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Legal Sidebar

Litigation over State Attempts to Lower Drug Costs: Prescription Drug Affordability Boards (PDABs)

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Prescription drug affordability continues to dominate headlines, with President Trump taking actions to implement Most Favored Nation Pricing by negotiating directly with pharmaceutical companies and proposing new prescription drug payment models for Medicaid, Medicare Part B, and Medicare Part D drugs. At the same time, pharmaceutical companies continue to challenge the implementation of the Medicare Drug Price Negotiation Program, with two pharmaceutical companies asking the U.S. Supreme Court to intervene as the program announced prices for the second round of selected drugs.

Against this backdrop, several states have also taken actions meant to lower drug costs, enacting various measures including price transparency laws, anti-gouging statutes, outcomes-based contracts, state drug wholesale importation programs, and prescription drug affordability boards (PDABs). Many of these state measures, including PDABs, face significant and ongoing legal challenges from drug manufacturers.

PDABs are independent, state-level boards that review prescription drug costs. Some state PDABs are empowered to take additional actions to lower the prices of certain drugs by establishing upper payment limits (UPLs), which generally limit the amount that in-state purchasers may pay for the drug. As of August 2025, at least ten states have active PDABs, while at least eleven other states are considering legislation that would create PDABs.

Drugmakers have responded by challenging the constitutionality of PDABs and raising legal questions about their interaction with federal laws such as Medicare, Medicaid, and patent law. For instance, Amgen, Inc., the maker of the reverse transcriptase inhibitor Enbrel (a popular treatment for various types of arthritis and other inflammatory diseases) has now twice sued the State of Colorado over the state's attempts to set a UPL for Enbrel. The first suit, which Amgen filed in 2024 before the state set a UPL for Enbrel, was dismissed on procedural grounds. Amgen filed its second lawsuit in October 2025, after Colorado set a UPL for Enbrel, and that suit is currently pending in federal district court. In both suits, Amgen has argued that Colorado's PDAB law is preempted by federal patent laws and is invalid under the Constitution's Dormant Commerce Clause. This sidebar analyzes some of the legal arguments in these cases and discusses several considerations for Congress in light of the litigation against state PDAB laws.

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Background

In 2019, Maryland became the first state to enact legislation to establish a PDAB. Since that time, several other states have created their own PDABs, some of which are more comprehensive than others. For example, some states (e.g., Maine, Massachusetts, and New Hampshire) have only empowered their PDABs to conduct drug affordability reviews and make pricing recommendations, actions that do not directly control a drug's price. On the other hand, at least five states (Colorado, Maryland, Minnesota, Washington, and Oregon) have authorized their PDABs to establish UPLs, which dictate the maximum price that can be paid or reimbursed for a drug by an in-state payer. Colorado's PDAB is notable, as Colorado is the only state that has actually set a UPL for a drug, and the two challenges brought by Amgen are the first cases to challenge the ability of PDABs to do so.

UPLs generally apply to state payers, including Medicaid (a joint federal-state program) and state health plans, but UPLs may apply more narrowly or broadly, depending on state law. For example, Minnesota's PDAB law specifically exempts UPLs from applying to Medicare or any health insurance plan regulated by the Employee Retirement Income Security Act (ERISA). By contrast, Colorado's PDAB law states that its UPLs will "appl[y] to all purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state in person, by mail, or by other means." The Colorado law contains a broad carveout, stating that a UPL will not be enforced against "a carrier or state agency that is required pursuant to state or federal law to purchase or reimburse a payer for a prescription drug" for which a UPL has been established. Colorado also subsequently clarified that a UPL will not apply to purchases by wholesalers, Medicare, or self-funded health plans regulated by ERISA.

Colorado's PDAB law allows the Board to select drugs meeting certain legislative criteria for affordability reviews in order to determine if the selected drug's price is "unaffordable for Colorado consumers." If a drug's price is found to be unaffordable, Colorado's PDAB may vote to set a UPL for that drug. As of the date of this writing, Colorado has undertaken affordability reviews for at least five brand-name drugs, including Enbrel, Stelara, Genvoya, Cosentyx, and Trikafta.

On February 23, 2024, Colorado's PDAB voted to establish a UPL for Enbrel, which is indicated for use in several autoimmune diseases, including rheumatoid arthritis, ankylosing spondylitis, and plaque psoriasis. In 2024, when conducting its affordability review of Enbrel and determining the drug was "unaffordable," the Board analyzed Enbrel's therapeutic benefit, its cost, and Colorado patients' ability to access the medication. The Board found that Enbrel's wholesale acquisition cost (WAC) had increased 1,582.24% since the drug was first FDA-approved in 1998.

In October 2025, Colorado became the first state to establish a UPL for any drug, unanimously voting to set a UPL for Enbrel of $600 per 50 mg unit; the price is similar to the Medicare maximum fair price for Enbrel, as negotiated by the Centers for Medicare and Medicaid Services as part of the Medicare Drug Price Negotiation Program. Enbrel's UPL is scheduled to take effect on January 1, 2027.

Legal Challenges to PDABs: *Amgen, Inc. v. Mizner*

To date, Amgen has filed two lawsuits, both in federal district court in Colorado, to challenge the constitutionality of the Colorado PDAB law and the UPL it set for Enbrel. The company asserted similar claims in each suit, with the distinction that the first suit was filed in March 2024, before the PDAB established a UPL for Enbrel, and the second on October 30, 2025, after the PDAB established a UPL. This section discusses the latest updates from both cases.

Amgen's First Lawsuit

In its first lawsuit, Amgen argued that Colorado's PDAB law violated the Supremacy Clause of the U.S. Constitution and was preempted by both federal patent law and Medicare law. The company also alleged that the PDAB law violated the Due Process Clause of the Fourteenth Amendment because it lacked necessary procedural protections for the Board to guide its decision-making and to avoid setting a "constitutionally inappropriate price[]." Amgen further posited that the PDAB law failed to provide sufficiently detailed standards to determine whether a selected drug was "unaffordable" and to set a UPL. The manufacturer also urged that Colorado's PDAB law violated the Dormant Commerce Clause because it was attempting to regulate "commercial transactions that occur entirely outside of the state of Colorado."

In response, Colorado argued that the district court lacked subject matter jurisdiction, because Amgen had not suffered an actual injury that was caused by the state's PDAB law. The state also claimed that a UPL had not yet been and might never be set for Enbrel, and that without a UPL in place, the suit was not ripe for judicial review. Colorado characterized the UPL as a "downstream payment regulation" that didn't directly apply to drug manufacturers like Amgen. On the merits, the state argued that any UPL it might set in the future would be a constitutional exercise of the state's police power to regulate for the protection of the health, safety, and welfare of its citizenry. The state further argued that because any UPL would not apply to Amgen directly, it could not be preempted by federal patent law. The state also urged that the patent exhaustion doctrine would also apply, such that once Amgen sold a drug to a wholesaler, the company would "exhaust" its patent rights and would lack control over subsequent drug sales.

On March 28, 2025, the U.S. District Court for the District of Colorado dismissed Amgen's case for lack of subject matter jurisdiction. Because the court dismissed the case on procedural grounds, it did not reach the merits of the parties' constitutional arguments. In its decision, the court discussed two issues, both of which are related to Amgen's standing to bring the suit: first, whether Amgen is directly regulated by the Colorado PDAB law, and second, whether Amgen has standing as an unregulated party.

In concluding that Amgen was not being directly regulated by Colorado's PDAB law, the court discussed the complexity of the prescription drug supply chain, noting that "[n]early all of Amgen's domestic sales are to wholesale distributors for the list price [also known as the WAC], and the wholesalers then sell Amgen's products to providers, hospitals, and pharmacies." Analyzing both the language of the Colorado PDAB statute and its legislative history, the court concluded that any UPL established in Colorado would not apply to wholesalers who purchase Enbrel directly from Amgen. The court found instead that "a UPL applies directly only to downstream transactions for the actual sales and reimbursements of the prescription drug dispensed to Colorado consumers." The court reasoned that the statute's use of the article "the" demonstrated lawmakers' intention to "cabin application of UPLs" to drug sales in which "'*the*' prescription drug is '*dispensed or distributed in Colorado*.'" The court also observed that the statute's legislative history indicates that the state intended for the UPL to "apply specifically to the state and municipalities, contractors and vendors, commercial health plans, providers, and pharmacies." For these reasons, the court said, Amgen was not directly regulated by the PDAB law and thus must establish standing to challenge the statute as an unregulated party.

With respect to the ability to establish standing as an unregulated party, the Colorado District Court looked to the Supreme Court's decision in *FDA v. Alliance for Hippocratic Medicine*, in which the Court found that an unregulated party could demonstrate standing by showing a "predictable chain of events leading from the government action to the asserted injury." The court disagreed with Amgen's argument that "basic economics and common sense" supported its standing argument, finding that the company was merely assuming that any UPL set for Enbrel would be lower than the WAC. In addition, the court said that the company did not factor into its standing argument the "complexity of the [drug distribution] supply chain," including rebates and other discounts that would also impact pricing. The court further

found that Amgen had not articulated a concrete injury, especially since a UPL had not yet been set for Enbrel. The court explained, "Amgen *might* be able to demonstrate harm *if* the Board sets a UPL for Enbrel; *if* that UPL is set lower than the WAC for Enbrel; and *if* wholesalers react by demanding that Amgen absorb any costs associated with the same." In other words, in the court's view, Amgen's economic arguments were overly speculative and thus could not be used to establish standing.

In April 2025, Amgen appealed the district court's ruling to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). Although Colorado District Court decisions are typically appealed to the U.S. Court of Appeals for the Tenth Circuit, Amgen appealed its case to the Federal Circuit, which has exclusive jurisdiction over patent appeals. The parties entered a joint stipulation of voluntary dismissal of the appeal in January 2026, stating that the "circumstances of [the] litigation have materially changed," because the state of Colorado set a UPL and Amgen filed a new lawsuit.

Amgen's Second Lawsuit

Amgen filed its second suit against the state of Colorado in Federal District Court on October 30, 2025, after Colorado's PDAB set a UPL on Enbrel. The second case was assigned to a different Colorado District Court judge than the first. As in its first complaint, Amgen asserts three claims: first, that the PDAB law is preempted by federal patent law; second, that the PDAB law violates the Due Process Clause of the Fourteenth Amendment; and third, that the PDAB law violates the Dormant Commerce Clause. Although the company's arguments are essentially the same in both cases, the second complaint articulates the harm that Amgen claims it will suffer if the UPL takes effect in January 2027.

Amgen first argues that the plain meaning of the Colorado PDAB statute applies the UPL for Enbrel directly to Amgen, "so long as the drug is eventually dispensed or administered in Colorado." In other words, Amgen argues that it is directly regulated by the law, which would provide an easier path for Amgen to demonstrate standing. The company goes on to state that even if it is not directly regulated by the state law because the law "applies only to downstream transactions," as the district court in the first case found, it will still "suffer substantial, irreparable harm" as a result of the UPL on Enbrel. To that end, Amgen argues that when the UPL takes effect, even if it does not apply directly to drug wholesalers, who typically purchase drugs at WAC, wholesalers "will not agree to purchase a product for more than what they can lawfully recover from reselling that product." The company also points to the legislative history of the state PDAB to illustrate that the statute's intended effect was to lower the prices that drug manufacturers can charge. Amgen further argues that implementation of the UPL for Enbrel would cause Amgen to incur lost revenue in the form of administrative costs for renegotiating contracts and modifying its payment systems.

On November 19, 2025, Colorado offered to stay enforcement of Enbrel's UPL while the case was being resolved, but the company declined the state's offer. Two days later, Amgen filed a motion for a preliminary injunction, requesting that the court issue an injunction to restrain the Colorado PDAB from enforcing Enbrel's UPL. The company asserts that it is entitled to an injunction because it will likely prevail on its claims that the PDAB violates federal patent law and deprives the manufacturer of due process. The company did not make any arguments about the Dormant Commerce Clause in the motion for a preliminary injunction. As of the date of this writing, the court has not yet decided the motion, and the litigation remains ongoing.

Considerations for Congress

In the midst of the continuing congressional debates over prescription drug prices, states have initiated their own legislative efforts to lower the cost of prescription drugs. More lawsuits against PDABs could

be filed, particularly if other states attempt to establish UPLs on Enbrel or other drugs, which could result in federal district or appellate courts reaching different conclusions about the constitutionality of PDABs.

It also remains to be seen whether court rulings regarding other state regulations of prescription drug prices will have implications for the PDAB litigation, particularly to the extent that there are similar patent preemption and/or Dormant Commerce Clause issues presented. For example, in October 2024, the U.S. Court of Appeals for the Eighth Circuit invalidated a Minnesota "anti-gouging" law in *Association for Accessible Medicines v. Ellison*, reasoning that the state law violated the Dormant Commerce Clause. In another example, several drug manufacturers, joined by PhRMA—the drug industry's trade association—filed a wave of lawsuits challenging state regulation of contract pharmacies in the 340B Drug Discount Program. Some of these suits, which are working their way through federal district and appellate courts, involve patent preemption and Dormant Commerce Clause challenges as well.

Legal scholars have noted the significant hurdles states face when attempting to regulate prescription drug prices, including some of the constitutional issues discussed above. Some scholars argue that "excessively priced" medications do not support the "public purposes of the patent system" and that federal patent laws should not hinder states from "addressing the urgent problem of excessively priced patented medications." In response, Amgen and some federal courts insist that the patent system is of vital importance to incentivize the costly drug research and development process and offset the cost of clinical trials and other testing needed to discover and obtain FDA approval of a new drug. Other legal scholars have advocated for more states to adopt PDABs that set UPLs at the Medicare-negotiated maximum fair price.

Congress may resolve these debates by amending federal patent laws to rebalance market incentives; Congress could also explicitly clarify whether and to what extent, if any, states should be permitted to regulate the prices of patented pharmaceuticals. Additionally, if Congress wished to further regulate the price of pharmaceuticals, it could consider what role, if any, states should have in that price regulation.

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