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Legal Sidebar

State Regulation of Prescription Drug Prices: Prescription Drug Affordability Boards and Related Litigation

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As conversations about health care costs, including prescription drug prices, continue in the 118th Congress, the federal Medicare Drug Price Negotiation Program, created in the Inflation Reduction Act, has continued to move forward. Despite several lawsuits challenging the program's validity under the federal Constitution and the Administrative Procedure Act, the Biden Administration recently announced negotiated prices for the first 10 selected drugs. The prices, which take effect in 2026, are to apply only to Medicare. At the same time, several states have also taken actions aimed at lowering drug costs for in-state payers. States have considered a variety of legislative approaches in the last five years, including price transparency laws, antigouging statutes, outcomes-based contracts, and prescription drug affordability boards (PDABs). Some of these state measures, including PDABs, face significant legal challenges from drug manufacturers.

PDABs are independent, state-level boards that review prescription drug costs, and some states have authorized their PDABs to take additional actions to lower the prices of certain drugs. As of April 2024, at least eleven states have enacted some form of a PDAB, and several others are considering such legislation. As the ensuing examples show, drugmakers have challenged the constitutionality of PDABs and raised 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 sued the State of Colorado after its PDAB voted in February 2024 to establish an upper payment limit (UPL) for Enbrel. Amgen challenged several aspects of Colorado's PDAB law, including that it is preempted by federal patent laws and is invalid under the Constitution's Dormant Commerce Clause. Additional lawsuits against the Colorado PDAB, as well as those challenging laws in other states, are anticipated, as Colorado recently found other drugs to be "unaffordable" for its consumers. This Sidebar analyzes some of the legal arguments in the Colorado case, *Amgen, Inc. v. Mizner*, and offers several considerations for Congress in light of the new state PDAB law trend.

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Background

In 2019, Maryland became the first state to enact legislation to establish a PDAB. Since that time, other states have taken various legislative approaches to PDABs, some of which are more sweeping than others. For example, some states have only empowered their PDABs to conduct drug affordability reviews and make pricing recommendations, which do not directly affect the drug's price. On the other hand, at least four states (Colorado, Maryland, Minnesota, and Washington) have authorized their PDABs to establish UPLs, which dictate the maximum price that can be paid or reimbursed for a drug in the state. Colorado's PDAB law, for example, 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." To date, Colorado has undertaken such a review for at least five brand-name drugs, including Enbrel, Stelara, Genvoya, Cosentyx, and Trikafta. If a drug's price is found to be unaffordable, Colorado's PDAB may set a UPL for that drug.

The Colorado PDAB statute defines the UPL as "the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the prescription drug." In other words, rather than focus on the price set by the manufacturer, the statute sets a price ceiling for in-state payers. UPLs and their applicability may differ by state. For example, Minnesota's PDAB law ties the UPL for drugs selected for the Medicare Drug Price Negotiation Program to the market fair price (MFP) negotiated under the Program, while providing statutory considerations for establishing a UPL for other drugs found to be unaffordable.

UPLs generally apply to state payers, including Medicaid and state health plans, but may apply more narrowly or broadly depending on state law. For example, Colorado 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 as a payer for a prescription drug" for which a UPL has been established. Colorado has also clarified that UPLs will not apply to purchases from wholesalers, Medicare, or self-funded plans regulated by ERISA. By contrast, Minnesota's law specifically exempts the UPL from applying to Medicare or any plan regulated by the Employee Retirement Income Security Act (ERISA).

In accordance with state law, before setting a UPL for an "unaffordable" drug, the Colorado PDAB must first identify eligible drugs, select drugs for an affordability review, and conduct such a review to determine whether the drugs are unaffordable for Colorado consumers. On February 23, 2024, a five-member PDAB in Colorado voted to establish a UPL for Enbrel (etanercept), which is indicated for use in several autoimmune diseases, including rheumatoid arthritis, ankylosing spondylitis, and plaque psoriasis. In conducting its review of the drug, the Board analyzed Enbrel's therapeutic benefit, cost, and patients' ability to access the medication. In accordance with the statute, the Board sought input from patients, caregivers, scientists, and medical doctors, as well as the manufacturer. The Board found that approximately 3,400 people in Colorado were using Enbrel in 2022, and that Enbrel's wholesale acquisition cost (WAC) had increased 1,582.24% since the drug was first FDA-approved in 1998.

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

Amgen, the manufacturer of Enbrel, filed a lawsuit challenging the constitutionality of the Colorado PDAB law in federal district court on March 22, 2024. In its complaint, Amgen asserts that Enbrel "provides disease-transforming and life-changing relief" to Coloradans, and has provided the state's patients "lower pain, less [disease] progression, and greater function" for decades. The company alleges that the state's law violates the Constitution's Supremacy Clause and is preempted by federal patent law

and Medicare law. Amgen additionally argues that Colorado's PDAB law violates the Due Process Clause of the Fourteenth Amendment because it lacks necessary procedural protections for the Board to avoid setting a "constitutionally inappropriate price[]." The drug maker further argues that the state law does not provide sufficient standards to determine whether a selected drug is "unaffordable" or for setting the UPL. Amgen further posits that Colorado's PDAB law violates the Dormant Commerce Clause by regulating "commercial transactions that occur entirely outside of the state of Colorado."

The case is proceeding in the federal district court for the District of Colorado. Amgen filed its motion for summary judgment on June 24, 2024, and Colorado filed a cross motion for summary judgment on August 9, 2024. The parties' patent law preemption and Dormant Commerce Clause arguments are discussed in further detail below.

Supremacy Clause and Patent Law Preemption

The Supremacy Clause, found in Article VI, clause 2, forms the backbone of federal preemption doctrine. It states that the Constitution and federal laws "made[] under the Authority of the United States, shall be the supreme Law of the Land," and are binding "notwithstanding" state law. The Supreme Court has distinguished between *express preemption* (i.e., Congress includes specific statutory language that says state laws are preempted) and *implied preemption* (i.e., the structure and purpose of the statute implies that Congress did not intend for states to legislate). Field preemption, a type of implied preemption, occurs where federal law is "so pervasive" that the states have no room to supplement it. The other type of implied preemption, conflict preemption, occurs when compliance with both state and federal law is impossible (impossibility preemption) or where the state law creates an obstacle to a federal law's objectives (obstacle preemption).

Pharmaceutical patents allow the holder of the patent the right to exclude competitors from making, using, selling, or importing the patented invention for a set period of time (generally 20 years from the date the patent application was filed). Patent monopolies are intended to encourage innovation and allow pharmaceutical companies to recoup costs related to research, development, and approval of their products, which can be both costly and time consuming. Patents may cover many different aspects of a drug beyond its active ingredient (such as methods of using or making the drug), and successful products are often covered by many patents. One study found that Enbrel (which was first marketed in 1998) has been covered by at least 47 different patents, creating what some critics call a "patent thicket." Additional patent filings and patenting strategies have also extended Enbrel's monopoly, with the latest patent on Enbrel set to expire in 2029, which would give the drug about 31 years of effective patent protection.

In its motion for summary judgment, Amgen argues that Congress carefully balanced the pharmaceutical field's competing interests via the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, which applies to chemical drugs, and the Biologics Price Competition and Innovation Act (BPCIA), which applies to biologics (such as Enbrel). These laws enable pathways for the development of generic drugs and biosimilars ("follow-on" products that are identical or similar to a brand-name drug or biologic). Amgen argues that "Congress has . . . struck an intentional balance" through both laws by allowing manufacturers a "reward" (i.e., a patent monopoly) for the development of a new therapy "while encouraging lower prices through competition after the patent term ends." Amgen says that Colorado's PDAB, and the UPL it will set for Enbrel, "impermissibly re-balances the statutory framework of rewards and incentives" set by federal patent laws, and is thus preempted.

In support of its argument that federal patent law preempts the Colorado PDAB statute, Amgen points to the U.S. Court of Appeals for the Federal Circuit's (Federal Circuit's) decision in *Biotech Industry Organization v. District of Columbia* (*BIO*), in which the court held that a D.C. law barring excessive pricing of patented drugs was preempted by federal patent law. (The plaintiff points to this case because although 10th Circuit precedent would ordinarily control, the Federal Circuit has exclusive jurisdiction

over patent appeals.) In *BIO*, the court found that the D.C. law created an obstacle to patent law's goal of providing appropriate incentives to innovate. The Federal Circuit concluded, "By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to rebalance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs."

Colorado responds with both procedural and substantive arguments. First, the state argues that the court lacks subject matter jurisdiction, because Amgen cannot demonstrate an actual injury or causation. Colorado urges that a UPL has not been and may never be set for Enbrel and that without a UPL in place, the suit is not ripe. On the merits, the state argues that any UPLs it may set are a constitutional exercise of its police power—the state power to regulate to protect the health, safety, and welfare of its citizenry. Because any UPL would not apply to Amgen directly (as it regulates what payers can pay, not what manufacturers charge), the state argues that cannot be preempted by federal patent law. Colorado further posits that the patent exhaustion doctrine applies, such that once Amgen sells its drug to wholesalers (at whatever price it likes), Amgen "exhausts" its patent rights and can no longer use its patent rights to control subsequent sales of the drug. The state argues, "Enshrined nowhere in federal patent law is a principle that a state may not regulate downstream transactions for the health and welfare of its citizens after a patent holder has sold its product." Rather, the state contends that "the opposite is clear: once Amgen sells its patented product, its rights and benefits under the federal patent law system are exhausted."

Colorado distinguishes the Federal Circuit's ruling in *BIO* by arguing that, unlike DC's price-gouging law, the Colorado PDAB law does not directly regulate the manufacturer's sale prices, and that "[t]his key difference means that patent exhaustion would have occurred by the time Enbrel would be subject to a UPL." Similarly, the state says the law would not be preempted by the Hatch-Waxman Act or the BPCIA because of the exhaustion concept; the manufacturer receives the "enhanced profit" that Congress intended through its sale to wholesalers, which the PDAB law does not regulate directly. In support of its argument, Colorado cites the 2017 Supreme Court decision in *Impression Products v. Lexmark International*, where the Court observed that "the Patent Act does not guarantee a particular price," but rather "ensures that the patentee receives one reward . . . for every item that passes out of the scope of the patent monopoly."

Dormant Commerce Clause

Article I, Section 8, clause 3 of the Constitution gives Congress power "[t]o regulate Commerce with foreign nations, and among the several States, and with the Indian Tribes." The Supreme Court has interpreted the Commerce Clause as not only a "positive grant of power to Congress," but also as a limitation on states' ability to enact laws that unduly restrict interstate commerce, even if Congress has not legislated in that area. Two principles have emerged from the Court's modern Dormant Commerce Clause decisions. First, states may not legislate in ways that discriminate against out-of-state goods or "nonresident economic actors." Such state laws are considered *per se* invalid (i.e., they are presumed to violate the Dormant Commerce Clause) and are struck down—unless the state can show that the law is narrowly tailored, advances a legitimate local purpose, and the state had no nondiscriminatory alternatives. Second, a state may not make even a facially neutral law that unduly burdens interstate commerce. To evaluate the constitutionality of such facially neutral laws, the Court has applied the *Pike* balancing test and will generally uphold laws that serve a "legitimate local purpose" if the local benefit clearly exceeds the burden on interstate commerce.

At times, the Supreme Court has applied an "extraterritoriality principle" in its Dormant Commerce Clause jurisprudence to hold that a state cannot enact a facially neutral law with the effect of "directly controlling" economic activities that occur "wholly outside the boundaries of" the state. In the 2003 case *Pharmaceutical Research and Manufacturers of America v. Walsh*, the Court appears to have taken a step

back from the extraterritoriality doctrine, declining to extend its earlier precedents. The *Walsh* case concerned a district court's decision to preliminarily enjoin a Maine statute that allowed the state to negotiate additional rebates with drug manufacturers to fund price reductions for in-state Medicaid drugs. A majority of the Court held that the district court erred by enjoining the state law, which, it held, did not violate the Dormant Commerce Clause. The Court distinguished the Maine law from "price control or price affirmation statutes," finding that the law did not expressly or effectively regulate out-of-state transactions and did not require manufacturers to "sell their drugs to a wholesaler for a certain price."

More recently, in 2023, the Court upheld a California law banning the in-state sale of pork meat from pigs that had been "confined in a cruel manner." In that case, *National Pork Producers v. Ross*, the Court rejected the argument that state regulations that are not facially discriminatory but affect out-of-state interests are "almost *per se*" invalid. The fractured ruling in *National Pork Producers* indicates disagreement among the justices about how to evaluate Dormant Commerce Clause challenges to state regulations, however, and the relevance of extraterritoriality in future challenges is unclear.

In its motion for summary judgment, Amgen argues that the Colorado PDAB law violates the Dormant Commerce Clause because it "directly regulates transactions that occur entirely outside of Colorado." The company posits that the UPL regulates "upstream" transactions, because it applies to "*any* financial transaction" involving the drug, which could include, for example, "a sale by a manufacturer in Ohio to a distributor in Illinois." In support, Amgen points to a 2018 Fourth Circuit decision and a 2023 Minnesota federal district court decision, both of which involved anti-price-gouging statutes. Citing to the principle of extraterritoriality, the courts held that states may not directly regulate the sale of a pharmaceutical product that occurs in another state just because that product was eventually sold in the state.

Colorado responds by arguing that UPLs do not violate the Dormant Commerce Clause because they apply equally to in-state and out-of-state transactions, do not affect drug prices charged in other states, and do not constitute a "substantial burden" under the *Pike* test. First, Colorado says that a UPL set by its PDAB would not benefit in-state companies at the expense of competitors in other states, because "the same UPL that applies to an in-state pharmacy's purchase of a medication dispensed in Colorado applies to an out-of-state pharmacy's purchase of the same medication dispensed in Colorado." The state also argues that even if a UPL for Enbrel is set in Colorado, and even if such an action were to affect transactions for Enbrel purchases in other states, this would not violate the Dormant Commerce Clause and does not implicate the extraterritoriality doctrine. The state argues that its PDAB statute aligns with Justice Gorsuch's analyses in both a Tenth Circuit opinion characterizing the extraterritoriality doctrine and the majority's opinion in *National Pork Producers*. The state asserts that a law does not violate the Dormant Commerce Clause "just because it may impact transactions occurring outside of" the state.

Colorado also distinguishes the two recent decisions from the Fourth Circuit and the Minnesota district court striking down state price-gouging statutes on the basis that they violate the Dormant Commerce Clause. Colorado argues that the Fourth Circuit's decision in *Frosh* predates the Supreme Court's decision in *National Pork Producers*, where the Court declined to apply the extraterritoriality doctrine. The state urges that under the PDAB law, "Wholesalers, pharmacists, and providers can sell and buy drugs at any price. But if the price exceeds the UPL that applies to a drug that is dispensed or distributed in Colorado, then those drugs cannot be sold in Colorado." The state further posits that *Ellison* is distinguishable because in that case, the state admitted that the challenged price-gouging law applied to manufacturers' sales to wholesalers who distribute drugs in the state, which is not the case here. Colorado argues that "a UPL does not apply that broadly," and that "liability . . . cannot reasonably attach" to a purchaser that "is not responsible for a drug being dispensed or distributed" in the state.

Considerations for Congress

In the midst of the continuing congressional debates over prescription drug prices, states have initiated legislative efforts to lower the cost of prescription drugs. More lawsuits against PDABs could be filed, which could result in federal district or appellate courts reaching different conclusions about their constitutionality. It is also possible that some of the other ongoing lawsuits aimed at states' attempts to regulate prescription drug prices in other ways could have implications for PDAB litigation, particularly to the extent that there are similar patent preemption and/or Dormant Commerce Clause issues presented. For example, litigation is continuing in cases addressing state "antigouging" laws, which also present both patent and Dormant Commerce Clause questions. The Minnesota district court ruling discussed above concerning the state's antigouging law was appealed to the U.S. Court of Appeals for the Eighth Circuit. In another example, several drug manufacturers, joined by PhRMA—the drug industry's trade association—recently filed more 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.

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 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." On the other hand, 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 obtain FDA approval of a new drug. Congress may resolve these debates by amending federal patent laws to rebalance market incentives or explicitly clarify whether and to what extent, if any, states should be permitted to regulate the prices of patented pharmaceuticals.

Some Members of the 118th Congress have introduced legislation aimed at reducing drug costs, with various bills that take different approaches. For example, some proposals aim to make research and development of drugs less expensive, while others propose to increase transparency around drug development costs. Some proposals focus on a specific program, like Medicare, while others would take a broader approach. Additionally, in December 2023, the House passed the Lower Costs, More Transparency Act, parts of which could lower out-of-pocket drug costs for some elderly Americans and would require disclosure of certain drug cost information by pharmacy benefit managers and health insurance companies. At the time of this writing, the legislation has not been taken up by the Senate.

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