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. 1:24-cv-00810-NYW

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 SUMMARY JUDGMENT

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INTEREST OF AMICI CURIAE[1]

The Pharmaceutical Research and Manufacturers of America (hereinafter "PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies are dedicated to developing medicines that enable patients to lead longer, healthier, and more productive lives. Every day, PhRMA members work to produce cutting-edge medicines, medical treatments, and vaccines that save, extend, and improve the lives of countless Americans. In 2022 alone, PhRMA member companies invested nearly $101 billion in the search for new treatments and cures. *See* PhRMA, *Research and Development Policy Framework*, https://phrma.org/policy-issues/Research-and-Development-Policy-Framework. PhRMA also advocates in support of public policies that are focused on improving patient access to life-changing, and often lifesaving, medicines.

The Chamber of Commerce of the United States of America (hereinafter "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

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[1] Counsel for PhRMA and the Chamber have consulted with counsel for all parties. No party objects to PhRMA and the Chamber filing this brief as *amici curiae*. 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.

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

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

INTRODUCTION AND SUMMARY OF ARGUMENT

Since 2019, eight states have enacted statutes, like Colorado's, authorizing state boards to review and render judgment on the "affordability" of patented prescription pharmaceuticals. Three of those states, including Colorado, have empowered their boards to implement price controls by setting an upper limit on the price that sellers may charge for a particular drug in that state. Companies often invest billions of dollars in research and development on a single drug—in reliance on the promise that they can recoup their investment during their period of federally-guaranteed patent exclusivity. Statutes like Colorado's threaten to upend this regime, authorizing unaccountable state boards to deprive companies of the return on their investment—and of the ability to fund ongoing research into new medicines—on the basis of malleable and inconsistent standards and misunderstandings of the complex pharmaceutical pricing regime. If allowed to continue, these boards will create a patchwork of inconsistent price controls varying state-by-state. This new wave of price controls and "affordability reviews" is accordingly of growing and critical significance to the biopharmaceutical industry.

The Court should grant Amgen's motion and enjoin the Colorado Prescription Drug Affordability Review Board ("PDAB") from deeming prescription drugs to be "unaffordable" or setting upper payment limits. 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 the larger economy. Second, state drug price controls upset the delicate

balance that Congress has struck between interests in reducing prescription drug costs and interests in encouraging pharmaceutical innovation and compensating drug patent holders for the billions of dollars that they spend on research, development, and approval of each new drug. Third, the experience of PhRMA's and the Chamber's members confirms that Colorado's price control scheme has no discernable standard for determining "affordability" and therefore violates the Fourteenth Amendment's Due Process Clause.

ARGUMENT

I. The Colorado PDAB's Attempts to Deem Innovative Drugs "Unaffordable" Threaten the Entire Biopharmaceutical Industry

Although this lawsuit arises in the context of a single "affordability" determination affecting a single drug, Colorado's PDAB—and its unfettered and often arbitrary decisionmaking—is of critical concern to the broader innovator pharmaceutical community and the national economy.

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 "[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, rather than its actual price to consumers. § 10-16-1406(1); *see infra*, p. 18 (explaining how those measures differ).

Based on those criteria, the PDAB initially identified over four hundred

prescription drugs as eligible for an affordability review.[2] The overwhelming majority of the drugs considered eligible for affordability reviews are protected by federal patents.[3] Indeed, the PDAB Act's legislative history makes clear that this legislation was targeted at patented products rather than generics or biosimilars.[4]

At a March 31, 2023, public meeting, the PDAB then identified factors to "prioritize" in selecting among those hundreds of drugs for an affordability review.[5] The Board assigned "weights" to each factor, arbitrarily designating how much each factor would affect a single drug's ranking in a prioritized list.[6]

With no guidance from regulations or statutes, the PDAB concluded that it would prioritize drugs by "Patient Count" (assigned a weight of 25.888%); "5 Year Change in WAC" (assigned a weight of 22.961%); "Patient Out of Pocket Cost" (assigned a weight of 19.541%); "Total Paid Amount" (assigned a weight of 16.284%); and "Average Paid Per Person Per Year" (assigned a weight of 15.326%).[7] The

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

[3] *Id.*

[4] *See, e.g.*, Hearing of Colo. S. Comm. Health and Human Services, Mar. 17, 2021, (statement of Senator Smallwood) ("We're targeting brand-name specialty medicines rather than generic. The target as I understand it are the brand-name drugs."), https://sg001-harmony.sliq.net/00327/Harmony/en/PowerBrowser/PowerBrowserV2/20210317/-1/11018#info.

[5] *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.

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

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

"weights" assigned to each factor have no basis in statute or regulation nor any apparent connection to a drug's actual affordability—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, the "Total Paid Amount," which includes the largest numbers by far, was the only factor that actually mattered in determining the prioritized list.[8]

That "prioritization" effort produced 50 priority-eligible drugs.[9] 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, without using any statutorily-required standards, down to 25 prescription drugs.[10] From there, the statute gave the PDAB unfettered discretion to select drugs for an affordability review. In selecting drugs for review, the statute allows the PDAB 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).

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[8] *Id.*

[9] PDAB, Prescription Drug Affordability Board DRAFT Meeting Minutes (Aug. 4, 2023), https://drive.google.com/file/d/1LQGtrPi0RsDybD8CQbfinofdV20k0Drr/view; Boram Kim, *Colorado PDAAC Schedules Additional Meeting to Finalize Its List of Recommended Priority Drugs for Affordability Reviews* State of Reform (July 21, 2023), https://bit.ly/4cFg0jB.

[10] PDAB, Prescription Drug Affordability Board Meeting 11 (Aug. 4, 2023), https://drive.google.com/file/d/1lFzp6RV6iIwqoYW8MQJTBz_qLGMyfbgc/view.

Ultimately, the board selected five drugs—developed and manufactured by five different manufacturers—for affordability reviews: Enbrel (the subject of this lawsuit), Genvoya, Cosentyx, Stelara, and Trikafta.[11] The Board did not select these five medicines based on any particular determination that they were more likely to be "unaffordable" than any among the other 50 "priority" drugs or for that matter the 400 eligible drugs. Instead, the Board simply sorted by "patient count," zeroed in on patent-protected drugs by removing drugs with generic or therapeutic equivalents, and determined that the most popular drugs would be targeted first.[12] The Board has since concluded that Trikafta and Genvoya are not unaffordable, but that Enbrel, Cosentyx, and Stelara are unaffordable.

The Board will now proceed to impose a price control on sales of Enbrel and is expected to vote on initiating price control proceedings for Cosentyx and Stelara on July 3, 2024. But it will not impose price controls on drugs by competing manufacturers, even competing manufacturers with drugs treating the same diseases whose drugs may be less affordable than Enbrel, Cosentyx, and Stelara.

In short, the Board's efforts are hugely consequential for the entire industry, including patients and healthcare markets as a whole. Each manufacturer is now

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[11] *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.

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

subject to the risk that the Board will pick its product as a "priority" based on arbitrarily-set and meaningless "weights," deem its drug "unaffordable" based on unclear and arbitrary standards, and deny the manufacturer the ability to set its own prices while continuing to allow its competitors to set their own prices.

And Colorado's statute is part of a troubling trend: in total, at least eight states since 2019 have enacted affordability review statutes, and Minnesota and Washington[13] have empowered their respective drug pricing boards to set price controls like Colorado's upper payment limit.[14] The factors these three boards are required by statute to consider in assessing "affordability" vary greatly.[15] On top of these varying statutory requirements, each board is empowered to set its own review criteria with only limited statutory guidance.[16] Given the wide array of criteria these boards are considering, different review boards may reach different conclusions about

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[13] Maryland has also empowered its review board to implement price controls, but the Maryland PDAB is not able to implement a price control until its plan for doing so is approved by a special legislative committee. Md. Code Ann., Health Gen § 21-2C-13(d). The price controls contemplated by Maryland's PDAB statute, however, appear to be limited in scope than those in Colorado, Minnesota and Washington, likely applying only to purchases made by the state. *Id.* § 21-2C-14(a).

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

[15] *Id.*

[16] C.R.S. § 10-16-1406(4)(j) ("Any other factors as determined by rules promulgated by the board"); 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").

the affordability of the same drug. As discussed in more detail below, this patchwork of "affordability" findings and price controls will obstruct the biopharmaceutical market, curtail innovation, and hinder patient access to new and innovative therapies, including based on the patient's residence.

This Court will be the first to consider this kind of price control, and it should enjoin Colorado's law. Many other states are considering PDAB legislation that would empower their boards to implement price controls.[17] 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.

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 that development, Congress in 1984 passed the Drug Price Competition and Patent Term Restoration Act ("the Hatch-Waxman Act"), which extended the period of patent exclusivity for drugs while also speeding generic entry upon expiration of the patent. In 2009, Congress enacted the Biosimilar Price Competition and Innovation Act ("BPCIA"), which establishes a similar regime for biologics. The federal patent regime has worked as intended. Because of the established exclusivity period—which enables innovators to charge

[17] 2024 State Legislation to Lower Prescription Drug Costs, Nat'l Acad. For State Health Pol. (June 21, 2024), https://nashp.org/state-tracker/2024-state-legislation-to-lower-pharmaceutical-costs/.

market-based prices based on the scope of their patents—investments in biopharmaceutical research have continued to flourish, with the industry spending more than $100 billion in research and development per year.

Colorado's price control scheme recalibrates the balance that Congress carefully struck in the Hatch-Waxman Act, the BPCIA, and other federal patent laws. It is preempted because it conflicts with the patent rights that Congress created and disrupts the balance Congress struck between encouraging innovation and reducing the costs of prescription drugs.

A. Recognizing the immense costs of pharmaceutical innovation, Congress deliberately 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 also 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 such profits during the period of patent exclusivity is the incentive 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 cost 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. 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.

BIO, 496 F.3d at 1373.

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 one new medicine.[18] Some pharmaceutical companies have invested an average of over $10 billion per new drug.[19] And research and development costs do not end at U.S. Food and Drug Administration (FDA) approval; 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.[20]

Manufacturers developing new drugs also face incredibly long odds. Only one compound in 5,000 that enters preclinical testing will achieve FDA approval, for a failure rate of 99.98%.[21] Among the small share of investigational medicines that get as far as entering clinical trials, only 12% ever achieve approval by the FDA, and of those approved, only one in five will ever generate revenues that exceed the average cost of developing a medicine.[22]

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[18] *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.

[19] *See* Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Translational Med., No. 105, at 3-4 (2016), https://bit.ly/2PWRKRC.

[20] *See* DiMasi, *supra* n.18 at 26.

[21] 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.

[22] *See* DiMasi et al., *supra* n.18 at 25-26; 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)

In short, patent protection—and the right to set prices for drugs—is particularly necessary to promote development of pharmaceutical products because it is extraordinarily difficult, costly, and rare to develop a successful new drug.

Recognizing this, Congress in 1984 enacted the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Act was in significant part a response to pharmaceutical manufacturers' concerns that they 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. It also stemmed from Congress's recognition that unique costs and features 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). 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 extended to "create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs." *Id.* at 18.

The Hatch-Waxman Act balanced consumer access to affordable medication against the critical need for sufficient economic incentives to invest in innovation, by speeding and simplifying the process for approval and sale of generic versions of an

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https://onlinelibrary.wiley.com/doi/10.1002/hec.1538.

innovator's drug after the period of patent exclusivity expires. This carefully-crafted framework 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)).

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, are a wide range of therapeutic products developed from "natural sources—human, animal, or microorganism—and may be produced by biotechnology methods."[23] A "biosimilar," in turn, is a version of a biologic that is "similar" to the reference product.

In the BPCIA, like 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 this concern by creating an expedited pathway for approval of biosimilars after the patent term expires.[24]

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[23] FDA, *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.

[24] *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, 806 (2010).

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 their 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.[25] Since 2000, PhRMA members have invested approximately $1 trillion in the search for new treatments and cures, including almost $101 billion in 2022 alone. *Research and Development Policy Framework*, PhRMA, https://phrma.org/policy-issues/Research-and-Development-Policy-Framework.

The biopharmaceutical industry invests billions of dollars into United States medical and health research and development. This investment accounts for 78.6% of all U.S. industry investment in this field. And the industry employs 193,000 research and development employees—more than any other U.S. industry.[26]

And 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.[27] This includes significant progress in the development of therapies for rare

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

[26] 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.

[27] Analysis Group, Inc., *Innovation in the Biopharmaceutical Pipeline* 1 (Dec. 2021),

diseases.[28] 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.[29]

C. State price controls upset this delicate balance

State drug price controls like those authorized by Colorado's PDAB statute are irreconcilable with the regime that Congress established. Colorado has determined that Congress's balance is wrong: that pharmaceutical manufacturers should not be entitled to set their own prices during the patent term Congress granted, and that lowering prices for consumers should take priority over incentivizing research and development of new drugs. This is exactly what preemption doctrine forbids. The Colorado price control regime is a "clear attempt to restrain" manufacturers' pricing decisions, and thus "diminish[] the reward to patentees in order to provide greater benefit to [some] consumers." *BIO*, 496 F.3d at 1374. This 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 because its healthcare system relies on the strengths of market competition to balance cost control, patient access, and continued innovation. More

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https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Innovation_in_Biopharmaceuticals.pdf.

[28] 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.

[29] *Id.*

than half of all new drugs are launched first in the United States, with an average lag time of one year before launching in other major industrial nations.[30] State drug pricing regimes like Colorado's pose a threat to America's leadership status in the biopharmaceutical industry.

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 on the ability to earn a return on the massive investment and risk-taking that go into developing a new drug.[31] The ability to earn a return on investment is of course contingent on future pricing.[32] Price controls like Colorado's accordingly create less favorable terms for investment, causing researchers to scale back certain development programs.[33] Investments in early stage assets and biotechnology companies, which currently reflect an increasing share of the biopharmaceutical development pipeline,[34] will decline as well.

Colorado's decision to impose price controls in contravention of the patent laws

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

[31] 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).

[32] *Id.*

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

[34] *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..

that Congress established will hinder continued biopharmaceutical innovation, ultimately harming patients reliant on the industry. Price controls will also affect what kind of drugs are developed going forward. Certain therapeutic areas are disproportionately affected by reductions in revenue because these areas are riskier to invest in. For example, investment in treatments targeting sensory organs, the nervous system, and antineoplastic and immunomodulating agents are particularly vulnerable.[35] Treatments for conditions such as cancer and Alzheimer's disease are, therefore, likely to be adversely affected by state price controls.[36] With reduced prices, there will be less incentive (and ability) to invest in these therapeutic areas.

That the state may take a different view on whether price controls during the patent term will hinder innovation, to the ultimate detriment of manufacturers and patients alike, does not eliminate the square conflict between the state's law and the federal statutory scheme. It is enough that Congress took that view, and authorized an extended patent term that carries with it the power to set prices.

III. The PDAB Statute And Review Procedures Violate Due Process

As described above, Colorado's price control statute unconstitutionally violates the Supremacy Clause. But the Court should independently grant Amgen's motion for summary judgment because the PDAB statute violates the Due Process Clause of the 14th Amendment. When a state price control is implemented by an

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

[36] *See Id.*

administrative board, due process requires the board 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. Comm'n of Kansas*, 260 U.S. 48, 59 (1922). Without these safeguards, there is no guarantee that an agency is not acting arbitrarily or improperly targeting manufacturers for impermissible reasons—and no guarantee or way to ascertain whether it is even implementing the policy the legislature enacted.

In the price-setting context, given the critical nature of the right at issue, the need for due process protections are particularly great to allow for meaningful judicial review and to ensure public accountability. Due process requires guaranteeing industry participants the ability to charge prices that are "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 also 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, the PDAB's affordability reviews are essentially standardless and open-ended.

The experience of PhRMA'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. An insured consumer's out-of-pocket cost, rather, is directly decided by the consumer's health insurance plan as part of the insurance benefit design. And the costs determined by insurance companies are often dependent on negotiations with pharmacy benefit managers ("PBMs") who act as intermediaries between manufacturers and insurance plans. Moreover, the drug's out-of-pocket cost may include both coinsurance and co-payments required of the patient by the patient's insurer. And certain manufacturers offer patient assistance programs that make drugs available at no cost to patients who demonstrate financial need and who lack adequate insurance coverage. Manufacturers 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 needed medicines. Moreover, 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 is not determinative of whether it is "unaffordable" for a patient.

Colorado's PDAB statute offers no ascertainable standards for determining a drug's affordability. As Amgen explains, ECF No. 24 at 24-25, the Board's goal in an

affordability review is to determine whether certain drugs are "unaffordable for Colorado consumers," C.R.S. § 10-16-1401(3), but no statute or regulation defines what it means for a drug to be "unaffordable." Instead, the PDAB statute requires the Board to consider a set list of factors but does not tell the Board how to value those factors, and then permits the Board to consider "any other factors" established 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 "Health Equity Factors," tasking the Board with determining whether a drug's pricing has "contributed to health inequities in priority populations," without explaining how this will be determined. 3 Colo. Code Regs. § 702-9:3.1(E)(2)(j)(ii). The statute requires the Board to consider a drug's "therapeutic alternatives" without providing any discernable standard for how those "alternatives" are identified or how prices will be compared between them. 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 to date reflect this standardless approach. The Board has considered five drugs. Each review produced a report which is hundreds of pages long, and three drugs were deemed unaffordable while two were deemed not unaffordable. These reports contain 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) just reflect 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.[37] Such a scheme certainly cannot provide due process to the manufacturers subject to it, as it provides no procedures that "adequately safeguard[] against confiscatory rates, and therefore, ensure[] a constitutional rate of return." *Mich. Bell*, 257 F.3d at 592-93.

CONCLUSION

For the foregoing reasons, and for the reasons set for in Plaintiffs' briefs, this Court should grant Plaintiffs' Motion for Summary Judgment and deny Defendant's Cross-Motion for Summary Judgment.

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Respectfully submitted,

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

CERTIFICATE OF SERVICE

I hereby certify that on this July 1, 2024, 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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