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-810-NYW-SBP

MOTION OF BIOTECHNOLOGY INNOVATION ORGANIZATION FOR LEAVE TO FILE BRIEF AS AMICUS CURIAE

The Biotechnology Innovation Organization ("BIO") respectfully moves the Court for leave to file an amicus brief in support of Plaintiffs' response in opposition to the Defendants' cross-motion for summary judgment. Copies of the proposed brief and proposed order are attached. Counsel for BIO has conferred with counsel for all parties: while counsel for Plaintiffs do not oppose this motion for leave to file an amicus brief, counsel for Defendants represented that Defendants oppose the motion.

1. BIO is the world's largest biotechnology trade organization, representing more than 1,000 member companies and research organizations—from startups to Fortune 500 companies—who research and develop biotechnological products, including lifesaving medicines. BIO's members, which include Plaintiff

Amgen Inc. and four other companies whose products were selected for affordability review in Colorado (Gilead, Janssen, Novartis, and Vertex), are involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges, such as sustainably growing nutritious food, improving animal health and welfare, enabling manufacturing processes that reduce waste and minimize water use, and advancing the health and well-being of families.

2. In particular, BIO advocates for innovation in biotechnology in the healthcare space to bring treatments and cures to patient populations in the U.S. and throughout the world. Biological medicines, which include Amgen's Enbrel, are now used to treat previously untreatable diseases and have prolonged and improved the lives of countless patients. However, development of a biological medicine generally requires a decade or more of research, as well as a fully capitalized investment that on average exceeds $2 billion.

3. On August 9, 2024, Defendants filed their cross-motion for summary judgment (which was combined with their opposition to Plaintiffs' motion for summary judgment). On September 6, 2024, Plaintiffs filed their opposition to Defendants' cross-motion for summary judgment (which was combined with their reply in support of their motion for summary judgment). BIO seeks to file a brief as *amicus curiae* in support of Plaintiffs' opposition to Defendant's cross-motion for summary judgment.

4. Numerous courts—including the United States Supreme Court, various United States Courts of Appeals, and various United States District Courts—have allowed BIO to file amicus briefs, particularly when the merits issues implicate the biopharmaceutical industry. *See, e.g.*, Brief of BIO, *Bristol Myers Squibb Co. v. Becerra & Janssen Pharms., Inc. v. Becerra*, Nos. 24-1820 & 24-1821 (3d Cir. July 19, 2024); Brief of BIO, et al., *FTC v. Amgen Inc.*, No. 1:23-cv-3053 (N.D. Ill. Aug. 24, 2023); Brief of BIO, *All. for Hipprocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 11, 2023); Brief of BIO, et al., *United States ex rel. Tracy Schutte v. SuperValu Inc. & United States ex rel. Thomas Proctor v. Safeway, Inc.*, Nos. 21-1326 & 22-111 (U.S. Mar. 28, 2023).

5. "Though not addressed in the Federal Rules of Civil Procedure, this Court has broad discretion to allow participation of *amicus curiae*." *SEC v. Cetera Advisors LLC*, No. 19-cv-2461-MEH, 2020 WL 13470960, at *1 (D. Colo. Aug. 25, 2020); *see also Sgaggio v. Young*, No. 20-cv-1977-PAB, 2022 WL 970008, at *3 (D. Colo. Mar. 31, 2022) (broadly noting that "[u]nder [Federal] Rule [of Appellate Procedure] 29, a person or entity may participate as *amicus curiae* if it has an interest in the case, the matters it seeks to address are relevant, and its participation is desirable" (citation omitted)). While "[t]here is no precedent in the Tenth Circuit concerning the considerations a district court must analyze in deciding whether to allow *amicus* participation," *Cetera Advisors*, 2020 WL 13470960, at *1, the "most important factor" is "the usefulness of information and argument presented by the potential amicus curiae to the court." *Id.* at *1, *3 (citations omitted) (allowing

amicus to file brief on that factor alone). BIO's amicus brief, described further below, provides valuable perspective, based on the experience of BIO's 1,000+ member companies, regarding how, as a practical matter, Colorado's Prescription Drug Affordability Review Board ("PDAB") Statute would undermine the goals of numerous federal statutes.

6. Counsel for Defendants appear to have based their opposition on the mistaken premise that it was improper for BIO "to request to file an amicus brief . . . at this late stage," suggesting, with reference to the Federal Rule of Appellate Procedure ("FRAP") 29, that Plaintiffs' only "principal brief" was their opening motion for summary judgment, and that Plaintiffs' opposition to Defendants' cross-motion for summary judgment does not qualify.

7. As an initial matter, the FRAP do not apply in district court proceedings like this one, and neither the local rules of the District of Colorado nor your Honor's practice standards restrict amicus briefs. Accordingly, there is no applicable requirement that amicus briefs must follow a party's "principal brief" as Defendants argue. More importantly, BIO's proposed amicus brief complies with both the letter and the purpose of the FRAP requirements. An opposition brief to a dispositive motion is, in fact, a principal brief—the primary brief through which a party stakes out its position in opposition to the motion. Moreover, the underlying purpose of FRAP 29 is to ensure that each party has an opportunity to respond to the arguments of any amicus in support of the opposing party. Here, Defendants have every

opportunity to respond to BIO's arguments in their reply brief, as would have been the case if Defendants had been the only ones who moved for summary judgment.

8. Notably, under Defendants' apparent position, no amicus brief could ever address arguments made by a defendant in support of its cross-motion for summary judgment. Here, Defendants' cross-motion for the first time makes a number of arguments concerning the nature of federal exclusivity rights as well as the national system for pricing drugs that are fundamentally flawed, and which BIO is well-positioned to rebut (*i.e.*, BIO is asserting response arguments rather than reply arguments). Had Defendants moved first, Defendants appear to acknowledge that BIO would have had an opportunity to file an amicus brief in support of Plaintiffs' opposition in order to address Defendants' erroneous premises. Likewise, had the parties filed cross-motions for summary judgment simultaneously, BIO would be permitted to file an amicus brief in response to Colorado's motion. The happenstance of which party moved first in the cross-motion briefing schedule should not determine whether BIO has an opportunity to respond to flawed arguments in Defendants' motion.

9. Notably, other federal district courts have allowed amicus briefs in the same procedural posture as the present one. *See, e.g.*, *Pfizer, Inc. v. U.S. Dep't of Health and Hum. Servs.*, No. 1:20-cv-4920-MKV (S.D.N.Y.), ECF Nos. 49, 60, 62 (allowing amicus brief of PhRMA in support of Plaintiff Pfizer's opposition to Defendant HHS's cross-motion for summary judgment).

10. Additionally, the general trend in the appellate courts is toward greater liberality in allowing amicus briefs. Indeed, the Supreme Court recently eliminated the requirement for an amicus to file a motion for leave to file if the parties withheld consent. *See January 2023 Memorandum*, Office of the Clerk, Supreme Court of the United States, https://www.supremecourt.gov/casehand/AmicusGuide2023.pdf. The Supreme Court recognizes the value of amicus participation in helping the court to resolve novel, complicated questions of law. The same is equally true of amicus participation in this complicated case.

11. BIO can provide a unique and helpful perspective on this case, and its proposed brief covers aspects of the relevant legal arguments in a manner both distinct from other *amici* in this case and responsive to Defendants' arguments in their cross-motion for summary judgment.

12. In particular, BIO responds to Defendants' arguments regarding Plaintiffs' patent preemption claims and shows that Defendants' arguments are so broad that they would effectively eviscerate the incentive to innovate that motivated Congress to create numerous federal regulatory exclusivities, in addition to patent protections. If Colorado's summary judgment arguments prevail, all of these other federal regulatory exclusivities, which were expressly adopted to spur innovation of new drugs and biologics, will be susceptible to being wiped out by state law, in which case those federal exclusivity rights will lose their incentivizing power altogether.

13. BIO also responds to Defendants' arguments concerning how drug-pricing operates in the national market. In particular, BIO explains how Colorado's

policy of dictating prices conflicts with the premise underlying federal healthcare programs that rely on discounts set through market forces to establish the reference price for the rebates/discounts available under those statutes to preferred purchasers. Defendants' attempt to set low prices by state government fiat is fundamentally inconsistent with those federal pricing schemes. *See BIO v. District of Columbia*, 496 F.3d 1362, 1371-74 (Fed. Cir. 2007).

14. The issues in this case directly implicate the interests of BIO and its 1000+ members, who also are subject to, or may in the future be subject to, the Colorado PDAB process or similar processes in other states. BIO therefore respectfully requests leave from this Court to file the attached amicus brief in this matter.

Dated: September 13, 2024

Respectfully submitted,

By: */s/Douglas H. Hallward-Driemeier*

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CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2024, I electronically filed the foregoing Motion with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to attorneys of record.

/s/ Douglas H. Hallward-Driemeier
Douglas H. Hallward-Driemeier

Counsel for Amicus Curiae BIO

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BRIEF OF AMICUS CURIAE BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTEREST OF AMICUS CURIAE[1]

The Biotechnology Innovation Organization ("BIO") is the world's largest biotechnology trade organization, representing more than 1,000 member companies and research organizations—from startups to Fortune 500 companies—who research and develop biotechnological products, including lifesaving medicines. BIO's members, which include Plaintiffs (referred to herein as "Amgen") and four other companies whose products were selected for affordability review in Colorado (Gilead, Janssen, Novartis, and Vertex), are involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges, such as sustainably growing nutritious food, improving animal health and welfare, enabling manufacturing processes that reduce waste and minimize water use, and advancing the health and well-being of families.

In particular, BIO advocates for innovation in biotechnology in the healthcare space, to bring treatments and cures to patient populations in the U.S. and throughout the world. Biological medicines, which include Amgen's Enbrel, are now used to treat previously untreatable diseases and have prolonged and improved the lives of countless patients. However, development of a biological medicine generally requires a decade or more of research, as well as a fully capitalized investment that on average exceeds $2 billion.

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

Colorado's Senate Bill 21-175, as amended by House Bill 23-1225 (collectively, the "PDAB Statute"), poses a direct threat to the Congressional policies and overall legal framework or method (hereinafter, the "Framework") as reflected in federal statutes that are essential to the development and dissemination of groundbreaking pharmaceutical treatments throughout the United States. The Cross-Motion for Summary Judgment (the "Cross-Motion") filed by Defendants (referred to herein as "Colorado") reflects a serious misunderstanding of those federal policies and Framework, and of how Colorado's law will operate in a manner that will frustrate and conflict with them. Amicus BIO, reflecting the combined experience of its 1,000+ member companies, can assist the Court in understanding the full extent of the conflict between Colorado's PDAB Statute and federal law.

INTRODUCTION AND SUMMARY OF ARGUMENT

I. Amgen's patent preemption claim challenges Colorado's attempt to deprive drug manufacturers of the benefit of exclusivity rights granted to them by Congress as a way to encourage innovation in the pharmaceutical industry. That issue is of critical interest to BIO's members; indeed, BIO litigated the leading case in the area, which struck down a similar state effort to deprive pharmaceutical companies of the benefits of their patent rights by imposing price caps on sales of their medicines within the state. *See Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1372 (Fed. Cir. 2007) (treating the District of Columbia as a state for preemption purposes).

Contrary to Colorado's Cross-Motion, those federal policies and Framework would not cease to be relevant, nor would Colorado's law frustrate them any less if,

as Colorado now argues (for the first time and contrary to the statutory language), the PDAB Statute operates only on downstream sales. The market for pharmaceutical products in the United States operates to a very significant extent through wholesalers and distributors. Indeed, Colorado acknowledges that "[s]ubstantially all of Amgen's sales in the United States are to pharmaceutical wholesale distributors." Cross-Motion at 2. If the mere fact that distribution of drugs and biologics takes place through middlemen were sufficient to defeat the manufacturer's exclusivity right to recoup their investment in developing that drug or biologic, states would be free to trample not only on patent rights, but the numerous other exclusivity rights that Congress has adopted with specific application to the life sciences industry. In other words, the arguments in Colorado's Cross-Motion as to Amgen's patent preemption claim are so far-reaching that they are self-defeating.

II. More fundamentally, several of the arguments in Colorado's Cross-Motion, including both with respect to preemption by federal healthcare programs and Dormant Commerce Clause, fail to appreciate fully both the extent to which drug pricing occurs through an integrated national market and the extent to which Congress has affirmatively harnessed that national market to benefit federal healthcare programs. Colorado's policy of state government-dictated drug prices is inconsistent with the fundamental premise underlying those federal healthcare programs: that prices are generally to be dictated by national *markets*, rather than set by state government fiat.

ARGUMENT

I. The Colorado PDAB Statute Impermissibly Interferes with the Federal Policies and Framework of Encouraging Innovation in New Drugs and Biologics Through Exclusivity Rights.

Colorado's Cross-Motion makes the mistaken argument that Amgen's patent rights are irrelevant to Amgen's lawsuit simply because Amgen first sells Enbrel to wholesalers and distributors outside of Colorado, even though that same Enbrel ultimately is dispensed to a patient in Colorado (and is thus squarely within the scope of the PDAB Statute). That argument, if adopted, would eviscerate the numerous Congressionally mandated exclusivity rights, including both patent rights and many others, that Congress has specifically conferred on biotechnology and pharmaceutical companies in order to incentivize their innovation of new medical therapies. Colorado does not deny, as the Federal Circuit recognized in *BIO*, that federal patent law preempts state caps on the prices of patented drugs, because doing so "diminish[es] the reward to patentees" in order to "provide greater benefit to [in-state] drug customers." 496 F.3d at 1374.

Further, as Colorado's Cross-Motion argues, the vast majority of drugs and biologics, including Amgen's Enbrel, are distributed through wholesalers and distributors (although even application of the PDAB Statute to a direct sale—for example, from a manufacturer to a specialty pharmacy—would frustrate federal patent rights). *See* Cross-Motion at 2. Thus, if Colorado's argument were right, Colorado and every state would be free to deprive pharmaceutical and biotechnology companies of the benefit of their patent exclusivity by simply being explicit that it is only capping the price at which the drugs could be *re*-sold to in-state drug customers.

But as Amgen's Opposition explained, federal law preempts state laws that frustrate federal law *indirectly* as well as those that do so *directly*. *See* Amgen Combined Reply and Opp. at 13-14. More generally, the numerous regulatory exclusivities that Congress has created specifically for pharmaceutical and biotechnology companies reflect that Congress was focused on creating *genuine* incentives for biotechnology innovation, not ephemeral rights that states could easily circumvent through clever draftsmanship. *Cf. Haywood v. Drown*, 556 U.S. 729, 742 (2009) ("[T]he Supremacy Clause cannot be evaded by formalism.").

Congress has employed exclusivity rights far more broadly than just "patents" in the life sciences space, reflecting Congress's recognition that periods of exclusivity are *essential* to drive the innovation that has produced breakthrough treatments in the United States over the past several decades. Because of these policies and Framework, the United States has been the global leader in critical new developments in the life sciences space.

As the U.S. Food and Drug Administration ("FDA") recognizes, while patents are a "property right" granted by the U.S. Patent and Trademark Office, regulatory exclusivities in the life sciences space go beyond generally applicable patent rights. Such regulatory exclusivities "refer[] to certain delays and prohibitions on approval of competitor drugs" that ensure the manufacturer will have the opportunity to market its product free of certain types of competition. *Frequently Asked Questions on Patents and Exclusivity*, Food and Drug Administration, https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-

questions-patents-and-exclusivity. The FDA's website lists no fewer than *seven* different types of regulatory exclusivities, above and beyond patent rights, that Congress has provided to incentivize drug and biologic innovation. These include:

- **Orphan Drug Exclusivity** (ODE) – 7 years
- **New Chemical Entity Exclusivity** (NCE) – 5 years
- **Generating Antibiotic Incentives Now (GAIN) Exclusivity** – 5 years added to certain exclusivities
- **New Clinical Investigation Exclusivity** – 3 years
- **Pediatric Exclusivity** (PED) – 6 months added to existing Patents/Exclusivity
- **Patent Challenge** (PC) – 180 days . . .
- **Competitive Generic Therapy** (CGT) – 180 days . . .

Id. (citing 21 C.F.R. §§ 314.108, 316.31, 316.34 and §§ 505A, 505E, 505(j)(5)(B)(iv), 505(j)(5)(B)(v) of the Food, Drug, and Cosmetic Act). *See also, e,g.*, *Baker Norton Pharms., Inc. v. FDA*, 132 F. Supp. 2d 30, 31 (D.D.C. 2001) (citing 21 U.S.C. § 360cc(a)) (characterizing the seven-year "market exclusivity" conferred by orphan drug designation/approval as a "non-patent" exclusivity).

Colorado's arguments, if adopted, would not only defeat Congress's innovative purposes with respect to patent rights, but all of these regulatory exclusivities and the Framework as well. If Colorado (and every state) is free to deprive a patent holder of its right to price its patented drug free of state law mandates simply by making the law apply as a technical matter to the wholesaler's resale of the product into the state, then Colorado can deprive manufacturers of the incentives provided by these other federal provisions as well. It matters not whether Colorado *has* gone after these other regulatory exclusivities *yet*; by the logic of Colorado's argument, it (and every state) *could* do so under state statutes like the PDAB Statute.

The example of federal orphan drug exclusivity is particularly apposite. Indeed, Colorado amended its PDAB Statute to include "orphan drug status" as one of the factors for the PDAB to consider in evaluating whether a drug is affordable. Congress enacted the Orphan Drug Act ("ODA") in 1983, and the Hatch-Waxman Act ("HWA") in 1984, to provide manufacturers with limited periods of market exclusivity for drugs that treat rare diseases and conditions. During the ODA period of market exclusivity, the FDA may not approve another application for the same drug for the same disease or condition. *See* 21 U.S.C. § 360cc(a). And during the HWA period of market exclusivity, the FDA cannot approve generics of the protected drug. *See* 21 U.S.C. § 355(j)(5)(F)(ii).

In enacting the ODA and HWA, Congress enabled manufacturers to recoup the high costs of developing these novel compounds notwithstanding the conditions' smaller patient populations. Without the ODA and HWA, manufacturers would have little to no incentive to develop orphan drugs, given that such drugs treat diseases affecting fewer than 200,000 people in the United States. Even though orphan drugs can dramatically improve patient welfare and even save lives, their demand is small compared to their extremely high research-and-development costs. The ODA and HWA solve this problem by enabling manufacturers to recoup their high development costs through Congressionally mandated regulatory exclusivity periods in which prices can be determined free from certain forms of competition. Specifically, in the ODA, Congress aimed to "facilitate the development of drugs for rare diseases or conditions" because it found that, without this additional financial incentive, "it [was]

not financially feasible, except as a public service, for a pharmaceutical manufacturer to expend research and development funds on drugs for these rare diseases or conditions." H.R. Rep. 97-840, at 6 (1982). Similarly, with the HWA, Congress sought to "create a new incentive for increased expenditures for research and development" of new drugs. H.R. Rep. 98-857, pt. 1, at 15 (1984).

The Colorado PDAB Statute lists "orphan drug status" as a factor in assessing affordability, without giving any indication as to which direction that consideration should weigh in the analysis; it simply lists such status as a factor in the affordability review without further explanation. *See* Colo. Rev. Stat. § 10-16-1406(4)(g). One could easily imagine the Colorado PDAB reaching the conclusion that the very exclusivity that Congress has provided orphan drugs has led to the price being unaffordable for patients with rare diseases. The Colorado law appears to permit the Board to consider this exclusivity right as a factor *in favor* of selecting the drug for affordability review. *See id.* § 10-16-1406(2)(e).

The Generating Antibiotic Incentives Now ("GAIN") Act, enacted in 2012 as part of the Food and Drug Safety and Innovation Act, provides another example of the conflict between Colorado's arguments and the policies embodied in federal law. Concerned with the "public health threat of antibacterial drug resistance," Congress passed the GAIN Act to "stimulat[e] the development and approval of new antibacterial . . . drugs" by providing an exclusivity *extension* of five years that could even be added onto other exclusivities. *Report to Congress on Generating Antibiotic Incentives Now*, Food and Drug Administration (Aug. 29, 2017),

https://www.fda.gov/files/about%20fda/published/Report-to-Congress-on-Generating-Antibiotic-Incentives-Now-%28GAIN%29.pdf. Under the arguments in Colorado's Cross-Motion, the Colorado PDAB would be free to undermine such an exclusivity by imposing an upper payment limit ("UPL") on the resale of those new antibacterial products by wholesalers and distributors, even though doing so would reduce manufacturers' incentive to invest in and develop such critical drugs and thereby frustrate Congress's intent in the GAIN Act. Again, it does not matter that Colorado has not *yet* selected such a drug for a UPL—it *could* do so per the PDAB Statute. If Colorado's Cross-Motion prevails, manufacturers would need to take serious pause before making such investments in the future because they could not know if states would try to counteract the benefits of Congressionally mandated regulatory exclusivity, and those companies may make the quite logical decision not to innovate. The federal government would thus lose a major tool in addressing other critical public health threats through similar legislation.

"[W]hen federal and state laws collide, the Constitution is clear: Federal law wins." *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1187 (10th Cir. 2023). A state law is "preempted when it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Standing Akimbo, LLC v. United States*, 955 F.3d 1146, 1165-66 (10th Cir. 2020) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). Colorado's interpretation of the scope of its legal authority amounts to an assertion that states may freely engage in broad activities preempted not only by federal patent law but all other federal prescription drug exclusivity

programs that Congress explicitly enacted to balance access with innovation. The PDAB Statute therefore cannot stand. *See BIO*, 496 F.3d 1362, 1374 (striking down D.C. law that "[b]y penalizing high prices . . . chose[] to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs" and therefore stood "as an obstacle to the federal . . . balance of objectives as established by Congress").

II. The PDAB Statute Impermissibly Interferes with the Price of Drugs Outside of Colorado, Including with Federal Healthcare Program Pricing Mechanisms that Affirmatively Rely on the National Market.

The larger premise that underlies all of Colorado's arguments in its Cross-Motion—that the PDAB Statute operates only on wholesalers' resale of products in the state, not manufacturers' out-of-state sales—rests on a fundamental fallacy. Colorado would have the Court believe that manufacturers will sell to wholesalers at the manufacturer's national price, and then wholesalers will resell those products in Colorado at the State's lower UPL. That is pure fantasy. Wholesalers will not sell into Colorado at a loss. Likewise, Colorado cannot assume that wholesalers will cease selling to Colorado patients, which would defeat the statute's objectives. Thus, for the statute to work as intended, Colorado must in fact assume that manufacturers will provide "rebates" to wholesalers to offset the state's price controls. *See*, *e.g.*, Cross-Motion at 3-6 (discussing role of "rebates" in the national drug pricing system).[2] Indeed, the PDAB Statute's legislative history confirms that is what the legislature

[2] Theoretically, manufacturers could achieve the same result by other means (chargebacks, upfront price concessions to wholesalers, etc.), but this would not impact the downstream MDRP and 340B Program analysis that follows.

assumed, as Amgen details in its opposition. *See* Amgen Combined Reply and Opp. at 9. To operate as Colorado truly intends, the PDAB Statute would thus interfere with sales *outside* Colorado (as explained below), and even threaten the basic assumption that underlies numerous federal healthcare pricing statutes: that drug prices are generally set not by state governments, but by market forces, the product of which federal law then takes as the baseline for setting federal program prices.

This is true, for example, under both the **Medicaid Drug Rebate Program ("MDRP")** and the **340B Program**, each of which effectively entitles preferred purchasers to the benefit of the "best price" that market participants are able to negotiate for themselves. Colorado's Cross-Motion fails to explain how the PDAB Statute, which can only operate if manufacturers give wholesalers rebates or other discounts to offset the lower UPL, interacts with these federal drug pricing programs.

Through the **MDRP**, manufacturers generally agree to provide rebates to state Medicaid programs on state Medicaid utilization of their drugs in exchange for an agreement by the state programs to provide coverage for the manufacturers' drugs. 42 U.S.C. § 1396r–8(a), (b). This commitment is reflected in a binding contract between a manufacturer and the federal government (on behalf of states), called a National Drug Rebate Agreement ("NDRA"). Under federal law and the NDRA, Medicaid "rebate liability" for most branded drugs is calculated as the greater of (1) 23.1% of the "average manufacturer price" ("AMP"), or (2) AMP minus "the lowest price available from the manufacturer" to certain purchasers (*i.e.*, the "best price" negotiated in the commercial marketplace). 42 U.S.C. §§ 1396r–8(c)(1)(A)–(C). In

effect, state Medicaid programs pay the lower of the best negotiated price in the market or a discount off the average manufacturer price.

Similarly, through the **340B Program**, as a condition of their drugs' being covered by Medicaid and Medicare Part B, manufacturers must sell outpatient drugs at or below a discounted "ceiling price" to specified safety net providers, called "covered entities," if the drugs are "made available to any other purchaser at any price." 42 U.S.C. §§ 256b(a), 1396r-8(5). Each drug's ceiling price is calculated by subtracting the MDRP rebate amount from the drug's AMP, meaning those entities also get the benefit of the states' MDRP rebate (which is based on the drug's "best" market prices). 42 U.S.C. § 256b(a)(1).

If the Colorado PDAB scheme functions as the State must implicitly assume—*i.e.*, that manufacturers give rebates to wholesalers to account for the lower UPL—then manufacturers would risk setting a new "best price" for those products based on the UPL set by Colorado. By potentially forcing a new "best price," the PDAB Statute would directly conflict with the federal MDRP and 340B Program, which utilize a nationwide "best price," but only on the premise that the manufacturer has voluntarily agreed to that price in a market-based arrangement. *See Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 114-15 (2011). Colorado cannot avoid that very real conflict with federal law by hiding behind the fantasy that somehow (and notwithstanding that this is not what the statute says) the UPL only applies to the consumer and does not affect the rebate the manufacturer has to offer the wholesaler. As noted above, if that were the entire story, then the PDAB Statute would end up

depriving Colorado consumers of those products, because no wholesaler would buy a drug at a higher wholesale price and then sell that drug to Colorado consumers at a lower UPL.

A price set by the PDAB Statute would then potentially have ***nationwide repercussions***, as other states' Medicaid programs and 340B entities across the country would be entitled to the same low Colorado price—not because of the Colorado law directly, but because of the way Colorado's price would be filtered through the Framework of federal pricing statutes. Because federal healthcare pricing laws affirmatively adopt and use a company's "best price," on the premise that companies choose to set a new "best price" by agreeing to such a price in the market, it would frustrate those federal laws if Colorado's UPL were instead to mandate a new "best price" by state governmental fiat.

Even though Colorado's UPL would initially apply to sales outside governmental programs, Colorado's UPL would stand as an obstacle to Congress's purposes, because it would interfere with the *method* Congress chose to implement drug pricing within federal health programs. *See Colo. Dep't of Pub. Health & Env't v. United States*, 693 F.3d 1214, 1224 (10th Cir. 2012) ("A state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach [its] goal."). As noted above, Congress chose not to unilaterally set the price of drugs under these federal programs, but instead chose to rely on nationwide *average* prices, and discounts on the manufacturer's sales in the market *outside* of those government programs. *See* 42 U.S.C. § 1396r–8(c)(1)(A)-(C) (MDRP); *id.* § 256b(a)(1) (340B

Program); 42 C.F.R. 447.504(c) (expressly excluding MDRP and 340B prices from calculation of AMP). Colorado threatens to thwart that federal statutory scheme by attempting to substitute a state government-set price for one that would instead have been determined by the manufacturer's negotiations with other market actors. As the Supreme Court has held, when Congress has resolved that prices should "be determined by market forces," a state law that "threaten[s] to distort the market" that Congress relied on to effectuate federal policy is "pre-empted." *Transcon. Gas Pipe Line Corp. v. State Oil & Gas Bd.*, 474 U.S. 409, 422, 424-25 (1986).

If the UPL is set low enough, it may effectively establish the federally mandated national discount amount and price for ***all nationwide sales*** of a drug under the MDRP or 340B programs, respectively.[3] As described above, Congress has provided that state Medicaid programs, through the MDRP, are entitled to a rebate that is the greater of a specified discount off the AMP or the AMP minus "the lowest price available from the manufacturer" to certain purchasers. 42 U.S.C. §§ 1396r–8(c)(1)(A)–(C). While this "best price" is defined to exclude sales under various federal health programs, *see* 42 C.F.R. 477.505(c), sales made at the UPL for patients not covered by one of those programs could (depending on how the statute is construed) establish a new "best price" under the MDRP, increasing a manufacturer's Medicaid rebate liability for its drug nationwide. And, because the "ceiling price" at which

[3] Because a UPL will inevitably impact wholly out-of-state transactions, the PDAB Statute also raises dormant Commerce Clause concerns, in addition to the preemption concerns that are the focus of this brief. *See* Amgen Combined Reply and Opp. at 28 n.6 (collecting cases).

manufacturers can sell drugs to 340B covered entities is calculated based on Medicaid rebates, *see* 42 U.S.C. § 256b(a)(1), Colorado's UPL could effectively establish a new price for 340B entities nationwide as well.

What's more, if Colorado can set a low government mandated price that effectively becomes the new "best price" for MDRP and 340B purposes, then any state can do so. Congress's objective of creating a uniform drug-pricing system in federal programs, benchmarked against commercial market prices, "could never be achieved" if each and every state could set by unilateral edict a new "best price" under the MDRP, nationally impacting Medicaid rebates and 340B prices. *Tweed-New Haven Airport Auth. v. Tong*, 930 F.3d 65, 74 (2d Cir. 2019) (holding that Connecticut could not regulate airport runway length because "[t]his localized, state-created limitation is incompatible with the FAA's objective of establishing a 'uniform and exclusive system of federal regulation in the field of air safety'" (citation omitted)); *see also Egelhoff v. Egelhoff*, 532 U.S. 141, 148 (2001) (holding that a state statute was preempted by ERISA where ERISA's goal of national uniformity would be "impossible . . . if plans are subject to different legal obligations in different States"). Congress never intended for one state to be able to unilaterally interfere with the drug pricing process in federal programs; it certainly did not intend that this process be hindered by potentially *every* state.

Colorado's attempt to avoid federal preemption simply by declaring that the PDAB Statute does not apply to sales under the "Medicare, TRICARE, or the Federal Employee Health Benefits program," ECF No. 29 at 40-41 (quoting PDAB UPL Policy

at 2), does not address the more fundamental conflict between the PDAB Statute and Congress's affirmative decision to employ market forces to help determine discounts under the Medicaid and 340B programs.[4] Because the PDAB Statute impermissibly interferes with the market-based system Congress designed, it is preempted by federal law. *See Standing Akimbo*, 955 F.3d at 1166 (rejecting reading of statute that "would substantially impede" IRS operations); *Colo. Dep't of Pub. Health*, 693 F.3d at 1224 (holding that Colorado could not enforce storage of hazardous waste law against Unites States' storage of chemical weapons given "the detail Congress has provided regarding how and when the DOD must destroy these weapons"). The PDAB Statute therefore cannot stand.

CONCLUSION

For the foregoing reasons, and for the reasons set forth in Amgen's Reply and Opposition, this Court should deny Defendants' Cross-Motion for Summary Judgment.

Dated: September 13, 2024

Respectfully submitted,

By: */s/Douglas H. Hallward-Driemeier*
Douglas H. Hallward-Driemeier

[4] Notably, the UPL Policy cited by Colorado is interpretive guidance, which is not binding under Colorado law. *See Meyer v. Colo. Dep't of Soc. Servs.*, 758 P.2d 192, 195 (Colo. Ct. App. 1988) ("[A] general statement of policy does not establish a 'binding norm,' nor does it finally determine the issues or rights to which it is addressed" (quoting 2 K. Davis, *Administrative Law Treatise* 7.5 (2d ed. 1979))); Colo. Rev. Stat. § 24-4-103(1). (noting that "interpretative rules or general statements of policy . . . are not meant to be binding as rules"). This is particularly so when the face of the PDAB Statute contains no such exception; the Colorado legislature could have excluded drugs regulated by various federal healthcare programs from the UPL requirement, but chose not to do so. *See Demarest v. Manspeaker*, 498 U.S. 184, 190 (1991).

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CERTIFICATE OF SERVICE

I hereby certify that on September 13, 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.

/s/ Douglas H. Hallward-Driemeier
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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-810-NYW-SBP

[PROPOSED] ORDER GRANTING THE MOTION OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION FOR LEAVE TO FILE A BRIEF AS AMICUS CURIAE

Upon consideration of the Motion of Biotechnology Innovation Organization for Leave to File Brief as Amicus Curiae,

IT IS HEREBY ORDERED that the Motion is GRANTED.

Dated: September ___, 2024

_____
Honorable Nina Y. Wang
United States District Judge