explained, once those conditions are satisfied, Amgen’s bearing the cost of a UPL is both a contractual requirement and an economic necessity given that wholesalers have no ability to absorb discounts below list price. *Cf. Invenergy Renewables LLC v. United States*, 422 F. Supp. 3d 1255, 1272–74 (Ct. Int’l Trade 2019) (plaintiff renewable energy company had standing to challenge imposition of customs duties on solar panels, even though duties were paid by third-party importers, because “[b]oth economic logic and detailed testimony” showed that duties would increase the price plaintiff had to pay for solar panels (quotation marks omitted)).

Ultimately, moreover, Amgen does not need to establish with “absolute certainty” how wholesalers will react to a price cap on Enbrel. *Nat. Res. Def. Council v. Nat’l Highway Traffic Safety Admin.*, 894 F.3d

95, 104 (2d Cir. 2018). Standing can be based on third-party conduct that is “reasonably predictable.” *Growth Energy v. EPA*, 5 F.4th 1, 33 (D.C. Cir. 2021) (per curiam) (quoting *Competitive Enter. Inst.*, 970 F.3d at 384); see also *Dep’t of Com.*, 588 U.S. at 768 (upholding standing based on the “predictable effect of Government action on the decisions of third parties”); *New Jersey v. EPA*, 989 F.3d 1038, 1048 (D.C. Cir. 2021) (“[A]n entire line of cases finds” standing based on “third-party conduct that is voluntary but reasonably predictable.” (quoting *Competitive Enter. Inst.*, 970 F.3d at 384)). For example, in *Davis v. FEC*, 554 U.S. 724 (2008), the Supreme Court held that a political candidate had standing to challenge a rule that would have “allow[ed] his opponent to receive [campaign] contributions on more favorable terms” because at the time the candidate filed suit, there “was no indication that his opponent would forgo that opportunity”—even though, in the end, the opponent *did* choose to forgo the opportunity. *Id.* at 734. It was enough for standing that at the time of filing suit, it was reasonably likely that the opponent would act in such a way that the plaintiff would be injured. Here, too, there is no “indication” that wholesalers will be able or willing to absorb all the costs of a price cap, *id.*, and their reaction is at least “reasonably predictable,”

Growth Energy, 5 F.4th at 33 (quoting *Competitive Enter. Inst.*, 970 F.3d at 384).

Further, while Amgen showed that it will bear 100% of the cost of a price cap, Amgen would have standing even if it were likely to bear only 1% of that cost. It is well established that any amount of financial injury is enough for standing. *See, e.g., Carpenters Indus. Council*, 854 F.3d at 5 (“A dollar of economic harm is still an injury-in-fact for standing purposes.”). So Amgen would have standing as long as *one* of its wholesalers is likely to react in a way that imposes *some* financial cost on Amgen. For the reasons Mr. Costello explained, the idea that Amgen will not incur *any* financial injury from an Enbrel price cap applicable to its wholesalers is completely implausible.

3. Colorado recognizes that drug manufacturers will bear the cost of price caps on their drugs.

The text and structure of Colorado’s law, its legislative history, and the Board’s proceedings further confirm that, contrary to the State’s arguments in this case, the State understands perfectly well that setting an upper payment limit on a drug will impose costs on that drug’s manufacturer.

To start, in creating the Board, the Colorado legislature specified that to avoid “conflicts of interest,” a Board member must not be “an employee, board member, or consultant of” a drug “manufacturer or a trade association of manufacturers.” Colo. Rev. Stat. § 10-16-1402(3)(b). This restriction would be unnecessary if manufacturers truly lacked a concrete interest in the Board’s imposition of upper payment limits. The statute says nothing about conflicts arising from a Board member’s affiliation with wholesalers and distributors.

The statute also provides that, in carrying out the Board’s mandate to “protect Colorado consumers from excessive prescription drug costs,” *id.* § 10-16-1403(1), the Board should focus on the list prices charged by manufacturers. The manufacturer’s list price is the *only* factor the Board is allowed to consider to determine which drugs are eligible for affordability reviews, *id.* § 10-16-1406(1), and it is the first listed factor for determining whether a drug is unaffordable, *id.* § 10-16-1406(4). Consistent with this statutory guidance, the Board’s affordability evaluations for Enbrel and other drugs have focused heavily on the price charged by the drug’s manufacturer. *See, e.g.*, Appx588, Appx607, Appx611, Appx614–624 (Enbrel affordability report with “Appendix A”

devoted entirely to Amgen's list price). This emphasis on manufacturers' prices belies the State's position that a UPL is not expected to have any effect on what manufacturers can charge for their drugs.

Further contradicting that position, the statute expressly recognizes that imposing a price cap on a drug may lead the drug's manufacturer to stop selling the drug in Colorado. Whenever the Board establishes an upper payment limit for a drug, it must "[i]nquire of manufacturers of the prescription drug as to whether each such manufacturer is able to make the prescription drug available for sale in the state" notwithstanding the UPL. Colo. Rev. Stat. § 10-16-1407; *see also id.* § 10-16-1408 (addressing situations where "a manufacturer refuses to make the drug available as a result of an upper payment limit established for the prescription drug by the [B]oard"); *id.* § 10-16-1412 (requiring advance written notice from "[a]ny manufacturer that intends to withdraw from sale or distribution within the state a prescription drug for which the [B]oard has established an upper payment limit"). These provisions would make no sense if a UPL were not expected to have any adverse impact on manufacturers. The statute does not have any comparable provisions regarding wholesalers or distributors.

The legislative history of Colorado’s price-control statute confirms that the legislature expected the burden of an upper payment limit to fall on drug manufacturers. A leading sponsor of the legislation explained that manufacturers would 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 district court ignored this statement even though both parties noted it in their briefs (*see* Appx1299–1300, Appx1410–1411), and even though it strongly corroborates Mr. Costello’s identical description of how the market works, *see* Appx1443–1446.

* * *

The district court should have resolved this case on the merits and invalidated Colorado’s law, which is clearly preempted under this Court’s controlling precedent. As a matter of common sense, basic economics, and unrebutted record evidence, Amgen has established Article III standing. Amgen is already incurring costs as a result of the Board’s proceedings, the Board is poised to impose a price cap on sales of Amgen’s patented

drug, and that price cap will undoubtedly cause at least some financial harm to Amgen. Nothing more is required.

CONCLUSION

This Court should reverse and remand for the district court to address the merits of Amgen's claims.

Respectfully submitted,

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June 13, 2025

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), I certify that this brief:

(i) complies with the type-volume limitation of Federal Circuit Rule 32(a) because it contains 11,661 words, including footnotes and excluding the parts of the brief exempted by Federal Circuit Rule 32(b) and Federal Rule of Appellate Procedure 32(f); and

(ii) complies with the typeface and style requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6) because this document has been prepared using Microsoft Office Word and is set in 14-point Century Schoolbook font.

Date: June 13, 2025

/s/ Paul Alessio Mezzina
Paul Alessio Mezzina

*Counsel for Amgen Inc.,
Immunex Corporation, and
Amgen Manufacturing, Limited*

ADDENDUM

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Nina Y. Wang**

Civil Action No. 24-cv-00810-NYW-SBP

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

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.

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Plaintiffs' Motion for Summary Judgment and Memorandum in Support [Doc. 24 ("Plaintiffs' Motion for Summary Judgment")] and Defendants' Combined Cross-Motion for Summary Judgment and Response in Opposition to Plaintiffs' Motion for Summary Judgment [Doc. 29 ("Defendants' Motion for Summary Judgment")] (collectively, the "Motions").

The Court has reviewed the Motions and the related briefing, see [Doc. 35; Doc. 42], the applicable case law, and the entire docket. For the reasons set forth herein,

Appx0001

Defendants' Motion for Summary Judgment is respectfully **GRANTED** as to standing, and Plaintiffs' Complaint is **DISMISSED without prejudice** for lack of subject matter jurisdiction. Plaintiffs' Motion for Summary Judgment is therefore **DENIED as moot**.

BACKGROUND

I. Factual Background

Plaintiffs Amgen, Inc.; Immunex Corporation; and Amgen Manufacturing, Limited (collectively referred to as "Plaintiffs" or "Amgen") are the manufacturer and exclusive patent licensees of a prescription medication designed to treat various autoimmune conditions called ENBREL® (hereinafter, "Enbrel"). [Doc. 24 at 10].¹ Enbrel is covered by several United States patents, including two patents that limit competing biosimilar products from entering the market until 2029 (at the earliest). [*Id.* at 20; Doc. 1 at ¶¶ 52–53].

The prescription drug supply chain. As a manufacturer, Amgen sits at the top of the pharmaceutical supply chain, which "starts with the manufacturer who sells to a wholesaler for the wholesale acquisition cost ('list price')," and "[w]holesalers then sell to the pharmacy, who dispense the product to the patient with a doctor's prescription." *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practs. & Antitrust Litig.*, 44 F.4th 959, 965 (10th Cir. 2022). Nearly all of Amgen's domestic sales are to wholesale distributors for the list price (or "WAC"), and the wholesalers then sell Amgen's products to providers, hospitals, and pharmacies. [Doc. 29 at 13–14 & nn.1–3]; *see also* Amgen, Letter to Shareholders (2023) at 2, 42, 76, <https://investors.amgen.com/static-files/eeb1013b->

¹ When citing to the Parties' briefing, the Court uses the page numbers assigned by the Court's Case Management/Electronic Case File system.

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Health plans or “payers” and pharmacy benefit managers (“PBMs”) also play a key role in the pharmaceutical market. As to health plans, insured patients access prescription drugs through the prescription drug benefits of their health plans. *Pharm. Care Mgmt. Ass’n v. Mulready*, 78 F.4th 1183, 1188 (10th Cir. 2023). The cost of a prescription drug is shared between an insured and their health plan; an insured’s share of the cost is determined by the scope of the prescription drug benefit under their health plan. *In re EpiPen*, 44 F.4th at 965. The health plan controls the scope of the prescription drug benefit, including “what drugs the plan covers (the formulary), how much the plan will pay for those drugs (the cost-sharing terms), and at which pharmacies beneficiaries can have prescriptions filled (the pharmacy network).” *Mulready*, 78 F.4th at 1188.

Health plans often outsource the formulation and oversight of prescription drug benefits to PBMs. *Id.* Before a pharmacy fills a patient’s prescription, the pharmacy checks with the PBM to confirm whether the prescription drug is covered under the patient’s health plan and to ascertain the patient’s payment. *See Rutledge v. Pharm. Care Mgmt. Ass’n*, 592 U.S. 80, 84 (2024). The PBM reimburses the pharmacy on the health plan’s behalf in exchange for reimbursements and fees from the health plan. *Id.* PBMs also negotiate directly with manufacturers for rebates on prescription drugs. *See Mulready*, 78 F.4th at 1188.

Amgen is a member of PhRMA, a “voluntary nonprofit association representing the nation’s leading research-based pharmaceutical and biotechnology companies,” and Amgen’s CEO serves on PhRMA’s Board of Directors. [Doc. 27 at 1; Doc. 29 at 16 n.6]. According to PhRMA, “prices paid by wholesalers, pharmacies, PBMs, and health plan

sponsors all vary and are determined by negotiations between stakeholders, each with varying degrees of negotiating power.” [Doc. 29 at 16 (quoting PhRMA, *Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines* 1 (2017), <https://cdn.aglty.io/phrma/global/resources/import/pdfs/Follow-the-Dollar-Report.pdf> (“Follow the Dollar”))]. As a result of this structure, even though an insured patient’s “cost-sharing amount may exceed the price the health plan actually pays for a medicine or . . . what the patient would pay at the pharmacy counter without using insurance,” pharmacies may be contractually prohibited from informing patients about the lower cost alternative (i.e., paying cash for a prescription at the pharmacy counter). [Doc. 29 at 17 (citing Follow the Dollar at 6)].

In a hearing before Congress, Amgen’s CEO, Robert Bradway, testified that while “[c]ompanies in virtually every other industry compete by offering the lowest price,” the pharmaceutical industry players are “often . . . require[d] [to] match[] a competitor’s *higher* price.” [*Id.* at 16 & n.7 (quoting *Unsustainable Drug Prices: Testimony from the CEOs (Part II): Hearing Before the H. Comm. on Oversight & Reform*, 116th Cong. 5 (2020) (statement of Robert Bradway, CEO, Amgen), <https://tinyurl.com/mtj35txr>)]. “Prescription drug list prices increase so that manufacturers can absorb more and more payer demands for rebates and other discounts.” [*Id.* at 16–17 & n.8 (quoting Smart Brevity Studio x Amgen, *Inside the Drug Pricing Loop*, Axios, <https://www.axios.com/sponsored/amgen/inside-the-drug-pricing-loop> (last visited Mar. 26, 2025))]. Amgen’s CEO also testified that “the primary reason the list price of Enbrel® has increased as much as it has” is due to a pharmaceutical market “structured in a way

to benefit intermediaries”—e.g., wholesalers, PBMs, health plans, and pharmacies—and “not in a way to get lower prices to patients.” [*Id.* at 24 & n.21 (quoting *Testimony of Robert A. Bradway, Chairman and Chief Executive Officer Amgen Inc., Before the U.S. House Committee on Oversight and Reform* 7 (Oct. 1, 2020), <https://tinyurl.com/mufwzev3> (“Bradway Written Statement”))]. Indeed, the pharmaceutical industry is rife with “counterintuitive pricing behavior.” See Bradway Written Statement 8. For example, Amgen often “pay[s] higher and higher rebates to remain on [PBMs’] formulary,” and “increases in list prices . . . significantly increase total rebates paid to the PBMs” but “generally have limited impact on net prices.” *Id.* at 7. As a result, “Amgen has increased list prices over the years in response to competitor list price increases to remain available as a choice on PBM formularies.” *Id.*

Colorado’s Prescription Drug Affordability Review Program. In 2021, the Colorado General Assembly enacted legislation to “protect Colorado consumers from excessive prescription drug costs.” Colo. Rev. Stat. § 10-16-1403(1); *see also* Colo. Rev. Stat. §§ 10-16-1401 to -1416 (the “Act”); 2021 Colo. Sess. Laws 1256. The Act also established a five-member “Prescription Drug Affordability Review Board” (or “the Board”), Colo. Rev. Stat. § 10-16-1402, tasked with (1) “[p]erform[ing] affordability reviews of prescription drugs,” and (2) potentially “establish[ing] upper payment limits for” prescription drugs (like Enbrel) that the Board deems unaffordable for Colorado consumers, *id.* § 10-16-1403(1). The Board implemented procedures for these two statutory directives through both rules and policies. *See* 3 Colo. Code. Regs. §§ 702-9:1.1 to -9:5.1; Prescription Drug Affordability Board (“PDAB”) Policies 01 to 05, <https://tinyurl.com/djct93ch>; *see also* [Doc. 29 at 18]. The Court refers to the Act and the

Board's procedure-implementing rules and policies collectively as the "Affordability Program."

According to the Board, the focus of the affordability review is not to determine "the appropriateness of a manufacturer's price," but "whether *use* of a drug, consistent with standard medical practice or the FDA label, is unaffordable for Colorado consumers." [Doc. 29 at 19 (emphasis added) (citing Colo. Rev. Stat. § 10-16-1406(3))]. The Board further contends that an unaffordability determination "does not impact any rights or obligations of anyone selling or purchasing the [subject] prescription drug," because it is "not a final agency action" and "serve[s] standalone purposes of transparency and accountability." [*Id.* at 20 (citing Colo. Rev. Stat. §§ 10-16-1407(1), -1407(9), -1408(1)(c))].

The Board approved a list of 604 prescription drugs eligible for affordability reviews in June 2023. [Doc. 24 at 20–21; Doc. 29 at 25]. Approximately six weeks later, the Board selected five of those prescription drugs for affordability reviews, one of which was Enbrel. [Doc. 24 at 21; Doc. 29 at 25; Doc. 1-2 at 5]. In February 2024, members of the Board—acting pursuant to the Affordability Program—voted to declare Enbrel unaffordable for Colorado consumers and voted to "select Enbrel for establishment of an upper payment limit" (or "UPL"). [Doc. 24 at 11]; see *also* Colo. Rev. Stat. § 10-16-1407(1)(a) (providing that the Board may establish a UPL if it determines that a drug is "unaffordable for Colorado consumers"). The Act defines UPLs 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). In other words, a UPL sets a

price ceiling applicable to various purchase points along the pharmaceutical supply chain, provided that the drug purchased is dispensed or distributed in Colorado. *See id.*

Amgen’s participation in the affordability review of Enbrel. The Board’s affordability review of Enbrel occurred over a span of six months and included three public Board meetings on December 8, 2023; February 16, 2024; and February 23, 2024. [Doc. 29 at 25 & n.22 (citing publicly available recordings of 2023 and 2024 Board meetings, respectively)]. Amgen participated at each of the foregoing Board meetings; participated in a September 2023 stakeholder meeting facilitated by the Board; voluntarily submitted information to the Board in October 2023; and provided written comments to the Board ahead of both February 2023 Board meetings. [Doc. 29 at 25].

The Board’s affordability review of Enbrel culminated in a 500-plus-page affordability review report, which the Board approved by vote on February 23, 2024. [*Id.* at 26]; PDAB 2023 Affordability Review Summary Report: Enbrel (Feb. 23, 2024). The Board subsequently voted to initiate rulemaking to establish a UPL for Enbrel and set a preliminary timeline for rulemaking hearings in September, October, and December 2024. [Doc. 29 at 26 & n.23]. The timeline was later modified by the Board and based on the record before the Court, the first rulemaking hearing for establishing a UPL for Enbrel is set for April 11, 2025. *See* [Doc. 46; Doc. 47; Doc. 48; Doc. 48-1].

II. Procedural History

On March 22, 2024, Amgen filed this action seeking declaratory and injunctive relief with respect to the constitutionality of the Act. [Doc. 1]. Amgen asserts four claims challenging the validity of the Act: (1) preemption under federal patent law (“Count I”); (2) violation of due process (“Count II”); (3) interference with federal healthcare programs

(“Count III”); and (4) violation of the Commerce Clause (“Count IV”). [*Id.* at 26–36].

In May 2024, the Parties sought and received leave to file consolidated cross-motions for summary judgment without separate statements of undisputed material facts as contemplated by Local Rule 56.1. [Doc. 18; Doc. 20]. The Court held oral argument on the Motions for Summary Judgment on October 22, 2024. See [Doc. 42]. The Motions are ripe for review and the Court addresses the Parties’ arguments below.

LEGAL STANDARD

I. Standing

Federal courts are courts of limited jurisdiction. Under Article III of the United States Constitution, federal courts only have jurisdiction to hear certain “cases” and “controversies.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157 (2014). As such, courts “are duty bound to examine facts and law in every lawsuit before them to ensure that they possess subject matter jurisdiction.” *Wilderness Soc’y v. Kane Cnty.*, 632 F.3d 1162, 1179 n.3 (10th Cir. 2011) (Gorsuch, J., concurring). Indeed, courts have an independent obligation to determine whether subject matter jurisdiction exists, even in the absence of a challenge from any party. *1image Software, Inc. v. Reynolds & Reynolds, Co.*, 459 F.3d 1044, 1048 (10th Cir. 2006) (citing *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 514 (2006)). A court may not simply presume jurisdiction to reach the substantive issues before it. See *Colo. Outfitters Ass’n v. Hickenlooper*, 823 F.3d 537, 543 (10th Cir. 2016). Rather, a federal court must resolve jurisdictional issues before reaching the merits. *United States v. Springer*, 875 F.3d 968, 973 (10th Cir. 2017).

The doctrine of standing serves as “[o]ne of those landmarks” in identifying “the ‘Cases’ and ‘Controversies’ that are of the justiciable sort referred to in Article III.” *Lujan*

v. Defs. of Wildlife, 504 U.S. 555, 560 (1992); see also *Citizen Ctr. v. Gessler*, 770 F.3d 900, 906 (10th Cir. 2014) (standing is jurisdictional). Under Article III, standing requires three elements: injury in fact, causation, and redressability. *Colo. Outfitters*, 823 F.3d at 544. These three elements of standing are “an indispensable part of the plaintiff’s case,” and thus the plaintiff must support each element “with the manner and degree of evidence required at the successive stages of the litigation.” *Lujan*, 504 U.S. at 561 (quotation omitted). At the summary judgment stage, a plaintiff’s standing must be supported by specific evidentiary facts and not by mere allegations. *Id.*

“[T]he proof required to establish standing increases as the suit proceeds.” *Rio Grande Found. v. Oliver*, 57 F.4th 1147, 1162 (10th Cir. 2023) (quotation omitted). “At the pleading stage, general factual allegations of injury resulting from the defendant’s conduct may suffice, while on summary judgment, the plaintiff must set forth by affidavit or other evidence specific facts which for purposes of the summary judgment motion will be taken to be true.” *Id.* (cleaned up).

II. Rule 56 of the Federal Rules of Civil Procedure

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is warranted “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). “A dispute is genuine if there is sufficient evidence so that a rational trier of fact could resolve the issue either way. A fact is material if under the substantive law it is essential to the proper disposition of the claim.” *Crowe v. ADT Sec. Servs., Inc.*, 649 F.3d 1189, 1194 (10th Cir. 2011) (citation and quotations omitted).

“Cross-motions for summary judgment are treated as two individual motions for

summary judgment and held to the same standard.” *Banner Bank v. First Am. Title Ins. Co.*, 916 F.3d 1323, 1326 (10th Cir. 2019); *see also Buell Cabinet Co. v. Sudduth*, 608 F.2d 431, 433 (10th Cir. 1979) (“Cross-motions for summary judgment are to be treated separately; the denial of one does not require the grant of another.”). However, the summary-judgment burden slightly differs depending on which party bears the ultimate burden at trial. A movant that does not bear the ultimate burden of persuasion at trial does not need to disprove the other party’s claim; rather, the movant must only point the Court to a lack of evidence for the other party on an essential element of that party’s claim. *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 671 (10th Cir. 1998). Once this movant has met its initial burden, the burden then shifts to the nonmoving party to “set forth specific facts showing that there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). But “if the moving party has the burden of proof [at trial], a more stringent summary judgment standard applies.” *Pelt v. Utah*, 539 F.3d 1271, 1280 (10th Cir. 2008). A moving party who bears the burden at trial “must establish, as a matter of law, all essential elements of the issue before the nonmoving party can be obligated to bring forward any specific facts alleged to rebut the movant’s case.” *Id.*

When considering the evidence in the record, the Court cannot and does not weigh the evidence or determine the credibility of witnesses. *See Fogarty v. Gallegos*, 523 F.3d 1147, 1165 (10th Cir. 2008). At all times, the Court views each motion in the light most favorable to the nonmoving party. *Banner Bank*, 916 F.3d at 1326.

ANALYSIS

In Defendants’ Motion for Summary Judgment, Defendants argue, *inter alia*, that this Court lacks subject matter jurisdiction because Amgen does not have standing and

the case is not ripe. [Doc. 29 at 28]. The Court begins with Defendants' standing argument, because it may not reach the merits of the action without first assuring itself that it has subject matter jurisdiction over each of the claims. See *Colo. Outfitters*, 823 F.3d at 543.

I. Subject Matter Jurisdiction

A. Applicable Law

A plaintiff's "burden to demonstrate standing for each form of relief sought . . . exists at all times throughout the litigation." *Collins v. Daniels*, 916 F.3d 1302, 1314 (10th Cir. 2019) (quotations omitted). To establish standing, a plaintiff must show it (1) suffered an injury in fact that (2) is fairly traceable to the defendant's conduct and (3) can be redressed by a favorable judicial decision. See *Baker v. USD 229 Blue Valley*, 979 F.3d 866, 871 (10th Cir. 2020). However, because causation and redressability are often "flip sides of the same coin," *Sprint Commc'ns Co. v. APCC Servs., Inc.*, 554 U.S. 269, 288 (2008), "the two key questions in most standing disputes are injury in fact and causation," *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380–81 (2024).

An injury in fact must be "concrete, meaning that it must be real and not abstract," and the injury must be "actual or imminent, not speculative," meaning that it "must have already occurred or be likely to occur soon." *All. for Hippocratic Med.*, 602 U.S. at 381 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013)). Where, as here,² "a

² Amgen seeks, *inter alia*, (1) a declaratory judgment that the Affordability Program is facially unconstitutional; and (2) an injunction against the establishment and enforcement of a UPL for Enbrel. [Doc. 1 at 36–37]. A declaratory judgment and an injunction are both forms of prospective relief. See, e.g., *Collins*, 916 F.3d at 1314 (declaratory relief); *Colo. Cross Disability Coal. v. Abercrombie & Fitch Co.*, 765 F.3d 1205, 1211 (10th Cir. 2014) (injunctive relief).

plaintiff seeks prospective relief,” the plaintiff must establish “a sufficient likelihood of future injury.” *Id.*; see also *Colo. Cross Disability Coal. v. Abercrombie & Fitch Co.*, 765 F.3d 1205, 1211 (10th Cir. 2014) (“When prospective relief . . . is sought, the plaintiff must be suffering a continuing injury or be under a real and immediate threat of being injured in the future.” (quotation omitted)). With respect to causation, a plaintiff must also establish that its injury “likely was caused or likely will be caused by the defendant’s conduct.” *All. for Hippocratic Med.*, 602 U.S. at 382.

Standing is “usually easy to establish” in cases challenging regulations that “require or forbid some action by the plaintiff”—i.e., where the government is directly regulating the plaintiff. *Id.* Conversely, standing is “ordinarily substantially more difficult to establish” where an unregulated plaintiff challenges the government’s “unlawful regulation . . . of someone else.” *Id.* at 382–83 (collecting cases). The Court’s inquiry thus begins with whether Amgen is subject to direct regulation under the Act.

B. Amgen is Not Subject to Direct Regulation.

Defendants contend that Amgen is not subject to direct regulation under the Act because UPLs do not apply at the pharmaceutical manufacturer’s point of sale; instead, UPLs apply only to downstream actors. [Doc. 29 at 28–30]. Amgen argues that the statute contains no such express limitation. [Doc. 35 at 12–13]. The Court finds that both the statutory language and legislative history of the Act support the conclusion that a UPL does not directly apply to a wholesaler’s purchase from a manufacturer at the top of the supply chain. Instead, a UPL applies directly only to downstream transactions for the actual sales and reimbursements of the prescription drug dispensed to Colorado consumers.

The Act defines a UPL 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) (emphasis added). A UPL applies to “all purchases of and payer reimbursements for a prescription drug that is *dispensed or administered in the state*,” *id.* § 10-16-1407(5), including a consumer’s purchase from a pharmacy or provider, reimbursements by certain insurance payers, and pharmacies and providers’ purchases of the prescription drug, see 3 C.C.R. § 702-9:4.2.C.³ Amgen reads this language to include “*any financial transaction*” along the supply chain. [Doc. 35 at 12 (quoting Colo. Rev. Stat. § 10-16-1401(23))]. But the Court respectfully agrees with Defendants insofar as the statute’s use of the definite article “the” in the phrase “*the* prescription drug” demonstrates the General Assembly’s intent to cabin application of UPLs to financial transactions in which “*the*” prescription drug is “*dispensed or distributed in Colorado*.” Colo. Rev. Stat. § 10-16-1401(23); see also *Nielsen v. Preap*, 586 U.S. 392, 408 (2019) (“[G]rammar and usage establish that ‘the’ is ‘a function word . . . indicat[ing] that a following noun or noun equivalent is definite or has been previously specified by context.”).

Moreover, the statute instructs the Board, in establishing a UPL, to consider the costs of “administering,” “dispensing,” and “distributing” the prescription drug, see Colo.

³ The Court is respectfully unpersuaded by Amgen’s argument that the Board’s regulation, C.C.R. § 702-9:4.2.C, is inconsistent with the statutory language, Colo. Rev. Stat. § 10-16-1401(23). See [Doc. 35 at 12–13 (citing *Canyon Fuel Co. v. Sec’y of Labor*, 894 F.3d 1279, 1291 (10th Cir. 2018); *McCool v. Sears*, 186 P.3d 147, 151 (Colo. App. 2008))]. That the regulation provides further clarity to the statutory text does not render the two inconsistent and, for the reasons discussed above, the statute also supports Defendants’ interpretation of the Act.

Rev. Stat. § 10-16-1407(2), i.e., the costs associated with providers, pharmacies, and wholesalers, respectively. In passing the Act, the General Assembly expressly stated its intent for UPLs to apply specifically to the state and municipalities, contractors and vendors, commercial health plans, providers, and pharmacies. See 2021 Colo. Sess. Laws 1256, 1257. The UPLs contemplated by the Act do not apply to a prescription drug manufacturer’s point of sale; instead, UPLs apply to downstream transactions in the pharmaceutical supply chain.

Thus, the Court concludes based on the unambiguous statutory text that Amgen is not subject to direct regulation under the Act.⁴ Accordingly, Amgen cannot challenge the constitutionality of the Act under this theory of standing.

C. Amgen Fails to Establish Standing as an Unregulated Party.

According to Amgen, even if UPLs apply only downstream, “common sense and basic economics” support standing here because a price cap downstream will reduce prices upstream. [Doc. 35 at 13–17]. Thus, the Court next considers whether Amgen, as an unregulated party asserting various challenges to the Affordability Program, has satisfied the standard set forth in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024). For the following reasons, the Court finds that Amgen’s asserted future injury is simply too speculative to be “concrete” and “imminent.” See *id.* at 386–93 (claims of future injury are insufficient where plaintiffs cannot show that the harm is likely to occur).

To establish standing as an unregulated party, “the plaintiff must show a predictable chain of events leading from the government action to the asserted injury—in

⁴ The Court notes that, even if it did find ambiguity in the statutory text, the canon of constitutional avoidance supports the Court’s interpretation of the Act. See *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009).

other words, that the government action has caused or likely will cause injury in fact to the plaintiff.” *Id.* at 385. The Supreme Court has repeatedly emphasized that an Article III injury must be “actual or imminent, not speculative.” *Id.* at 381; see also *Clapper*, 568 U.S. at 409; *Lujan*, 504 U.S. at 560.

“In cases of alleged future injuries to unregulated parties from government regulation, the causation requirement and the imminence element of the injury in fact requirement can overlap” because both causation and imminence “target the same issue: Is it likely that the government’s regulation . . . of someone else will cause a concrete and particularized injury in fact to the unregulated plaintiff?” *All. for Hippocratic Med.*, 602 U.S. at 385 n.2. “Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending.” *Clapper*, 568 U.S. at 409 (quoting *Lujan*, 504 U.S. at 565 n.2).

Here, relying on “basic economics and common sense” and the Declaration of Patrick Costello, an Associate Vice President of United States Value and Access, Amgen argues that it has standing to challenge the Act because “a price cap on Amgen’s drug will result in less revenue for Amgen’s wholesalers and distributors, who will in turn demand lower prices or other compensation from Amgen, reducing Amgen’s profits.” [Doc. 35 at 9, 15–16 (citing [Doc. 35-1 (the “Costello Declaration”))]]. The Court respectfully disagrees with Amgen’s argument for at least two reasons.

First, the Court finds Amgen’s appeal to “basic economics and common sense” unpersuasive. Nothing in the record defines what the amorphous concepts of “basic economics and common sense” entail, or if such “basic economics and common sense”

even apply to the pharmaceutical industry. Amgen's position assumes, without establishing as an undisputed fact, that any UPL established will necessarily fall below the WAC, or what Amgen's customers currently pay. Furthermore, it does not consider the undisputed complexity of the supply chain and the various rebates, reimbursements, chargebacks, and discounts that are exchanged at various levels of the supply chain. To the extent that Amgen suggests that it will necessarily be injured regardless of whether, when, or what UPL may be set due to "basic economics and common sense," this Court respectfully declines to conclude that Amgen has carried its summary judgment burden of establishing injury-in-fact on such speculation. Indeed, Amgen's CEO testified before Congress that the pharmaceutical market is driven by "counterintuitive pricing behavior." [Doc. 29 at 24 & n.21 (quoting Bradway Written Statement at 7–8)].

Second, and more fundamentally, Mr. Costello has not articulated a specific and concrete injury to Amgen under the Affordability Program—particularly in light of the fact that no UPL for Enbrel has been set and it is unclear when and if such a UPL will be set. Instead, Mr. Costello's Declaration is based on two unfulfilled conditions precedent: (1) "*if* an upper payment limit is imposed on wholesalers' sales of Enbrel," *then* "there is no realistic chance that wholesalers will absorb the discount required to comply with the upper payment limit without passing cost on to Amgen," [Doc. 35-1 at ¶ 12 (emphasis added)]; and (2) "*if* Colorado dictates that wholesalers must sell the products for less than WAC," *then* "Amgen cannot reasonably expect wholesalers to purchase products at WAC, without any discount or reimbursement from Amgen," [*id.* at ¶ 13 (emphasis added)]. But, at this juncture, Colorado has not fulfilled either of these prerequisites. Moreover, Mr. Costello's statement that "[t]here is no scenario in which an upper payment

limit for Enbrel would not negatively impact Amgen,” necessarily relies on both foregoing conditions and is conclusory in nature. [*Id.* at ¶ 14].

The Costello Declaration reinforces the speculative nature of Amgen’s theory of standing. Amgen *might* be able to demonstrate harm *if* the Board sets a UPL for Enbrel; *if* that UPL is set lower than the WAC for Enbrel; and *if* wholesalers react by demanding that Amgen absorb any costs associated with the same. Unless and until a UPL is set for Enbrel and at a price lower than WAC, however, Amgen’s alleged future injuries are hypothetical at best. In other words, Amgen’s theory of standing is premised on “the predictable effect” of a *hypothetical* UPL on the decisions of wholesalers.

Notably, Amgen fails to cite any authority for the proposition that an unregulated plaintiff can establish standing based on hypothetical government action. *Compare* [Doc. 35 at 13–17 (collecting cases)], *with Kane Cnty. v. United States*, 928 F.3d 877, 888–89 (10th Cir. 2019) (finding environmental group had standing to challenge government plans to “double the width of [two] roads” in scenic areas because widening the roads in a scenic area “would almost inevitably increase traffic”); *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 5 (D.C. Cir. 2017) (finding standing based on future economic injury where lumber companies challenged an existing “critical habitat designation” that would reduce their timber supply); *Wedges/Ledges of Calif., Inc. v. City of Phoenix*, 24 F.3d 56, 60–61 (9th Cir. 1994) (manufacturer and operator of crane arcade game had standing to challenge city policies where manufacturer demonstrated that city had “succeeded in destroying the market for crane games”); *Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015) (ethanol producers had standing to challenge EPA’s test fuel regulation prohibiting the producers’ product from being used as a test fuel); *Maine Lobstermen’s*

Ass'n v. Nat'l Marine Fisheries Serv., 70 F.4th 582, 592 (D.C. Cir. 2023) (finding lobstermen had standing to challenge already-promulgated rule that would “cost lobstermen \$50 to \$90 million”); *Dep't of Com. v. New York*, 588 U.S. 752, 764–68 (2019) (holding that “respondents have met their burden of showing that third parties will likely react in predictable ways to the citizenship question” that agency sought to reinstate in census where “evidence at trial established that noncitizen households have historically responded to the census at lower rates than other groups, and the . . . discrepancy is likely attributable at least in part to noncitizens’ reluctance to answer a citizenship question”).⁵ Even if the Board may one day establish a below-list-price UPL for Enbrel, the Court is not at liberty to assume or predict one of several possible outcomes to find Article III standing at this time. *Cf. Clapper*, 568 U.S. at 413–14 (declining to “abandon” the Supreme Court’s “usual reluctance to . . . endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment”); *Garcia v. Texas*, 564 U.S. 940, 941 (2011) (“Our task is to rule on what the law is, not what it might eventually be.”).

The economic injuries alleged by Amgen are too speculative and too attenuated to support standing in this case. Because Amgen’s “allegations of possible future injury are not sufficient,” the Court concludes that Amgen has failed to satisfy the requirement that “threatened injury must be certainly impending to constitute injury in fact.” See *Clapper*, 568 U.S. at 409 (cleaned up). And it is clear that the Court cannot presume subject matter jurisdiction in order to reach the merits of this case. *Cf. DaimlerChrysler*

⁵ Two cases cited by Amgen do not address standing whatsoever. See *Caldwell Wholesale Co. v. R J Reynolds Tobacco Co.*, 781 F. App'x 289, 291 (5th Cir. 2019) (per curiam); *Money Mailer, LLC v. Brewer*, 449 P.3d 258, 264 (Wash. 2019).

Corp. v. Cuno, 547 U.S. 332, 348 (2006) (holding that a taxpayer litigant cannot assume a particular disposition of government funds in order to establish standing); *Colo. Outfitters*, 823 F.3d at 543 (“[A] federal court can’t ‘assume’ a plaintiff has demonstrated Article III standing in order to proceed to the merits of the underlying claim, regardless of the claim’s significance.” (citing *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94 (1998) (explaining that “such an approach . . . carries the courts beyond the bounds of authorized judicial action and thus offends fundamental principles of separation of powers”))). Accordingly, Amgen has failed to meet its burden at summary judgment to establish standing, and this Court must dismiss Amgen’s Complaint without prejudice for lack of subject matter jurisdiction.

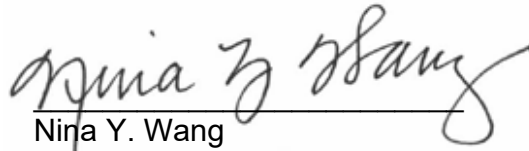
CONCLUSION

For the reasons set forth above, **IT IS ORDERED** that:

- (1) Defendants’ Motion for Summary Judgment [Doc. 29] is **GRANTED**;
- (2) Plaintiffs’ Complaint [Doc. 1] is **DISMISSED without prejudice** for lack of subject matter jurisdiction;
- (3) Plaintiffs’ Motion for Summary Judgment [Doc. 24] is **DENIED as moot**; and
- (4) The Clerk of Court is directed to **TERMINATE** this matter accordingly.

DATED: March 28, 2025

BY THE COURT:


Nina Y. Wang
United States District Judge

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Action No. 24-cv-00810-NYW-SBP

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

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.

FINAL JUDGMENT

In accordance with the orders filed during the pendency of this case, and pursuant to Fed. R. Civ. P. 58(a), the following Final Judgment is hereby entered.

Pursuant to the Order entered by United States District Judge Nina Y. Wang on March 28, 2025 (ECF No. 49), it is

ORDERED that summary judgment is hereby entered in favor of Defendants against Plaintiffs. It is

FURTHER ORDERED that Defendants shall have costs by the filing of a Bill of Costs with the Clerk of this Court within fourteen days of the entry of judgment, pursuant to Fed. R. Civ. P. 54(d)(1) and D.C.COLO.LCivR 54.1. It is

FURTHER ORDERED that this case is terminated.

Dated at Denver, Colorado this 28th day of March, 2025.

FOR THE COURT:
JEFFREY P. COLWELL, CLERK

By: s/C. Pearson, Deputy Clerk