No. 2025-01641

United States Court of Appeals for the Federal Circuit

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

v.

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

Appeal from the United States District Court for the District of Colorado, 24-cv-810-NYW-SBP (Hon. Judge Nina Y. Wang)

CORRECTED BRIEF OF AMICI CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF APPELLANTS AND REVERSAL

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CERTIFICATE OF INTEREST

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

1. The full names of the parties represented by me:

   Pharmaceutical Research and Manufacturers of America; the Chamber of Commerce of the United States of America.

2. The names of the real parties in interest represented by me:

   N/A.

3. Parent corporations and publicly held companies that own 10% or more of stock in Amici Curiae:

   None.

4. The names of all firms, partners, and associates that have not entered an appearance but either appeared for Amici Curiae in the trial court or are expected to appear in this Court:

   Matthew Farley.

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

   N/A (Amicus).

6. Organizational victims, debtors, or trustees in this appeal:

   None.

Dated: June 30, 2025

/s/ Jeffrey L. Handwerker
Jeffrey L. Handwerker

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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 research-based pharmaceutical and biotechnology companies. PhRMA's members invent medicines that allow patients to live longer, healthier, and more-productive lives. PhRMA members have invested more than $800 billion over the last decade in the search for new treatments and cures, including $96 billion in 2023 alone. They rely on the stability and supremacy of federal patent laws when making these investments. PhRMA also advocates in support of public policies focused on improving patient access to lifechanging, and often lifesaving, medicines.

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

[1] Amici Curiae submit this brief with the consent of all parties pursuant to Fed. R. App. P. 29(a)(2). *See* Fed. R. App. P. 29(a)(4)(D). No party's counsel authored this brief in whole or part, and no entity or person, other than amici, their members, or their counsel, made any monetary contribution intended to fund the brief's preparation or submission. *See* Fed. R. App. P. 29(a)(4)(E).

interests of more than 3 million companies and professional organizations of every size in every industry sector, 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 files amicus curiae briefs in cases, like this one, that raise issues of concern to the nation's business community.

This appeal presents questions of critical importance for PhRMA and the Chamber. The court below held that a business lacks standing to challenge a state law capping the price of its products, so long as the law nominally applies only to a downstream transaction. That holding—wrong both as a matter of constitutional law and basic economic common sense—will make it easier for states to evade judicial review while targeting PhRMA and Chamber members with unlawful price caps and other burdensome regulations. The decision will also empower unelected state boards to unilaterally direct private companies' drug-pricing decisions, in contravention of multiple constitutional provisions and federal patent law. These issues are of vital interest to the members of PhRMA and the Chamber.

INTRODUCTION AND SUMMARY OF ARGUMENT

The decision below undermines the U.S. patent system by preventing innovators from defending their exclusive right to market their products during the federally established patent term. States cannot be permitted to undermine federal intellectual property protections simply by directing regulations at parties further down the distribution chain. The district court erred as a matter of law in holding that Amgen lacks standing to protect its patents here.

Whether or not manufacturers are directly regulated—though under Colorado's law, they certainly are—manufacturers bear the cost of price caps that force wholesalers to sell their products at lower prices. As a matter of basic economic principles, capping the price at which a particular product may be purchased and reimbursed will affect the manufacturer of that product. Colorado's upper payment limit will necessarily affect Amgen, which demonstrated its imminent injury here through evidence that Colorado made no effort to rebut. Amgen thus plainly has standing to challenge Colorado's law. Indeed, as the entity that will primarily bear the law's economic burden, Amgen is unquestionably an appropriate party to do so.

The district court's approach to standing—precluding suit if there is *any* possibility that the government will choose not to enforce its law—is at odds with well-established precedent favoring judicial review of imminent governmental action. Concerningly, this unduly narrow standing theory would apply equally to plaintiffs challenging state and federal action, thereby insulating from judicial review wide swaths of governmental regulation until *after* it has caused irreparable harm.

Worse still, the ruling below has prevented review of Colorado's price control law even though it is preempted under this Court's binding precedent. Pharmaceutical companies invest billions of dollars in research and development—sometimes for a single drug—in reliance on Congress's promise that *if* a drug ultimately proves safe and effective, a manufacturer can recoup its up-front investments during a defined period of guaranteed patent exclusivity. Colorado's upper payment limit intentionally disrupts this careful balance by authorizing an unaccountable state board to deprive companies of their federal rights. Targeting patentees' rewards for developing successful drugs harms manufacturers and, by undermining the stability of patent protections generally, also harms the public that relies on the development of safe

and effective medicines, and indeed of other products protected by the patent laws.

Though Colorado's law was unprecedented when enacted, that is no longer the case: Since 2019, nine states have enacted statutes that authorize state boards to render judgment on the "affordability" of patented prescription pharmaceuticals, four of which authorize the boards to impose upper payment limits. At least a dozen states are considering legislation to enact or enhance the powers of similar boards. The resulting patchwork of state regulatory regimes is wholly incompatible with Congress's choice to stimulate investment by granting innovators exclusive rights during the term of their patents. Judicial review of Colorado's price-control law is necessary now.

ARGUMENT

I. Manufacturers Have Standing to Challenge Price Controls on their Products

The district court's decision distorts bedrock principles of standing, ignores the realities of pharmaceutical pricing, and runs counter to economic logic. Just today, the Supreme Court confirmed that "[t]he government generally may not target a business or industry through stringent and allegedly unlawful regulation, and then evade the resulting

lawsuits by claiming that the targets of its regulation should be locked out of court as unaffected bystanders." *Diamond Alternative Energy, LLC v. E.P.A.*, No. 24-7, slip op. at 23 (U.S. June 20, 2025). Limiting the price that a wholesaler may charge a pharmacy for a drug injures the manufacturer because it limits the price the manufacturer may charge the wholesaler. A court may presume economic injury in such circumstances, yet Amgen even offered uncontested evidence detailing its contractual relationships with wholesalers, rendering indisputable that Colorado's price controls will impose economic injury on the company. Longstanding precedent also establishes that manufacturers have standing to challenge such price controls *before* they go into force. If upheld, moreover, the decision below would make it easy for state regulators to avoid pre-enforcement judicial review of unconstitutional statutes. That result would undermine governmental accountability, the rule of law, and, in this case, principles of federalism.

A. Manufacturers are harmed by price caps on their products

The district court theorized that Amgen might face no injury from Colorado's price controls because those price controls purportedly apply only to downstream sales, like a wholesaler's sale of a drug to a retail

pharmacy. As Amgen explains, however, when wholesalers are forced to sell at a lower price, manufacturers are often contractually obligated to reimburse the wholesalers via "chargebacks," a point that Amgen supported with unrebutted evidence that the district court improperly disregarded. If upheld by this Court, the decision below would allow states across the country to impose stringent price caps on pharmaceutical manufacturers—or producers of goods in any other industry—while evading pre-suit challenges.

1. Patented brand-name drugs typically travel through a supply chain that includes manufacturers, wholesalers, retail and hospital pharmacies, and patients.[2] Wholesalers purchase from manufacturers at a price based on the drug's national list price, commonly known as the wholesale acquisition cost ("WAC").[3] Wholesalers may also charge distribution service fees and receive certain discounts, such as volume

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[2] Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships* 4, RAND Corp. (2021), https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf.

[3] *See* Ernst R. Berndt & Joseph P. Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets* 8 (Nat'l Bureau of Econ. Rsch., Working Paper No. 16297, 2010), https://www.nber.org/system/files/working_papers/w16297/w16297.pdf.

and prompt-payment discounts.[4] These adjustments aside, however, the WAC does not vary based on the end-purchaser; a uniform list price is used nationwide, as it would be difficult ahead of time to account for the many different circumstances under which a specific unit of medicine will be sold.

After purchasing drugs from manufacturers, a wholesaler distributes the products to pharmacies. Competition for business often leads wholesalers to sell brand-name drugs to pharmacies at net prices *below* WAC.[5] The pharmacy then sells the drug to its customers (i.e., patients), collecting payments from the patient and, in many cases, from a pharmacy benefit manager working on behalf of the patient's insurer.

In circumstances where the wholesaler is required to sell a drug to the pharmacy at a price lower than the WAC-based price, or where a particular pharmacy has negotiated for a lower price with the manufacturer, the manufacturer may be contractually obligated to make up the difference through what is known as a "chargeback."[6] A

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[4] Mulcahy & Kareddy, *supra* note 2, at 11.

[5] *See id*.

[6] *Id.* at 23.

chargeback is simply a mechanism for reconciling price differences.[7] For example, a wholesaler might pay the manufacturer $100 for a drug, while a pharmacy might negotiate to pay only $80. In that case, following the sale, the wholesaler would issue a chargeback to the manufacturer for $20 to make up the difference.

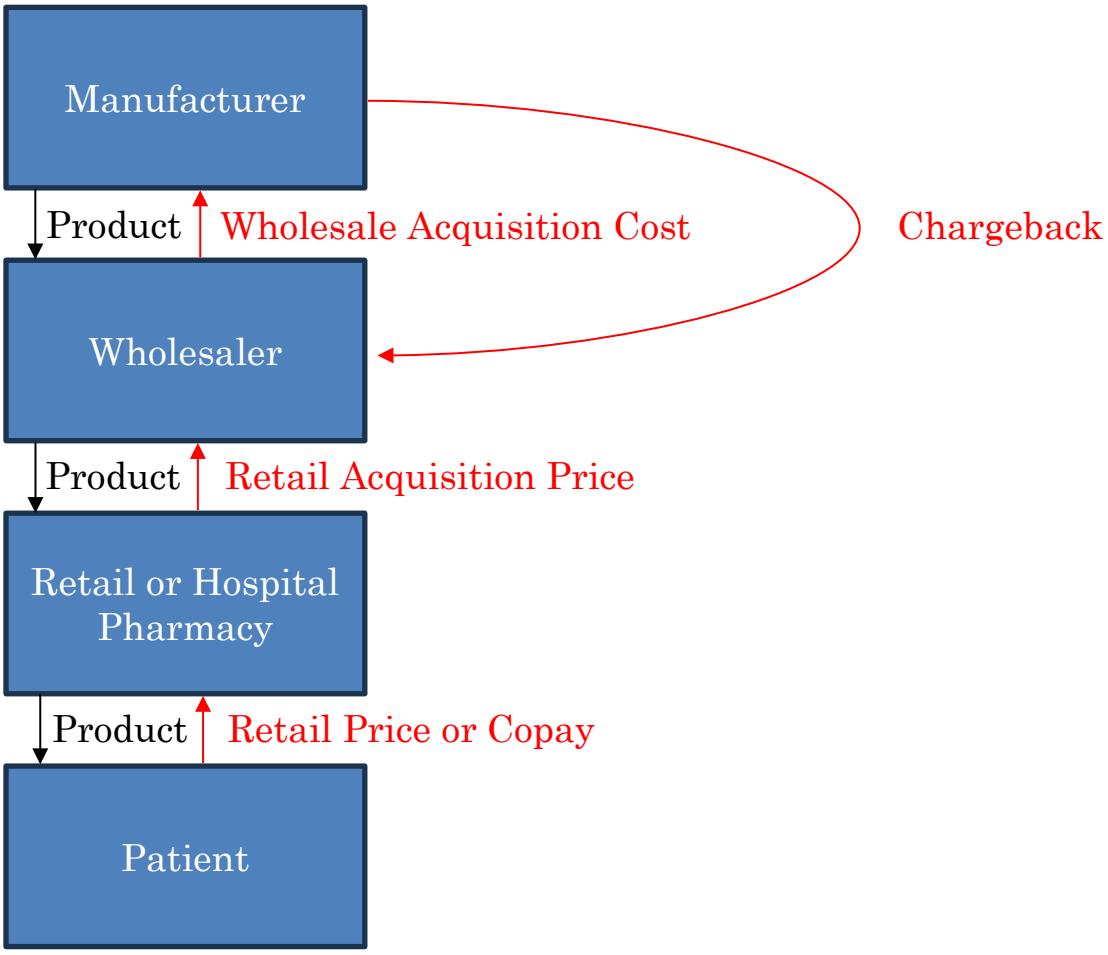

Figure 1. Basic diagram of brand-name drug supply chain, omitting payments to and from insurers and pharmacy benefit managers.[8]

[7] Berndt & Newhouse, *supra* note 3, at 9.

[8] Mulcahy & Kareddy, *supra* note 2, at 4.

Chargeback payments help prevent wholesalers from incurring losses associated with selling medicines for less than they paid to acquire them, including losses associated with the cost of unanticipated downstream discounts.

2. The price control that Colorado seeks to impose on Enbrel and other drugs will operate in a similar manner. The State's Prescription Drug Affordability Review Board ("Board") has determined that Enbrel is presently "unaffordable for Colorado consumers."[9] The Board will accordingly set a mandatory upper payment limit "appli[cable] to all purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in" Colorado. Colo. Rev. Stat. § 10-16-1407(5).

As Amgen's evidence shows, the upper payment limit will operate through the national supply chain to effectively constrain the prices that Amgen may charge for its selected product. Amgen demonstrated that wholesalers will continue to purchase drugs from the company for nationwide distribution at prices based on WAC, but the price of selected

[9] Prescription Drug Affordability Review Board, 2023 Affordability Review Summary Report: Enbrel 3 (Feb 23, 2024), https://perma.cc/72A5-N8KQ.

drugs sold by those wholesalers in Colorado will be capped by the State's upper payment limit. For each unit of drug sold in the State, therefore, Amgen established that a wholesaler will seek a chargeback to make up the difference between WAC and the upper payment limit.

While some aspects of the pharmaceutical supply chain may be "complex[]," Op. at 16, Amgen showed that *this* aspect is a straightforward, predictable part of its distribution system. Amgen's evidence, combined with "commonsense economic inferences," more than suffices: Amgen need not provide "evidence from expert economists" or even "from directly regulated parties." *Diamond*, slip op. at 18. Even if the upper payment limit nominally applies only to "downstream transactions," such as the wholesaler's sales to pharmacies, *id.* at 14, Amgen has shown that it will inevitably be forced to absorb much or all of the cost of these caps. *See Nat'l Infusion Ctr. Ass'n v. Becerra* ("*NICA*"), 116 F.4th 488, 500 (5th Cir. 2024) (relying on "basic economic rationality" and "predictable result[s]" of drug-price regulation to find standing). That is, Amgen, whose product is subject to an upper payment limit, will suffer the lion's share of the financial injury within the supply chain—and

accordingly is perfectly suited to challenge the price control on its own products.

B. Pre-enforcement review is appropriate based on demonstrated injury to Amgen

Courts have long rejected the district court's theory of standing and have allowed pre-enforcement suits by manufacturers to protect the position of their products in the marketplace. Amgen's injury is far more than speculative or distant—indeed, it is near-certain and imminent—and delaying review of Amgen's constitutional claim would compound harm to Amgen while serving no valid purpose.

1. The district court viewed Amgen's right to challenge the law's application to Enbrel as suspect on the ground that Amgen was "an unregulated party." Op. at 14. That is incorrect: As Amgen explains, "Amgen is a direct object of regulation because the price cap will regulate the price of Amgen's product." Br. at 38 (emphasis omitted). But even if Amgen were properly considered an unregulated party, lawsuits by "unregulated plaintiff[s]" are "typical APA suit[s]," because those parties "often will sue under the APA to challenge an allegedly unlawful agency rule that regulates others but also has adverse downstream effects on the plaintiff." *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S.

799, 826 (2024) (Kavanaugh, J., concurring). Yet under the district court's reasoning, such plaintiffs would lack a remedy *under Article III*, in a manner that even Congress could not fix.

As the Supreme Court has explained, a plaintiff need not be the direct object of governmental action to establish standing; instead, the plaintiff may rely on "the predictable effect of Government action on the decisions of third parties." *Dep't of Com. v. New York*, 588 U.S. 752, 768 (2019); *see Diamond*, slip op. at 9, 14. Courts have accordingly upheld the standing of supply chain participants where "regulation (or lack thereof) [will] cause downstream or upstream economic injuries to others in the chain," including "manufacturers, retailers, suppliers, competitors, or customers." *Diamond*, slip op. at 13 (quoting *Food and Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 384 (2024)); *see Energy Future Coal. v. E.P.A.*, 793 F.3d 141, 144 (D.C. Cir. 2015) (regulation of one company's use of another company's product renders "both" companies "object[s] of the action … at issue" (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992)). That principle suffices to establish Amgen's standing here to challenge price caps imposed on its products.

Indeed, courts have found standing in cases with much more circuitous theories of injury. In *Texas Association of Manufacturers v. United States Consumer Product Safety Commission*, 989 F.3d 368 (5th Cir. 2021), chemical manufacturers challenged an agency rule prohibiting the manufacture or sale of any children's toy or childcare article containing a certain concentration of a chemical that the manufacturers produced. *Id.* at 372-75, 380. The court of appeals upheld their standing, even though "[t]he record d[id] not contain any indication that [the manufacturers'] products are used or have been used in children's toys or child care articles." *Id.* at 377. "The Supreme Court routinely recognizes probable economic injury resulting from governmental actions that alter competitive conditions," the court of appeals explained, and the "threat of reduced sales to companies that manufacture children's toys and child care articles [wa]s sufficiently concrete" to support the plaintiffs' standing. *Id.* Here, of course, the supply chain linking Amgen to wholesalers' sale of its products to Colorado pharmacies is far more direct and concrete—and supported by actual evidence.

This Court, too, has long upheld the standing of putatively unregulated parties to challenge governmental action affecting their interests. Competitor standing exists, for instance, where "the challenged government action" only regulates a competitor, but nevertheless "nonspeculatively threaten[s] economic injury to the challenger by the ordinary operation of economic forces," such as a "price-lowering" effect. *Incyte Corp. v. Sun Pharm. Indus., Inc.*, 136 F.4th 1096, 1104 (Fed. Cir. 2025) (quoting *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357, 1364 (Fed. Cir. 2019)). The same logic applies here to a regulation that will—invariably and by design—lower prices throughout the pharmaceutical supply chain.

This Court's decision in *Canadian Lumber Trade Alliance v. United States*, 517 F.3d 1319 (Fed. Cir. 2008), is also instructive. There, the Court upheld the standing of the Canadian Wheat Board to challenge payments made to the North Dakota Wheat Commission, which promoted American wheat sales. *Id.* at 1332-34. In so holding, this Court rejected the government's argument that a plaintiff must provide a robust "empirical analysis" linking individual payments to "specific, demonstrated economic harms (e.g., lost sales, decreased market share)."

Id. at 1332. While a key purpose of standing is "to ensure that the plaintiffs have a stake in the fight," the Court explained, that purpose is adequately served through deployment of "economic logic" and does not require a significantly "higher level of certainty." *Id.* at 1333. Here, the economic harm to Amgen from binding price caps on its products is far more direct and predictable than the payments at issue in *Canadian Lumber*. Amgen's submission of unrefuted evidence to support its injury was more than sufficient, moreover, as "affirmative findings of fact" are not even necessary; where it is "rational to infer" injury as a matter of basic economics, injury-in-fact may be "*presumed*." *Id.* at 1334.

Manufacturers like Amgen will also "incur costs" well before an upper payment limit is actually set, as they "must now monitor" whether their prices will trigger regulatory provisions in several states. *State Nat'l Bank of Big Spring v. Lew*, 795 F.3d 48, 53 (D.C. Cir. 2015) (Kavanaugh, J.). Those compliance costs independently confer standing. *See Grand River Enters. Six Nations, Ltd. v. Boughton*, 988 F.3d 114, 121 (2d Cir. 2021) (courts of appeals are "nearly uniform" in upholding Article III standing based on "compliance costs associated with an increased regulatory burden").

2. The district court further erred in holding that Amgen's injuries were speculative simply because the Board has yet to set an upper payment limit for Amgen's products. *See* Op. at 16-17. As this Court has repeatedly explained, "a plaintiff need not 'await the consummation of threatened injury to obtain preventive relief.'" *Mil.-Veterans Advoc. v. Sec'y of Veterans Affs.*, 7 F.4th 1110, 1122 (Fed. Cir. 2021) (quoting *Biotech. Indus. Org. v. District of Columbia ("BIO")*, 496 F.3d 1362, 1370 (Fed. Cir. 2007)). A substantial likelihood is sufficient, a bar that has far been surpassed here. Pre-enforcement review is particularly necessary in cases like this, where a plaintiff faces the prospect of navigating numerous state pricing proceedings simultaneously, while not being able to secure pre-enforcement review of any of them.

BIO provides an on-point example of pre-enforcement review. There, the District of Columbia enacted legislation banning the sale of drugs for "excessive price[s]." 496 F.3d at 1365. Even though the District had yet to identify any excessive prices—much less apply the law to specific sales—this Court found that an association of manufacturers had standing to challenge the regime, given the "strong likelihood that the District [was] imminently likely to enforce [the law] against" them. *Id.* at

1370. Here, Colorado is just as "imminently likely" to enact an upper payment limit for Enbrel, which the State's Board has *already* declared "unaffordable." Op. at 6.

BIO is far from alone in recognizing the appropriateness of pre-enforcement review when the government regulates aspects of the pharmaceutical supply chain. In *NICA*, for instance, the Fifth Circuit upheld the standing of an association of cancer-drug infusion providers to challenge a statute requiring reduced prices for certain Medicare drugs. The government argued that the providers lacked standing, including because FDA had already approved a generic competitor, the entry of which into the market could render the selected drug "ineligible" for price controls. 116 F.4th at 499. But because the government could not show that entry of a generic competitor "predictably follows from FDA approval," the court of appeals disregarded that possibility as too "speculative." *Id.*

Here, the district court accepted Colorado's speculation that the Board might not set an upper payment limit for Enbrel (even though it had already selected the drug for a price cap), Op. at 16-17, and the court added its own speculation that the price cap might somehow be *higher*

than Enbrel's current price (even though the Board had already determined that the drug was "unaffordable"), Op. at 17. As in *NICA*, such unsupported speculation that the government *might* change course is insufficient to defeat standing.

NICA also makes clear that those affected by governmental price controls have standing to challenge them in advance "even if we do not know the exact price" that will ultimately be set. *NICA*, 116 F.4th at 499. The court of appeals there acknowledged that the plaintiff infusion providers would not be affected by the challenged law unless the directly regulated parties (pharmaceutical manufacturers) chose to accept reduced prices, rather than exiting the program altogether. Pointing to the familiar principle that standing may rest "on 'the predictable effect of Government action on the decisions of third parties,'" the court explained that manufacturers were unlikely to do so as a matter of "basic economic rationality." *Id.* at 500 (quoting *Dep't of Com.*, 588 U.S. at 768). The same is true here: As a matter of basic economic reality, directly regulated wholesalers are highly unlikely to fully absorb the price reductions mandated by Colorado's law.

Nor is there any practical or prudential reason to delay review until Colorado sets the upper payment limit. For one thing, Amgen incurs compliance costs now. *See State Nat'l Bank*, 795 F.3d at 53. Without pre-enforcement review, manufacturers like Amgen will be required to establish compliance regimes for state laws that, as explained below, are plainly preempted by federal law. Manufacturers will also need to alter their business practices, potentially even taking steps to withdraw a drug from sale within the regulating state. *See* Colo. Rev. Stat. § 10-16-1412. And these harms accrue well before any upper payment limit becomes binding.

In addition, Colorado has already determined that Enbrel is "unaffordable" for the State's consumers, and it is currently establishing an upper payment limit to reduce the drug's "excessive cost." Colo. Rev. Stat. § 10-16-1407(2). The State's rule simply leaves space to slot in numbers—"The upper payment limit for Enbrel is set at [price] per [unit]"[10]—and final rulemaking hearings to establish those numbers are

[10] Colo. Dep't of Regul. Agencies, Draft Enbrel Proposed Rule (Dec. 25, 2024), https://www.dora.state.co.us/pls/real/SB121_Web.Show_Rule?p_rule_id=10523.

underway.[11] Colorado is thus "all but certain" to set an upper payment limit below current prices. *NICA*, 116 F.4th at 500. Nor does the nature of Amgen's legal challenge depend on the particular price that the Board will set.

Finally, delaying judicial review until an upper payment limit has been set makes little sense because there will be no way for Amgen to recover from Colorado for harm inflicted while the litigation is ongoing. Even assuming Amgen could quantify economic damages from the price cap, the State's sovereign immunity would preclude recovery. An upper payment limit may become effective six months after it has been established, Colo. Rev. Stat. § 10-16-1407(5), but six months is likely insufficient to litigate such a constitutional challenge to judgment. To prevent irreparable harm, therefore, Amgen may be forced to seek emergency relief in the district court, potentially followed by a request for emergency relief on appeal. The judicial interest in orderly resolution of litigation thus further supports permitting this pre-enforcement challenge.

[11] *Id.*

C. The district court's cramped view of injury-in-fact undermines effective judicial review of state regulation

The district court's decision not only misapplies the law, it also undermines governmental accountability in a manner the Supreme Court rejected once again in *Diamond*. The court's reasoning would insulate broad swaths of market-moving regulation from pre-enforcement judicial review whenever a state or federal agency can assert some remote, counterfactual possibility that a law might not have its intended effect. Worse still, the court's narrow conception of standing applies equally to challenges to state *and* federal regulations.

Judicial review of governmental action serves a vital role in a functioning legal system. Courts have long recognized that "[t]he very essence of civil liberty … consists in the right of every individual to claim the protection of the laws." *Marbury v. Madison*, 5 U.S. 137, 163 (1803). Courts accordingly must exercise their powers to "guard the people from the arbitrary use of governmental power," *Kisor v. Wilkie*, 588 U.S. 558, 614 (2019) (Gorsuch, J., concurring), and have a "virtually unflagging obligation … to exercise the jurisdiction given them." *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976).

The need for meaningful review of agency action is particularly acute in light of the extraordinary growth of the administrative state. The United States government now comprises a "vast and varied federal bureaucracy" that "wields vast power … touch[ing] almost every aspect of daily life," *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 499 (2010), and has long since "expan[ded] … into new territories the Framers could scarcely have imagined," *Seila Law LLC v. CFPB*, 591 U.S. 197, 231 (2020). Its operations are effectuated through "hundreds of federal agencies poking into every nook and cranny of daily life," *City of Arlington v. FCC*, 569 U.S. 290, 315 (2013) (Roberts, C.J., dissenting), including by "produc[ing] reams of regulations—so many that they dwarf the statutes enacted by Congress." *Kisor*, 588 U.S. at 629 (Gorsuch, J., concurring in the judgment) (quotation marks omitted). This enormous expansion of the administrative state poses "a significant threat to individual liberty." *Seila Law LLC*, 591 U.S. at 240 (Thomas, J., concurring in part and dissenting in part).

States' regulatory regimes have mushroomed in similar fashion. States have collectively imposed more than 6.5 million regulatory

restrictions on private parties.[12] Five states together impose nearly 1.6 million regulatory restrictions, an increase from approximately 1.5 million just five years ago.[13] These rules layer on top of more than 1 million more imposed by the federal government.[14] State and federal agencies thus exercise significant control over private actors, especially those like Amgen with nationwide reach.

Judicial review is an essential check against this accretion of power. *See Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 65 (1976) (Brennan, J., concurring in the judgment) (describing "judicial review of administrative action" as "essential" for "protection of individuals illegally harmed" and for furthering "congressionally mandated goals"). Courts accordingly reject governmental attempts to delay or undermine the effectiveness of judicial review of agency action. For instance, statutes cannot be interpreted to displace the APA's judicial review

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[12] Mercatus Center, Snapshots of State Regulations: 2024 Edition (Aug. 6, 2024), https://www.mercatus.org/regsnapshots24.

[13] *Compare* Snapshots of State Regulations: 2024 Edition, *with* Mercatus Center, Quantifying Regulation in US States with State RegData 2.0 (Aug. 31, 2020), https://www.mercatus.org/research/data-visualizations/quantifying-regulation-us-states-state-regdata-20.

[14] Mercatus Center, Census of Regulatory Restrictions 10 (2022), https://www.mercatus.org/media/76001/download?attachment.

provision without "'clear and convincing evidence' of congressional intent to preclude judicial review." *Guerrero-Lasprilla v. Barr*, 589 U.S. 221, 229 (2020) (quoting *Reno v. Cath. Soc. Servs., Inc.*, 509 U.S. 43, 64 (1993)). And recently, the Supreme Court gave the Administrative Procedure Act's statute of limitations a broad interpretation in order to "vindicate[] the APA's 'basic presumption' that anyone injured by agency action should have access to judicial review," which "respects our 'deep-rooted historic tradition that everyone should have his own day in court.'" *Corner Post*, 603 U.S. at 824 (first quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967); and then quoting *Richards v. Jefferson Cnty.*, 517 U.S. 793, 798 (1996)).

In light of these principles, this Court has explained that the standing doctrine is not intended to thwart judicial review. Rather, its purpose is merely "to ensure that the plaintiffs have a stake in the fight and will therefore diligently prosecute the case." *Canadian Lumber*, 517 F.3d at 1333. Given this limited role, "[i]njury-in-fact is not Mount Everest." *Id.* The central importance of judicial review of governmental action counsels against infusing constitutional standing doctrine with heightened and (often) insurmountable evidentiary burdens divorced

from "commonsense economic principles." *Diamond*, slip op. at 14. Such artificial burdens are unnecessary to prevent suit by "mere bystander[s]" who lack "a personal stake in the dispute," or to "assure that the legal questions presented to the court will be resolved … in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action." *All. for Hippocratic Med.*, 602 U.S. at 379-80 (citations and quotation marks omitted).

Yet the decision below uses Article III as a shield against judicial review by disregarding the intended real-world effects of governmental regulation. If accepted, it would leave without a remedy countless businesses affected by unconstitutional governmental action. The opinion blesses a playbook, rejected in *Diamond*, in which the government can evade judicial review by ostensibly targeting only a limited portion of the supply chain—even if, in practice and by design, the regulation will affect other supply chain participants as well. *See Diamond*, slip op. at 19. Forcing injured manufacturers to rely on other regulated entities to challenge government action—even where those entities will not bear the economic burden of the regulation as a practical matter—would effectively shield significant regulations from judicial

scrutiny. That dynamic holds true here, where Amgen's evidence shows that regulated wholesalers have limited incentive to challenge Colorado's law.

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

Applying an unduly restrictive test for standing would be especially pernicious in the context of pharmaceutical patents and pricing, which reflect Congress's careful balancing of competing considerations. Drug development is a complicated, lengthy, and expensive endeavor. To incentivize such innovation, Congress has repeatedly acknowledged the importance of patent exclusivity for pharmaceutical products—a plan that has successfully stimulated an explosion of research and development.

Colorado's price-control scheme upsets that careful balance by restricting manufacturers' ability to market their products during the period of patent exclusivity. To permit a State to evade preemption through the creative drafting and interpretation of its statutes—even temporarily—would threaten the innovation at the heart of the patent system. The district court's erroneous view of standing effectively

prevents pre-enforcement judicial review of state laws that undermine patent rights.[15]

A. Federal patent law reflects a careful balance of incentives for innovation

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. The 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 allows the patent holder, as the sole entity entitled to offer its product, to "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). "[E]conomic rewards during the period of exclusivity are the carrot" for investing in development, and "the only limitation on the size of the

[15] The district court's standing holding also prevented it from ruling on Amgen's other claims, including its Commerce Clause claim. *See Ass'n for Accessible Medicines v. Ellison*, No. 24-1019, 2025 WL 1660112, at *2 (8th Cir. June 12, 2025) (accepting Commerce Clause challenge to drug price-control scheme).

carrot should be the dictates of the marketplace." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995); *accord 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." *Kewanee Oil Co.*, 416 U.S. at 480. Once the patent expires, others may rely on the disclosure to compete with the patent holder, "ultimately providing the public with the benefit of lower price through unfettered competition." *BIO*, 496 F.3d at 1373.

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 this Court recognized in *BIO* when striking down the District of Columbia's 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." *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 a single new medicine.[16]

New drug development also faces incredibly long odds. Only one compound in 5,000 that enters preclinical testing will achieve FDA approval, for a failure rate of 99.98%.[17] Among the small share of investigational medicines that get as far as entering clinical trials, less than 12% ever achieve approval by the FDA;[18] and of those approved,

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[16] 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.

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

[18] DiMasi et al., *supra* note 16, at 23.

only one in five will ever generate revenues that exceed the average cost of developing a medicine.[19]

Recognizing these challenges, Congress in 1984 enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as Hatch-Waxman Act. 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). To compensate for the time-consuming regulatory hurdles that developers must surmount, the Act "extend[ed] the amount of time for which [pharmaceutical] patents are issued." *Id.* at 19-20. This "create[d] a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs." *Id.* at 18. This carefully crafted framework reflects a considered balance: providing 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

[19] 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.

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 Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

What Hatch-Waxman did for patented and generic small-molecule drugs, the Biosimilar Price Competition and Innovation Act ("BPCIA") did for biologics, like Amgen's Enbrel. Pub. L. No. 111-148, §§ 7001-03, 124 Stat. 119, 804-21 (2010). Congress wanted to speed entry into the market of competing products (biosimilars). Rather than curtailing manufacturers' rights during the patent term, however, Congress created an expedited pathway for approval of biosimilars, which come to market after the biologic's patent term has expired.[20]

B. Colorado's law, which targets patented drugs and threatens pharmaceutical innovation, is preempted

The Hatch-Waxman Act and BPCIA spurred a dramatic increase in research and development for drugs that have saved countless lives and improved the quality of life for millions more. Colorado apparently thinks Congress got this balance wrong, and seeks to chart its own path without

[20] *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).

taking into account the enormous costs of drug development or the need to incentivize investments. The State's statute, and the Board's activities, cannot be squared with the legal regime favoring innovation that Congress created.

1. Colorado's price-control statute—as reinforced at every stage of the Board's review—myopically focuses on patented products. The law empowers the Board to "[p]erform affordability reviews of prescription drugs" and "[e]stablish upper payment limits for prescription drugs." Colo. Rev. Stat. § 10-16-1403(1)(b)-(c). Colorado initially identified 604 prescription drugs eligible for an affordability review based on their list prices.[21] *Id.* § 10-16-1406(1). The overwhelming majority are protected by federal patents.[22] That is unsurprising: Legislative history makes clear

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

[22] *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/2_PrioritzedSummaryList.

that Colorado's law *intentionally* targets patented products rather than generics or biosimilars.[23]

Next, the Board ranked eligible drugs using a methodology that prioritizes those with the highest total payment amounts.[24] The 50 highest-ranked drugs were then referred to an advisory council, which recommended narrowing the list to 23 drugs.[25] The council also recommended that the Board decline to select drugs with available alternatives, further reinforcing the focus on patented products.[26] From there, the law affords discretion to select drugs for an affordability review—but yet again, it homes in on patented drugs by directing officials to weigh whether the drug has an "equivalent … available for sale." Colo. Rev. Stat. § 10-16-1406(2)(a). Ultimately, Colorado selected five patented

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[23] *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.

[24] *See* Eligible Drug Dashboard, *supra* note 22.

[25] PDAB, Prescription Drug Affordability Board Meeting at 1:16:05-1:17:39 (Aug. 4, 2023), https://tinyurl.com/PDABMeeting.

[26] *Id.* at 1:09:35-1:09:44.

drugs for affordability reviews: Enbrel, Genvoya, Cosentyx, Stelara,[27] and Trikafta.[28] In selecting these drugs from the list of 23, officials expressly *removed* drugs with generic or therapeutic equivalents.[29]

Finally, in deciding whether to subject a drug to price controls, the Colorado statute once more requires the Board to consider the "cost and availability" of "alternatives to the prescription drug." Colo. Rev. Stat. § 10-16-1406(4)(b). Officials considered the implications of manufacturers' patents *only* insofar as "such intellectual property rights can be associated with increased drug prices."[30] Colorado has since concluded that Enbrel, Cosentyx, and Stelara are unaffordable and must be subject to an upper payment limit.

The Board will now proceed to impose price controls on sales of Enbrel.[31] The first rulemaking hearing to set an upper payment limit was held on May 23, 2025, and a second hearing is scheduled for July 11. After

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[27] At least one patent for Stelara has since expired.

[28] 2023 Activities Summary Report, *supra* note 21, at 6.

[29] *Board Meeting*, *supra* note 25, at 2:09:21-2:10:48.

[30] Affordability Review Summary Report, *supra* note 9, at C-11.

[31] *See* Draft Enbrel Proposed Rule, *supra* note 10.

a third hearing, the Board will enact a rule limiting the drug's price. *See* Colo. Rev. Stat. § 10-16-1407.

State drug price controls like those authorized by Colorado's law are irreconcilable with the regime that Congress established. The twin objectives of patent law are "reward[ing] innovators with higher profits and … keep[ing] prices reasonable for consumers." *BIO*, 496 F.3d at 1373. These objectives "are in dialectic tension," and "Congress, as the promulgator of patent policy, is charged with balancing these disparate goals." *Id.* Colorado's price-control regime is a "clear attempt to restrain" manufacturers' pricing decisions, and thus to "diminish[] the reward to patentees in order to provide greater benefit to [some] consumers." *Id.* 1374. Such state efforts are "contrary to the goals established by Congress in the patent laws." *Id.*

2. Review of Colorado's price-control scheme is necessary now. Though unprecedented when enacted, the law no longer stands alone. Since 2019, at least nine states have enacted affordability review statutes. [32] Four of those states—including Colorado, Maryland,

[32] Those states include Colorado, Maine, Maryland, Minnesota, New Hampshire, Oregon, Washington, Massachusetts, and New York. *See*

Minnesota, and Washington—have empowered their respective drug pricing boards to set price controls.[33] At least a dozen more are considering similar legislation to establish affordability review panels and upper payment limits for pharmaceuticals.[34]

This trend represents a fundamental threat to the United States' leadership in pharmaceutical innovation. So far, the Hatch-Waxman Act and the BPCIA have worked as Congress intended. Their incentives have encouraged innovators to boost their research spending, while also spurring massive growth in generic competition when periods of patent exclusivity expire. Before Hatch-Waxman, manufacturers invested less than $10 billion per year in research and development.[35] In the last decade, PhRMA members alone have invested approximately $800 billion

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Nat'l Acad. for State Health Pol., Comparison of State Prescription Drug Affordability Review Initiatives (Jan. 4, 2024), https://nashp.org/comparison-of-state-prescription-drug-affordability-review-initiatives/.

[33] *See* Colo. Rev. Stat. § 10-16-1407; Md. Code, Health-Gen. § 21-2C-13; Minn. Stat. § 62J.92; Wash. Rev. Code § 70.405.050.

[34] *See* Nat'l Acad. for State Health Pol., 2025 State Legislation to Lower Prescription Drug Costs (May 8, 2025), https://nashp.org/state-tracker/2025-state-legislation-to-lower-prescription-drug-costs/.

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

in the search for new treatments and cures, reaching about $100 billion per year during 2021, 2022, and 2023.[36] And these innovation efforts have been fruitful: Between 2000 and 2023, FDA approved nearly 900 new prescription medicines.[37]

The Colorado regime, and others like it, will undermine innovation. Manufacturers accept the massive up-front investments and uncertainty involved in drug development based on the prospect of earning a return—a prospect that is naturally contingent on future pricing.[38] Price controls like Colorado's accordingly create a less-favorable investment environment, causing researchers to scale back development programs and ultimately harming patients.

To be sure, Colorado may believe that mandating artificially low prices is worth the cost of hindering innovation, but that is immaterial.

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[36] PhRMA, 2024 PhRMA Annual Membership Survey Table 1, https://cdn.aglty.io/phrma/global/resources/import/pdfs/PhRMA_2024%20Annual%20Membership%20Survey.pdf.

[37] Andrew Powaleny, *Novel Medicines Approved in 2022 Offer Increased Treatment Options for Patients*, PhRMA Blog (Jan. 23, 2023), https://phrma.org/blog/novel-medicines-approved-in-2022-offer-increased-treatment-options-for-patients.

[38] 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).

What matters is that *Congress* has rejected that view. Federal law authorizes an extended patent term that carries with it the power to set prices. States are not free to strike a different balance.

CONCLUSION

The decision below should be reversed.

Dated: June 30, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 30, 2025, a true and correct copy of the foregoing was filed with the Clerk of Court using the Court's CM/ECF System, which will send notice of such filing to all registered users.

Dated: June 30, 2025

/s/ Jeffrey L. Handwerker
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