UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

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

BRIEF OF AMICI CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTEREST OF AMICI CURIAE[1]

Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the country's leading innovative biopharmaceutical research companies. PhRMA's members develop innovative medicines that transform lives and create a healthier world. PhRMA advocates in support of public policies to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.[2] PhRMA members produce medicines that are distributed to pharmacies and hospitals throughout the United States.

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, including the biopharmaceutical industry, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly

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[1] No party's counsel authored this brief in whole or in part, and no entity or person, other than *amici*, their members, or their counsel, contributed money intended to fund the preparation or submission of this brief.

[2] PhRMA, *Research and Development Policy Framework*, https://bit.ly/4mcoGn7 (last accessed Nov. 8, 2025).

files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

This case raises questions of critical importance for PhRMA and the Chamber, as the governmental actions being challenged represent a glaring overreach by an unelected state board into private companies' product-pricing decisions that will negatively impact the biopharmaceutical industry and the economy writ large. Specifically, attempts by the Colorado Prescription Drug Affordability Review Board to regulate the prices that manufacturers may charge for their products conflict with priorities set by Congress and violate core constitutional provisions. The legality of these price-control efforts is of vital interest to the members of PhRMA and the Chamber.

INTRODUCTION AND SUMMARY OF ARGUMENT

Companies invest billions of dollars in research and development—often on a single drug—in reliance on a promise: that *if* their R&D efforts result in a safe and effective new product that is approved by regulators, then they will be able to recoup their up-front investments via sales in the marketplace during the period, guaranteed by federal law, when they have the exclusive right to make, use, and sell their patented invention. State statutes like Colorado's SB21-175 threaten to upend this federally protected regime. The state's law authorizes an unaccountable state board to deprive companies of a market-based return on their reliance-based investments—and of their ability to fund ongoing research into new medicines—on the basis of malleable and inconsistent standards and a fundamental misunderstanding of the complex system for pharmaceutical pricing.

While Colorado's law was initially an outlier, it is no longer. Ten states have enacted statutes, like Colorado's, authorizing state boards to review and render judgment on the "affordability" of patented prescription pharmaceuticals. Four of those states, including Colorado, have empowered their boards to impose price controls on the private marketplace, by setting an upper limit on the price that sellers may charge or that payers may reimburse for a particular drug within the state. If allowed to proceed unchecked, such boards will create a patchwork of price controls that will vary by state, creating gross disparities within the national economy. This new wave of price controls is accordingly of growing and critical significance to the biopharmaceutical industry and to U.S. commerce.

PhRMA and the Chamber write to highlight three key points. First, state drug price controls are a growing threat to biopharmaceutical innovation and to pharmaceutical companies across the country, as well as to the larger economy. Second, state drug price controls upset the delicate balance that Congress struck in the federal patent laws between (on one hand) reducing prescription drug costs and (on the other hand) encouraging pharmaceutical innovation and compensating drug patent-holders for the billions of dollars that they spend on research, development, and obtaining approval of each new drug. Third, and as further confirmed by the experience of *amici*'s members, Colorado's price-control scheme has no discernable standard for determining "affordability" and therefore violates the Fourteenth Amendment's Due Process Clause.

The Court should grant Amgen's motion and enjoin the Colorado Prescription Drug Affordability Review Board (Board or PDAB) from enforcing a price cap for Amgen's product Enbrel.

ARGUMENT

I. The Board's Attempts to Deem Innovative Drugs "Unaffordable" and to Set Price Caps on Private Drug Sales Threaten the Entire Biopharmaceutical Industry

The rise of state boards like Colorado's Board—which engage in unfettered and often arbitrary decisionmaking to establish price controls—is of critical concern to the broader community of pharmaceutical innovators and to the national economy. The Board's proceedings demonstrate why: every stage of the Board's decisionmaking has been marked by unexplained choices made without statutory restraints.

Colorado's PDAB statute directs the Board to "[p]erform affordability reviews of prescription drugs" and to "[e]stablish upper payment limits for prescription drugs." C.R.S. § 10-16-1403(1)(b)-(c). The Board identifies the list of drugs eligible for affordability reviews based on certain pricing criteria relating to a drug's list price (also known as the Wholesale Acquisition Cost, or WAC), rather than its actual price to consumers. § 10-16-1406(1); *see infra*, p. 21-22 (explaining how those measures differ). Based on those criteria, the Board initially identified over six hundred prescription drugs as eligible for an affordability review.[3] The overwhelming majority of the drugs considered eligible for affordability reviews are protected by federal patents.[4] That is unsurprising: Legislative history makes clear that Colorado's law *intentionally* targets patented products, rather than generics or biosimilars.[5]

At a public meeting on March 31, 2023, the Board identified factors to "prioritize" in selecting among those hundreds of drugs for an affordability review.[6] The Board assigned "weights" to each factor, arbitrarily designating how much each

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[3] Prescription Drug Affordability Review Board ("PDAB"), 2023 Activities Summary Report 6 (July 1, 2024), https://perma.cc/H6TD-TF5S.

[4] PDAB, 2023 Colorado PDAB Eligible Prescription Drug List (Revised June 6, 2023), https://drive.google.com/file/d/1yPe9pbcBE-tQwr2ZuqPv7QxhDRr8iAFS/view.

[5] *See, e.g.*, *Hearing of Colo. S. Comm. Health & Human Services*, Mar. 17, 2021, at 6:14:48-15:06 (statement of Sen. Smallwood) ("We're more targeting brand-name specialty meds than we are the generic drugs … The target of this bill as I understand it are more the brand-name drugs."), https://sg001-harmony.sliq.net/00327/Harmony/en/PowerBrowser/PowerBrowserV2/ 20210317/-1/11018#info.

[6] *See* PDAB, Co. PDAB 2023 Eligible Drug Dashboard, Colorado Div. of Ins. (2023), https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/1_EligibleListSummary.

factor would affect a single drug's ranking in a prioritized list.[7] With no guidance from regulations or statutes, the Board decided that it would prioritize drugs by these metrics:

- "Patient Count," the number of patients who filed at least one claim for the drug during the measurement year (assigned a weight of 25.888%);
- "5 Year Change in WAC," capturing any increases in the drug manufacturer's list price (assigned a weight of 22.961%);
- "Patient Out of Pocket Cost," the average payment a patient makes at the pharmacy (assigned a weight of 19.541%);
- "Total Paid Amount," the total amount paid by payers as reflected in the state's All Claims Payers Database (assigned a weight of 16.284%); and
- "Average Paid Per Person Per Year," the sum of the Total Paid Amount during a given year divided by the Patient Count (assigned a weight of 15.326%).[8]

The "weights" assigned to each factor have no basis in statute or regulation. Nor do they have any apparent connection to a drug's actual affordability for patients—as reflected in the Board's decision to give more weight to the "5-year change in WAC" category than the "average paid per person per year" category. Moreover, because the Board failed to standardize the weights of the five categories,

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[7] PDAB, March 31 Prioritization Exercise Group Results (Mar. 31, 2023), https://drive.google.com/file/d/1wKWEl6X5QFWfXuhKyl3TsyGaLcu6cRlv/view.

[8] PDAB, FAQs: Colorado PDAB 2023 Eligible Drug Dashboard, https://tinyurl.com/4ck74cdm.

the "Total Paid Amount," which includes the largest numbers by far, was the *only* factor that actually mattered in ranking the prioritized list.[9] And because this "Total Paid Amount" *also* depended directly on the number of patients taking the drug, prioritization largely tracked the "Patient Count" rather than the "Average Paid Per Person Per Year."

That "prioritization" effort produced 50 priority-eligible drugs.[10] The prioritized list (which was nothing but the 50 drugs with the highest "Total Amount Paid") was referred to Colorado's Prescription Drug Affordability Advisory Council, which recommended narrowing the list—again, without any ascertainable statutory or regulatory standards upon which to rely—down to 23 prescription drugs.[11]

From there, the statute gives the Board unfettered discretion to select drugs for an affordability review. In doing so, the statute tells the Board to consider, for example, "input from the advisory council" and "aggregated data" of an unspecified nature. C.R.S. § 10-16-1406(2)(b)-(c). But nothing tells the Board what to make of those considerations—for instance, what *kind* of aggregated data are relevant.

Ultimately, the Board selected five drugs, developed and manufactured by five different manufacturers, for affordability reviews: Enbrel (the subject of this lawsuit),

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[9] *Id.*

[10] PDAB, Prescription Drug Affordability Board DRAFT Meeting Minutes (Aug. 4, 2023), https://drive.google.com/file/d/1LQGtrPi0RsDybD8CQbfinofdV20k0Drr/view.

[11] PDAB, Prescription Drug Affordability Board Meeting at 1:16:05 (Aug. 4, 2023), https://tinyurl.com/PDABMeeting.

Genvoya, Cosentyx, Stelara, and Trikafta.[12] The Board did not select these five medicines based on any particular determination that they were more likely to be "unaffordable" than any of the other "priority" drugs—nor, for that matter, than any of the hundreds of other drugs eligible for affordability reviews. Instead, the Board simply sorted by "patient count"; zeroed in on patent-protected drugs by expressly *removing* drugs with generic or therapeutic equivalents; and determined that the most popular drugs would be targeted first.[13] Worse still, officials gave attention to manufacturers' federally protected patent rights *only* insofar as "such intellectual property rights can be associated with *increased* drug prices."[14] The Board has since concluded that Trikafta and Genvoya are not "unaffordable," but that Enbrel, Cosentyx, and Stelara are.

Following its unaffordability determination, the Board proceeded to impose a price control, known as an Upper Payment Limit (UPL), on sales of Enbrel. The statute itself provides no methodology for the Board to set a price cap, instead permitting any pricing that "include[s] consideration" of four factors: the cost of

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[12] *Affordability Review Component Methodologies*, PDAB—Board Staff Memo (Sept. 15, 2023); Colo. Dep't Regul, Agencies, *Prescription Drugs Selected for Affordability Review* (Aug. 10, 2023), https://content.govdelivery.com/accounts/CODORA/bulletins/36a1f5c.

[13] PDAB, Prescription Drug Affordability Board Meeting at 2:09:21-2:10:48 (Aug. 4, 2023), https://tinyurl.com/PDABMeeting; PDAB, Prescription Drug Affordability Board DRAFT Meeting Minutes (Aug. 4, 2023), https://drive.google.com/file/d/1LQGtrPi0RsDybD8CQbfinofdV20k0Drr/view.

[14] PDAB, 2023 Affordability Review Summary Report: Enbrel C-11 (Feb 23, 2024) (emphasis added), https://perma.cc/72A5-N8KQ.

administering the drug, the cost of distributing the drug, whether there is a shortage of the drug, and the catch-all of "[o]ther relevant costs related to the prescription drug." C.R.S. § 10-16-1407(2).

The Board conducted its rulemaking over the course of four meetings. In its first meeting on May 23, 2025, the Board did not reveal its methodology. *See* Ex. G to Compl., ECF No. 1-7. Instead, it reviewed pricing data and quickly began focusing on the Maximum Fair Price (MFP) of Enbrel under the federal Inflation Reduction Act (IRA), a recently enacted federal statute under which manufacturers must "negotiate"[15] with the federal Centers for Medicare and Medicaid Services (CMS) for drug sales covered by Medicare. *See id.* at 28. Medicare pricing, of course, reflects a markedly different context—drug sales under a specific federal government benefits program, rather than private sales in the commercial market.[16]

During its second rulemaking session on July 11, 2025, the Board mainly heard witness testimony about whether to adopt a price cap, rather than about the

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[15] Although the process for establishing an MFP is characterized as a "negotiation," it is not a "negotiation" in any traditional sense of the word, calling into question its propriety as a benchmark. The IRA gives CMS the unilateral, nearly unconstrained authority to both set any price it wishes (below a statutory ceiling) and impose severe penalties—including withdrawal from Medicare and Medicaid—on manufacturers who do not agree to the CMS-set price (or even engage in the process), with little-to-no transparency into how CMS reached this price in the first place.

[16] The relevant provisions of the IRA are subject to several pending constitutional challenges, including an action brought by PhRMA and other plaintiffs. *See Nat'l Infusion Ctr. Ass'n v. Kennedy*, No. 25-50661 (5th Cir.); *cf. Dayton Area Chamber of Commerce v. Becerra*, 147 F.4th 626 (6th Cir. 2025) (without reaching merits, upholding dismissal for lack of venue of challenge to IRA provisions brought by Chamber and other chambers of commerce). The legality of the IRA provisions is not at issue in this case.

methodology for setting that cap. Ex. H to Compl. at 11-27, ECF No. 1-8. At the start of the third meeting, on August 22, Board members focused on the federal MFP once again. *See* Ex. I to Compl. at 7, ECF No. 1-9 (noting that the federal government is "setting a benchmark or a marker almost for" the Board). The Board then calculated the per-unit price of Enbrel based on MFP—$583.59—and inputted that price into its draft rule. *See id.* at 18-19.

The Board finally arrived at its UPL during the fourth rulemaking meeting on October 3, 2025. *See* Ex. J to Compl., ECF No. 1-10. Asserting that it would be "not legal" for the Board to set its UPL based directly on the federal MFP, the Chair recommended that the Board "just round up to $600." *Id.* at 11 (expressing a personal "need for round numbers"); *see id.* at 14 (viewing this methodology as "basing this on the MFP without … tying [the price] directly"). After hearing from various witnesses, the Board voted to adopt the $600 UPL for Enbrel. *See id.* at 27.

In short, the Board's efforts—though hugely consequential for the manufacturer of the selected drug and for the entire pharmaceutical ecosystem, including patients and the healthcare market as a whole—were fundamentally arbitrary. Each manufacturer is now subject to the risk that the Board will deem its product a "priority" based on arbitrarily set and meaningless "weights"; will declare its drug "unaffordable" based on unclear and arbitrary standards; and will deny the manufacturer the ability to set its own prices, while continuing to allow its competitors to set their own prices—even competing manufacturers with drugs treating the same diseases whose drugs (by some measures) could be considered less

affordable than the price-controlled products. The result is an ecosystem in which the basic terms of competition are set by state administrators, rather than by federal law and the marketplace.

As noted above, Colorado's statute is part of a troubling trend: At least ten states since 2019 have enacted affordability review statutes.[17] Three of them (Maryland, Minnesota, and Washington) have empowered their drug pricing boards to set price controls, like Colorado's UPL, for commercial market sales.[18] Other states are considering similar legislation that would empower their boards to implement price controls.[19] The impending distortion in the nationwide market for prescription drugs is accordingly substantial.

The problem would be serious enough if all of these state boards adopted the same price caps. But the factors they consider in assessing "affordability" vary greatly.[20] Each board is also empowered to set its own review criteria, with only

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[17] *See* Nat'l Alliance of State Pharmacy Ass'ns, Prescription Drug Affordability Boards: Potential Risks to Pharmacy Reimbursement (Nov. 13, 2025), https://naspa.us/resource/pdab/.

[18] *See* C.R.S. § 10-16-1407; Md. Code, Health-Gen. § 21-2C-13; Minn. Stat. § 62J.92; Wash. Rev. Code § 70.405.050; *see also* Karen Blum, *PBMs, Cost Sharing Eyed by State Legislatures* Specialty Pharmacy Continuum (May 29, 2024), https://www.specialtypharmacycontinuum.com/Policy. /Article/06-24/PBMs-and-State-Legislation-Trends/73830.

[19] Nat'l Acad. For State Health Pol., 2024 State Legislation to Lower Prescription Drug Costs (June 21, 2024), https://nashp.org/state-tracker/2024-state-legislation-to-lower-pharmaceutical-costs/.

[20] *See* Julie A. Patterson, et al., *Unanswered Questions And Unintended Consequences Of State Prescription Drug Affordability Boards*, Health Affairs (June 5, 2024), https://www.healthaffairs.org/content/forefront/unanswered-questions-and-unintended-consequences-state-prescription-drug-affordability.

limited statutory guidance.[21] Given the wide array of criteria (and inconsistent and poorly defined weighting of those criteria), different review boards are destined to reach different conclusions in assessing the "affordability" of the same drug—and consequently the prices set for the same drug could easily vary greatly by state. As discussed in more detail below, this patchwork of "affordability" findings and resulting price controls will obstruct the biopharmaceutical market, curtail innovation, and hinder patient access to new and innovative therapies—including based on where the patient purchases the drug.

This Court will likely be the first to decide the legality of price controls imposed by a state affordability review board. Whether these boards are permitted to continue unchecked will shape how innovative biopharmaceutical companies allocate scarce resources as they develop the next generation of treatments and cures. This Court should enjoin Colorado's law.

II. Colorado's Statute Impermissibly Disrupts the Delicate Balance Set by Federal Patent Law

Prescription drug development is a complicated, lengthy, and expensive endeavor. Recognizing the need to incentivize innovation, Congress in 1984 passed the Drug Price Competition and Patent Term Restoration Act. The law, commonly known as the Hatch-Waxman Act, extended the period of patent exclusivity for drugs,

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[21] *See* C.R.S. § 10-16-1406(4)(j) ("Any other factors as determined by rules promulgated by the board"); Md. Code, Health-Gen. § 21-2C-13(b)(3) ("Other relevant administrative costs related to the prescription drug product."); Wash. Rev. Code § 70.405.040(6)(f) ("Any additional factors identified by the board"); Minn. Stat. § 62J.91.2(8) ("any other factors as determined by the board").

while also speeding entry of generic competitors upon expiration of the patent. In 2009, Congress enacted the Biosimilar Price Competition and Innovation Act (BPCIA), which establishes a similar regime for biologics.

In the years since enactment of these laws, the federal patent regime has worked as intended. Because of the federally set exclusivity period—which enables innovators to charge market-based prices for products within the scope of their patents—investments in biopharmaceutical research have flourished. Last year alone, the industry spent more than $100 billion on research and development, as noted above.

Congress thus struck a careful balance in the Hatch-Waxman Act, the BPCIA, and other federal patent laws between encouraging innovation and reducing the price of prescription drugs. Colorado's price-control scheme fundamentally upsets that balance. The State's law accordingly conflicts with federally protected patent rights and is preempted by federal patent law.

A. Recognizing the immense costs of pharmaceutical innovation, Congress granted manufacturers the exclusive right to set drug prices during the patent term

Article I of the Constitution vests Congress with the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Patent laws encourage innovation by granting an inventor the exclusive right to make, use, and sell its patented invention for a limited period of time. 35 U.S.C. § 154(d)(1)(A). That right is valuable because the patent holder, as

the only one who can offer the product or process, can "charge prices of its choosing, including supracompetitive prices." *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 400-01 (3d Cir. 2015); *see Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964) ("The grant of a patent is the grant of a statutory monopoly."). The ability to gain market-based revenue during the period of patent exclusivity is the incentive that the patent laws offer "to inventors to risk the often enormous costs in terms of time, research, and development." *Kewanee Oil Co. v. Bicron Corp.,* 416 U.S. 470, 480 (1974).

In exchange for these rights during the exclusivity period, "patent laws impose upon the inventor a requirement of disclosure." *Id.* The inventor must fully and clearly describe the invention and "the manner and process of making and using it" so that any person skilled in that art could replicate it. 35 U.S.C. § 112(a). Once the patent expires, others may enter the market and compete with the patent-holder, driving down the price of the product to competitive levels. *Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1373 (Fed. Cir. 2007).

The federal patent scheme thus "embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). As the Federal Circuit recognized in *BIO*, in striking down a District of Columbia price-control statute, "Congress, as the promulgator of patent policy, is charged with balancing these disparate goals. The present patent system reflects the

result of Congress's deliberations." 496 F.3d at 1373. "Congress has decided that the patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use." *Id.*

Nowhere is that balance more important—and more carefully calibrated—than in the context of prescription medications. It takes billions of dollars, and many years of effort, to develop a single drug or therapeutic treatment. On average, a manufacturer will spend nearly $3 billion developing a single new medicine.[22] And research and development costs do not end with approval by the U.S. Food and Drug Administration (FDA); pharmaceutical manufacturers often undertake significant post-approval research as well, to help further ensure safety and efficacy and to refine drugs and their delivery systems to meet patient needs.[23]

Manufacturers developing new drugs also face incredibly long odds. Only one compound in 5,000 that enters preclinical testing will achieve FDA approval, a failure rate of 99.98%.[24] Among the small share of investigational medicines that get as far

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[22] *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25-26 (2016), https://bit.ly/30UAIdg.

[23] *Id.* at 26.

[24] Sandra Kraljevic et. al., Accelerating Drug Discovery, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://bit.ly/2Y2gwEK; *see also* Aroon D. Hingorani et al., *Improving the Odds of Drug Development Success Through Human Genomics: Modelling Study*, 9 Sci. Repo. Nature Rsch., No. 18911 2 (2019), https://www.nature.com/articles/s41598-019-54849-w (discussing failure rate of over 96%).

as entering clinical trials, moreover, only 12% ever achieve approval by the FDA.[25] And of those approved, only one in five will ever generate revenues that exceed the average cost of developing a medicine.[26] In short, patent protection—and the right to set a market-based price for drugs—is particularly necessary to incentivize manufacturers to attempt the extraordinarily difficult, costly, and rare steps necessary to develop a new drug that gains FDA approval.

Appreciating these challenges, Congress enacted the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Act reflects Congress's recognition that the perils of the drug-development and FDA-approval process necessitated a longer-than-normal patent term. H.R. Rep. No. 98-857(I), at 15-17 (1984). The Hatch-Waxman Act also stemmed from concerns that pharmaceutical manufacturers were not receiving the same protection as other inventors because the patent term for drugs first accrued and continued to run during the extensive FDA approval process. To compensate for the unique regulatory process for pharmaceutical research and development, the Act "extend[ed] the amount of time for which [pharmaceutical] patents are issued to include some or all of the time required for a manufacturer to test a product for safety and efficacy and to receive marketing approval." *Id.* at 19-20. The patent term was thus extended to "create a significant, new incentive which

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[25] DiMasi et al., *supra* note 22, at 23.

[26] John A. Vernon et al, *Drug Development Costs When Financial Risk is Measured Using the FAMA-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010) https://onlinelibrary.wiley.com/doi/10.1002/hec.1538.

would result in increased expenditures for research and development, and ultimately in more innovative drugs." *Id.* at 18.

The Hatch-Waxman Act also took account of the need for consumer access to affordable medication, by speeding and simplifying the process for approval and sale of generic versions of an innovator's drug *after* the period of patent exclusivity expires. Manufacturers hoping to introduce a generic version of a drug can rely on the branded drug's safety and efficacy studies to lower costs and reduce delay.[27]

What Hatch-Waxman did for ordinary patented and generic drugs, the BPCIA did for biologics, like Amgen's Enbrel, and biosimilars. Biologics, or biological products, comprise a wide range of therapeutic products developed from "natural sources—human, animal, or microorganism—and may be produced by biotechnology methods."[28] A "biosimilar" is a version of a biologic that is "similar" to the reference product.[29]

In the BPCIA, as in Hatch-Waxman, Congress recognized that the extended patent term it had afforded new biologic medicines would enable manufacturers to set their own prices and would delay the entry of competing biosimilars. Rather than curtailing manufacturers' rights during the patent term, however, Congress balanced

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[27] *See* 21 U.S.C. § 335(j); Robin Feldman & Gideon Schor, *Purple Is the New Orange: A Comparison of Competitive Information (?) in Generics and Biologics*, 2024 U. Ill. L. Rev. 1075, 1100-01 (2024).

[28] U.S. Food & Drug Admin., *What are "Biologics" Questions and Answers* (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

[29] *See* 42 U.S.C. § 262(i)(2).

this concern by creating an expedited pathway for approval of biosimilars after the patent term expires.[30] This carefully crafted framework thus provides substantial incentives for innovators to invest in research and development of new lifesaving and life-enhancing treatments that will benefit patients, while also "'get[ting] generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Lab., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

B. Hatch-Waxman has fostered decades of biopharmaceutical investment and progress

The Hatch-Waxman Act and the BPCIA have worked as intended. Their incentives encouraged innovators to boost research and development spending, while also promoting massive growth in generic competition when periods of patent exclusivity expire. Before Hatch-Waxman was enacted, manufacturers were investing less than $10 billion per year in research and development.[31] In the past decade, PhRMA members have invested approximately $850 billion in the search for new treatments and cures, reaching about $100 billion per year from 2021-2024.[32] This investment accounts for 78.6% of *all* U.S. industry investment in this field. And

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[30] *See* Krista Hessler Carver, et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L. J. 671, 807-08 (2010).

[31] Cong. Budget Off., Research and Development in the Pharmaceutical Industry, (Apr. 2021), https://www.cbo.gov/publication/57126#_idTextAnchor003.

[32] PhRMA, 2025 PhRMA Annual Membership Survey Table 1, https://phrma.org/resources/2025-phrma-annual-membership-survey.

the industry employs 193,000 research and development employees—more than any other U.S. industry.[33]

These innovation efforts have been fruitful. More than 700 new prescription medicines have been approved for use by the FDA in the last twenty years.[34] This includes significant progress in the development of therapies for rare diseases.[35] There are currently more than 700 orphan drugs in development, many by PhRMA members, for treatments for patient populations with rare cancers and genetic disorders.[36]

C. State price controls upset the delicate balance created by federal patent law

State drug price controls, like those authorized by Colorado's PDAB statute, conflict with the federal patent regime established by Congress. Colorado has determined that the balance struck by Congress between innovation and access is wrong: According to the State, pharmaceutical manufacturers should *not* be entitled to set their own prices during the statutory patent term, and the immediate goal of

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[33] TEConomy Partners, LLC & PhRMA, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates* 4 (Mar. 2024), https://phrma.org/resource-center/topics/economic-impact/industry-economic-impact.

[34] Analysis Group, Inc., *Innovation in the Biopharmaceutical Pipeline* 1 (Dec. 2021), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Innovation_in_Biopharmaceuticals.pdf.

[35] PhRMA, *2012-2021: A Decade of Innovation in Rare Diseases* 3 (2022), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_RD_Report_R9_Final_Updated-2-28-22.pdf.

[36] *Id.*

lowering prices should take priority over the longer-term goal of incentivizing research and development of new drugs. This sort of second-guessing by States of Congress's balancing of priorities is exactly what the Supremacy Clause forbids. The Colorado price control regime is a "clear attempt to restrain" manufacturers' pricing decisions, thus "diminishing the reward to patentees in order to provide greater benefit to [some] consumers." *BIO*, 496 F.3d at 1374.[37] The result is "contrary to the goals established by Congress in the patent laws." *Id.*

The United States leads the world in research and development for lifesaving treatments and cures precisely because its healthcare system relies on the strengths of market competition to balance cost-control, patient access, and continued innovation. More than half of all new drugs are launched first in the United States, with an average lag time of an entire year before being launched in other major industrial nations.[38] State drug-pricing regimes like Colorado's pose a threat to America's leadership in making new drugs available to patients.

The Colorado regime, and others like it, will have a profound impact on innovation by signaling to manufacturers and investors that high-value drugs will face a lower return on investment. Innovation decisions by a manufacturer depend

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[37] The PDAB's activities demonstrate how the Colorado regime targets patented products. The Board selected five drugs for unaffordability review based entirely on (1) patient count and (2) whether the drug has a therapeutic equivalent. Patented drugs, by their nature, are unlikely to have equivalents. *See* PDAB, Prescription Drug Affordability Board Meeting at 2:09:21-2:10:48 (Aug. 4, 2023), https://tinyurl.com/PDABMeeting.

[38] *New Prescription Drugs Typically Sold First in U.S., Reach Other Wealthy Nations Within a Year* RAND (Feb. 1, 2024), https://bit.ly/4ckxJgH.

on the ability to earn market-based revenues following the massive investments and risk-taking required to develop new drugs.[39] Such revenues are, of course, contingent on pricing.[40] Price controls like Colorado's UPL accordingly create less-favorable conditions for investment, causing investors and researchers to scale back their efforts.[41] Investments in early-stage assets and biotechnology companies, which reflect an increasing share of the biopharmaceutical development pipeline, will be particularly affected.[42]

Colorado's decision to impose price controls in contravention of the federal patent laws will ultimately harm the patients who rely on pharmaceutical innovation. Price controls will also distort the *kinds* of drugs that are developed going forward; certain therapeutic areas are riskier to invest in, and thus disproportionately affected by reductions in potential revenue. For example, investment in treatments targeting sensory organs, the nervous system, and antineoplastic and immunomodulating agents may be particularly sensitive to the size of the expected market for the treatment.[43] Treatments for conditions such as cancer and Alzheimer's disease,

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[39] Margaret E. Blume-Kohout et al., *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. Pub. Econ. 327, 327 (2013).

[40] *Id.*

[41] Bagley, Nicholas, et al., *It's time to reform the Orphan Drug Act,* NEJM Catalyst 4.6 (Dec. 19, 2018).

[42] *See* IQVIA Inst. for Human Data Sci. *The Changing Landscape of Research and Development: Innovation, Drivers of Change, and Evolution of Clinical Trial Productivity* 15, 19 (2019), https://bit.ly/3VLvQ5o.

[43] Pierre Dubois, et al., *Market Size and Pharmaceutical Innovation*, 46 RAND J. Econ. 844, 862 (2015).

therefore, may be among the most likely to be adversely affected by state price controls.[44]

Colorado may have a different view than Congress about the right tradeoff between innovation and access. The State may even dispute that market-based rewards during the period of patent exclusivity are necessary, or that price caps will hinder innovation. But for preemption purposes, it suffices that *Congress* has embraced this tradeoff, "decid[ing] that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use." *BIO*, 496 F.3d at 1373. Given that federal choice, States like Colorado may not "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1374.

III. The PDAB Statute and Review Procedures Violate Due Process

When a state price control is implemented by an administrative board, due process requires the board, at minimum, to be held to "ascertainable standards." *Smith v. Goguen*, 415 U.S. 566, 578 (1974). These "procedural safeguards … furnish protection against an arbitrary use of … delegated authority." *United States v. Rock Royal Co-Op., Inc.*, 307 U.S. 533, 576 (1939). The legislature, therefore, must "enjoin upon [administrative agencies] a certain course of procedure and certain rules of decision in the performance of [their] functions." *Wichita R. & Light Co. v. Pub. Utils.*

[44] *See id.*

Comm'n of Kansas, 260 U.S. 48, 59 (1922). Without these constitutionally minimum safeguards, there is no guarantee that an agency is not acting arbitrarily or improperly targeting manufacturers for impermissible reasons—nor any way to ascertain whether the agency is even implementing the policy the legislature enacted.

In the price-setting context, given the critical nature of the interests at issue, the need for due process protections is particularly great to allow for meaningful judicial review and to ensure public accountability. Due process requires affording industry participants the ability to charge prices that are at least "just and reasonable." *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587, 593 (6th Cir. 2001) (citing *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 770 (1968)); *see Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936); *Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990) (invalidating Nevada law freezing insurance rates because it provided no "mechanism to guarantee a constitutionally required fair and reasonable return"). As Amgen explains, *see* ECF No. 18 at 30-35, the PDAB's affordability reviews are essentially standardless and open ended. The experience of *amici*'s members in the Colorado PDAB process confirms as much.

As an initial matter, prescription drug pricing—and determining the actual cost of a drug—is exceedingly complex. The amount that a consumer pays at the pharmacy counter is not a direct result of the drug's list price. Instead, an insured consumer's out-of-pocket costs are set by the consumer's health insurance plan. And these costs are often dependent on negotiations with pharmacy benefit managers (PBMs), which act as intermediaries between drug manufacturers and insurance

plans. Moreover, a drug's out-of-pocket cost may include copayments, coinsurance, and deductibles required of the patient by the patient's insurer. Certain manufacturers also offer patient-assistance programs that make drugs available at reduced cost or for free to patients who demonstrate financial need and lack adequate insurance coverage. Manufacturers may also offer cost-sharing assistance programs to patients with commercial health insurance to help defray the patient's out-of-pocket costs for the manufacturer's medicines so that patients can access the medicine they need. On top of all this, the federal and state governments offer assistance programs for certain drugs, providing them at no cost to some patients. *See e.g.*, Part B: AIDS Drug Assistance Program (ADAP), Health Resources & Servs. Admin (granting states funds for distributing HIV/AIDS medications), https://tinyurl.com/4e6934na. For all these reasons, the list price of a medicine does *not* determine whether it is "unaffordable" for a patient.

Colorado's PDAB statute offers no ascertainable standards for determining a drug's affordability. As Amgen explains, *see* ECF No. 18 at 30-35, while the Board's ostensible goal in an affordability review is to determine whether certain drugs are "unaffordable for Colorado consumers," C.R.S. § 10-16-1401(3), no statute or regulation defines what that means. Instead, the PDAB statute merely requires the Board to consider a set list of factors but does not tell the Board how to value those factors; it then permits the Board to consider "any other factors" the Board establishes by regulation. C.R.S. § 10-16-1406(4)(j); 3 Colo. Code Regs. § 702-9:3.1(E).

The listed factors, both statutory and regulatory, provide no further guidance to a regulated entity. For example, the Board must consider objective factors like a drug's list price, but *also* subjective "[p]erspectives on benefits and disadvantages of the prescription drug" from doctors and scientists, 3 Colo. Code Regs. § 702-9:3.1(E)(2)(h)(ii)(3), without explaining how those considerations might impact the drug's affordability. The statute further requires the Board to consider a drug's "therapeutic alternatives," again without providing any discernable standard for how those "alternatives" are identified or how prices will be compared between them. And these are but a few of the undefined and unascertainable "standards" that the PDAB considers in an affordability review.

The PDAB's published affordability reviews reflect this standardless approach. To date, the Board has considered five drugs. Each review produced a report which is hundreds of pages long, containing hundreds of charts and tables and discussions of various statistics about patient-assistance programs, drug utilization, changes in list price, surveys of individual patients using the medication, and countless other topics. The Board then takes a vote to decide whether a drug is unaffordable, but there is nothing to guide any member's discretion, and the results reflect as much: Determinations as to affordability (or not) may reflect nothing more than the gut reaction of each member, informed by a variety of ill-defined factors that may point

in various directions. Thus, for example, a drug for which eligible patients pay only $5 per dose was still somehow found to be unaffordable.[45]

This legally unbounded process continues when the Board sets a UPL. Colorado's statute prescribes no methodology or constraints whatsoever for that decision, empowering the Board to establish a methodology "by rule" based on underdetermined factors such as any "relevant costs related to the prescription drug." C.R.S. Ann. § 10-16-1407(2)(d). And the Board has declined even to adopt a methodology here, simply tying the State's UPL to prices imposed by the federal government as part of the Medicare program. Lacking any clear direction, the Board then expressed a preference for "round numbers" and "just round[ed] up to $600." Ex. J at Compl. at 11, ECF No. 1-10. Such an arbitrary scheme fails to "adequately safeguard[] against confiscatory rates, and therefore, ensure[] a constitutional rate of return." *Mich. Bell*, 257 F.3d at 592-93. It accordingly violates the due process rights of manufacturers subject to it.

CONCLUSION

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

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[45] DRAFT Affordability Review Summary Report: Stelara, Ex. B (May 24, 2024), https://drive.google.com/file/d/1bS7B3WZc0SyCLDFXCh7Pr1RjbPbslzVr/view.

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CERTIFICATE OF SERVICE

I hereby certify that on this November 26, 2025, I electronically filed the foregoing Amicus Brief with the Clerk of the Court using the CM/ECF system which will send notification of such filing to attorneys of record.

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