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State Action to Lower Prescription Drug Prices: Navigating the Dormant Commerce Clause

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In the face of ever-rising health care costs, state policymakers continue to adopt new laws to curb the high cost of prescription drugs—from drug price-gouging protections to prescription drug affordability boards. This momentum, however, has been met with strong opposition from the pharmaceutical industry, which continues to challenge state prescription drug affordability laws in court.

Among other legal claims, the pharmaceutical industry regularly argues that state efforts to curb skyrocketing prescription drug prices affect out-of-state businesses, thereby violating the so-called Dormant Commerce Clause. The industry maintains this claim even though the Supreme Court recently affirmed that state laws do not violate the Dormant Commerce Clause simply because they have the practical effect of controlling out-of-state commerce. This publication discusses Dormant-Commerce-Clause-based litigation challenging state drug pricing laws and considerations for state policymakers when designing prescription drug affordability policies so that they may withstand judicial scrutiny.

This publication is part of a three-part series on legal developments that state policymakers should consider when designing new policies to lower health care costs. This series also addresses considerations for state policymakers related to federal patent law and preemption of state law by the Employee Retirement Income Security Act.

Background

Millions of people rely on prescription drugs to treat disease, improve health, alleviate suffering, and prevent death. Yet the high cost of prescription drugs jeopardizes access for many, forcing patients to make impossible decisions over whether to fill a prescription or ration the medication they need.[1] Medication nonadherence can have devastating effects on health, including worsening health outcomes and increased risks of morbidity and mortality.[2] It can also lead to higher overall health care costs due to complications.[3] And high prescription drug prices are an even greater barrier to access for patients with chronic conditions, low-income patients, and patients of color.[4] The high cost of prescription drugs is thus a public health and health equity issue.

Federal and state policymakers have taken several steps to lower prescription drug costs. At the federal level, Medicare has recently begun to negotiate prices for some of the costliest drugs, and Congress capped monthly cost-sharing for insulin at $35 per month for Medicare beneficiaries. Despite these targeted federal reforms, prescription drugs remain unaffordable for many, especially those with private health insurance who are not covered by programs such as Medicare or Medicaid.

To try to fill some of these gaps, states have leveraged their traditional powers to protect health, safety, and welfare to address market failures and lower prescription drug costs for consumers. State-level policies have focused on price gouging, price transparency, cost-sharing caps on specific drugs (e.g., insulin), pharmacy benefit manager (PBM) reform, and the creation of prescription drug affordability boards (PDABs), among other approaches.[5]

The Dormant Commerce Clause and State Drug Affordability Policies

The U.S. Constitution gives Congress the authority to regulate *interstate* commerce, a power that courts have interpreted to also implicitly limit state laws that *interfere with* interstate commerce. Under this so-called Dormant Commerce Clause, a state cannot discriminatorily favor in-state commerce while burdening out-of-state commerce. Even when a state law does not engage in this kind of economic protectionism, it may still violate the Dormant Commerce Clause if the law's in-state benefits are far outweighed by the burdens it imposes on interstate commerce. These are the only two categories of state laws that the Supreme Court has traditionally recognized as violating the Dormant Commerce Clause.[6],[7]

While the Supreme Court has historically recognized mainly two categories of Dormant Commerce Clause violation, some lower courts have recognized a third category: state laws that attempt to regulate transactions that occur wholly beyond a state's borders.[8] Drug companies have repeatedly deployed this so-called "extraterritoriality doctrine" to invalidate state prescription drug laws that impact out-of-state companies, such as drug

manufacturers and wholesalers (Table 1). Drug companies make these claims by pointing to the structure of the national prescription drug market where a limited number of drug manufacturers sell drugs to national wholesalers and distributors who, in turn, sell those drugs to retailers who dispense drugs to patients in different states. As states have adopted these policies, one consistent consideration is how to account for the fact that high drug costs stem from national market forces.

TABLE 1: STATE DRUG PRICING LAWS AND THE EXTRATERRITORIALITY DOCTRINE

CASE	COURT	STATE POLICY	BRIEF SUMMARY OF DECISION	CURRENT STATUS
PhRMA v. Walsh	Supreme Court (2003)	Maine's law incentivizes drug manufacturers to enter into a rebate agreement to extend lower-cost drugs to Medicaid beneficiaries and uninsured residents	Maine's law did not violate the Dormant Commerce Clause because the law did not expressly or implicitly regulate out-of-state transactions or require manufacturers to sell their drugs to a wholesaler at a certain price	N/A
AAM v. Frosh	4th Circuit (2018)	Maryland's generic drug price-gouging law prohibits drug manufacturers and wholesalers from excessively increasing the price of essential generic drugs made available for sale in the state	Maryland's law violates the Dormant Commerce Clause by impermissibly regulating business transactions between drug manufacturers and wholesalers that occur wholly outside Maryland	Supreme Court denied Maryland's *cert* petition (2019)
PhRMA v. Walsh	S.D. Miss. (2024)	Mississippi's 340B law prohibits drug manufacturers from adopting policies that restrict the use of contract pharmacies	Mississippi's law did not violate the Dormant Commerce Clause because the law applies only to 340B transactions within Mississippi with no intent to regulate out-of-state conduct	Appeal pending before 5th Cir.
AAM v. Ellison	8th Circuit (2025)	Minnesota's generic drug price-gouging law prohibits drug manufacturers from excessively increasing the price of essential generic drugs sold, dispensed, or delivered to consumers in the state	Minnesota's law violates the Dormant Commerce Clause by impermissibly regulating business transactions between drug manufacturers and wholesalers that occur wholly outside Minnesota	8th Cir. denied Minnesota's request for *en banc* review (2025)
AAM v. Bonta	E.D. Cal. (2025)	California's law prohibits reverse settlement payments as anti-competitive	California's law violates the Dormant Commerce Clause to the extent that it applies to settlement agreements that were negotiated or agreed to outside of California	Appeal pending before 9th Cir.

Source: Author's analysis

To date, there have been only a handful of decisions where federal courts have analyzed a state prescription drug laws under the Dormant Commerce Clause — with mixed results. While some of the more recent decisions have found state laws to violate the Dormant Commerce Clause, they follow a path that the Supreme Court recently narrowed. And the only Supreme Court decision involving a state drug pricing law, *Pharmaceutical*

Research and Manufacturers of America (PhRMA) v. Walsh, upheld the state law against an extraterritoriality challenge.[9]

Walsh involved a Maine law that restricted Medicaid's coverage of a drug unless its manufacturer entered into a rebate agreement with the state; these rebates would provide discounted prescription drugs to Maine's Medicaid beneficiaries and uninsured residents. PhRMA, the drug industry trade group, argued that the law violated the Dormant Commerce Clause by (1) discriminating against out-of-state commerce to subsidize in-state drug retail sales; and (2) violating the extraterritoriality doctrine. The Supreme Court rejected both arguments and concluded that Maine's law was evenhanded and did "not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect" nor require drug manufacturers to sell to a wholesaler for a certain price.[10] Thus, the law did not violate the Dormant Commerce Clause.

About 15 years after *Walsh*, another drug industry trade group, the Association for Accessible Medicines (AAM), challenged Maryland's generic drug price-gouging law under a similar theory. Maryland's law prohibited drug manufacturers and wholesalers from excessively increasing the price of essential generic drugs "made available for sale" in the state.[11] Most manufacturers and wholesalers, however, are located outside Maryland, so nearly all the wholesale pricing transactions targeted by Maryland occurred outside the state. In *AAM v. Frosh*, a divided three-judge panel of the Fourth Circuit Court of Appeals sided with AAM, finding that Maryland's law impermissibly regulated business transactions that occurred wholly outside Maryland and essentially allowed the state to regulate "transactions that did not result in a single pill being shipped to Maryland."[12]

Although courts have generally applied a presumption against extraterritoriality courts — which presumes that state laws operate only within state borders — the Fourth Circuit took a different approach.[13] The Fourth Circuit instead focused on the entities that would be most affected by Maryland's law and concluded that the law was designed to apply to out-of-state transactions. Price regulations that target the initial sales of the drug by out-of-state manufacturers and wholesalers — but not excessive prices charged by retailers selling the drug to in-state consumers — are impermissible under the Dormant Commerce Clause, the Fourth Circuit concluded. The Supreme Court denied Maryland's request for review, thwarting Maryland's generic drug pricing law.

Supreme Court Takes Up The Extraterritoriality Doctrine in National Pork Producers

It was only a matter of time before the Supreme Court agreed to hear a dispute over the Dormant Commerce Clause, albeit outside the context of prescription drug affordability. In *National Pork Producers Council v. Ross*, pork producers challenged a California law that prohibits the in-state sale of inhumanely sourced pork products. This ban applies regardless of whether the sourcing occurred in or out of state. Because California imports most of its pork, pork producers outside California argued that the law impermissibly controlled out-of-state pork production and "impose[d] substantial new costs on out-of-state pork producers who wish to sell their products in California."[14]

The Court rejected this argument, holding that state laws do not violate the Dormant Commerce Clause simply because they affect commerce beyond a state's borders. The Dormant Commerce Clause prohibits state laws that *directly* regulate out-of-state transactions that have no connection with the state, but that was not the case here.[15] California's law, the Court found, is permissible because it "regulates only products that companies choose to sell *'within'* California."[16] Even though California's law had the practical effect of requiring out-of-state farmers and distributors to change their pork-related operations to conform to California requirements, it did not impermissibly "project" California laws beyond its borders. The Court reached this conclusion even though the pork production industry (much like the pharmaceutical industry) is vertically integrated, where farmers in various states sell pigs to large processing firms with products that are distributed to retailers and consumers nationwide.

The Court made clear that the Dormant Commerce Clause does not create a *per se* rule against state laws that have extraterritorial effects. Rather, the Court was concerned that the pork producers' broad reading of the extraterritoriality doctrine could lead to "strange places" that would unduly limit traditional state authority to protect public health, impose state income taxes, or adopt environmental laws.[17]

The Court also reaffirmed its 2003 decision in *Walsh* and noted that *Frosh*, although not taken up by the Court, was consistent with prior precedent. The Court characterized *Frosh* as involving a "price control or price affirmation statute that tied the price of in-state products to out-of-state prices."[18] These types of state pricing laws, the Court noted, had a "specific" extraterritorial effect that (1) deliberately prevented out-of-state companies from using competitive

"In our interconnected national marketplace, many (maybe most) **state laws have the 'practical effect of controlling' extraterritorial behavior."**

Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 374 (2023).

pricing; or (2) deprived out-of-state businesses and consumers of a competitive advantage. As examples, the Court cited three older Supreme Court decisions where a state law was found to violate the Dormant Commerce Clause: a New York law that barred out-of-state dairy farmers from selling their products in New York at a lower price than was guaranteed for in-state producers and Connecticut and New York laws that required out-of-state distillers and beer merchants to limit in-state prices to those in neighboring states.[19] As the Court noted, however, the laws in those decisions involved purposeful discrimination against out-of-state economic interests rather than extraterritorial regulation.[20]

Early Signals on the Extraterritoriality Doctrine After National Pork Producers

In the two years since the Supreme Court's decision, the lower courts have taken somewhat differing approaches in applying *National Pork Producers* to state prescription drug laws. Some have upheld these laws by focusing on the laws' reach, while others have found ways to distinguish *National Pork Producers*.

In 2024, for instance, a federal district court in Mississippi applied the presumption against extraterritoriality when upholding a Mississippi law that prohibits drug manufacturers from adopting policies that restrict the use of contract pharmacies.[21] The use of contract pharmacies is a prominent issue in disputes between drug companies and certain health care providers over the 340B program.[22] Because the law does not explicitly limit its scope to drug manufacturers that operate in Mississippi, in *PhRMA v. Fitch*, the industry argued that the law "*directly* regulate[s] out-of-state transactions by those with *no* connection" to the state, which violates the extraterritoriality principle.[23] But the court disagreed. Applying the state's long-standing presumption against extraterritoriality,[24] the court found that the law contained no clear intent to regulate out-of-state conduct. For that reason, the court interpreted the state law as applying only to 340B transactions within Mississippi and therefore permissible under the Dormant Commerce Clause.

In contrast, some lower courts have distinguished *National Pork Producers* in holding that state prescription drug laws violate the extraterritoriality doctrine. In *AAM v. Ellison*, the Eighth Circuit Court of Appeals cited the extraterritoriality doctrine to invalidate a Minnesota generic drug price-gouging law that operates similarly to the Maryland law at issue in *Frosh*.[25] The panel remained wary of the Minnesota law's reach — and considered the drug manufacturers to be out-of-state entities — even though the law affected in-state licensure requirements. Under Minnesota law, manufacturers that sell drugs in the state must obtain a license to do so; those that fail to comply with the price-gouging law must relinquish their Minnesota license and forgo participating in the Minnesota market entirely.

In a short opinion, the Eighth Circuit sided with AAM.[26] By limiting the price at which out-of-state manufacturers sell drugs to out-of-state wholesalers to in-state prices, Minnesota improperly sought to set the price of drug transactions in states beyond its borders. Thus, the Minnesota law was a "price control or price affirmation" law with the "specific" extraterritorial effect of controlling out-of-state prices, which is impermissible under the Dormant Commerce Clause.[27] The court invoked *Frosh* and distinguished *National Pork Producers*, hypothesizing that under the Minnesota price-gouging law, "a Colorado manufacturer would be penalized if it sold drugs to a New Jersey distributor at prices above those proscribed by the Act and those drugs ended

"Minnesota regulates the price of out-of-state transactions, insists that out-of-state manufacturers sell their drugs to wholesalers for a certain price, and ties the price of in-state products — prescription drugs — to the price that out-of-state manufacturers charge their wholesalers."

Ass'n for Accessible Medicines v. Ellison, 140 F.4th 957 (8th Cir. 2025)

up in Minnesota." Such extraterritorial price regulation offends the Dormant Commerce Clause, the court concluded.

In another lawsuit filed by AAM, a California federal district court reached a similar conclusion, citing the extraterritoriality doctrine to enjoin a California law that prohibits reverse settlement payments.[28] Reverse settlement payments are payments from brand-name drug companies to generic drug manufacturers to delay or forgo introducing a more affordable, generic drug to the market, thus limiting competition. California's law treated reverse settlement payments — including those negotiated or entered into outside of California — as anticompetitive and therefore prohibited. In *AAM v. Bonta*, the district court ruled that the law was impermissible under the Dormant Commerce Clause to the extent that it applied to agreements that occurred outside California. This law, the court held, was different from the law in *National Pork Producers* — which restricted in-state sales of certain pork products with an indirect effect on out-of-state producers—because the reverse settlement payments law sought to "directly regulate out-of-state transactions by those with no connection to California."[29] California has appealed this decision to the Ninth Circuit Court of Appeals.

Making Sense of National Pork Producers for State Prescription Drug Policy

These mixed decisions notwithstanding, the Supreme Court's decision in *National Pork Producers* is welcome news for state policymakers that want to lower health care costs, including prescription drug costs. By clarifying that there is no *per se* rule against extraterritoriality, a state law does not violate the Dormant Commerce Clause solely because it has effects outside the state.

While some lower courts have recently applied the extraterritoriality doctrine to invalidate state laws, those decisions should not be read as sweeping broadly beyond the specific contexts in which they are decided. As the Fourth Circuit made clear in *Frosh*, its decision should not be read to authorize "a constitutional right to engage in price gouging" — or to suggest that states cannot enact legislation "to secure lower prescription drug prices for their citizens."[30] *Frosh* — which predates *National Pork Producers* — merely means that states cannot achieve these aims in the way that Maryland and Minnesota did by targeting only out-of-state commerce.

Given this precedent, state prescription drug pricing laws that target conduct or prices of in-state actors and drug sales have the clearest path to withstanding a legal challenge under the Dormant Commerce Clause. One example might be a state drug price-gouging law that focuses on downstream actors such as retailers. Although not in the drug pricing context, the Sixth Circuit Court of Appeals rejected an extraterritoriality doctrine claim by online merchants to a Kentucky price-gouging law.[31] The court upheld the law after concluding that it applied only to sales made to Kentucky consumers and did so even though enforcing the law "against third-party sellers on Amazon would have the inevitable effect of regulating the price charged outside of Kentucky."[32]

PDABs are another example. PDABs curb high drug prices by setting upper payment limits (UPL) — the maximum amount that may be billed or paid for a prescription drug — within the state. So, unlike the price-gouging statutes in *Frosh* and *Ellison* that applied to upstream manufacturers and wholesalers, UPLs typically apply to downstream transactions at in-state points of sale.

Amgen has already challenged Colorado's PDAB under the Dormant Commerce Clause after its drug, Enbrel, was deemed unaffordable. Citing *Ellison* and *Frosh*, Amgen argued that Colorado's PDAB law violates the extraterritoriality doctrine because the UPL applies broadly to "wholly out-of-state, upstream transactions."[33] Colorado, Amgen argued, is attempting to *directly* regulate drug sales in other states simply because the drugs were likely to end up in Colorado.[34] A federal district court in Colorado dismissed this challenge on procedural grounds because the UPL does not apply directly to manufacturers. Rather, the UPL applies to drugs that are dispensed or distributed in Colorado via "downstream transactions in the pharmaceutical supply chain" such as retailers.[35] While Amgen urged the court to construe the scope of the PDAB law broadly to apply the UPL to "any financial transaction along the supply chain," the court rejected this interpretation, concluding that Amgen, as an upstream actor not directly affected by the UPL, did not have standing to challenge the state law.[36]

Based on the reasoning in *National Pork Producers*, *Fitch*, and *Amgen*, PDAB laws are likely to survive extraterritoriality challenges because they focus on in-state, downstream actors such as retailers. This is true even though PDABs may influence the behavior of out-of-state upstream actors such as drug manufacturers and wholesalers.

Conclusion

In the absence of comprehensive federal action to address high drug costs, states can and will continue to take action — from price-gouging laws to PDABs. States that do so should be mindful of, and prepared to respond to, the pharmaceutical industry's efforts to derail those policies by weaponizing the Dormant Commerce Clause.

ENDNOTES

1 Grace Sparks et al. Public Opinion on Prescription Drugs and Their Prices. KFF. October 4, 2024. https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

2 Marie T. Brown et al. "Medication Adherence: Truth and Consequences." *The American journal of the medical sciences* vol. 351,4 (2016): 387-99. doi:10.1016/j.amjms.2016.01.010. https://www.amjmedsci.com/article/S0002-9629(15)37996-9/fulltext.

3 *Id*.

4 Sparks, *supra* note 1.

5 National Academy for State Health Policy. State Laws Passed to Lower Prescription Drug Costs: 2017-2025. https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2025/.

6 Oregon Waste Sys., Inc. v. Dep't of Env't Quality of State of Or., 511 U.S. 93, 99 (1994); *see also* Nat'l Pork Producers Council v. Ross, 598 U.S. 356 (2023) (analyzing the California law under the discrimination and *Pike* undue burden standards); *but see* Healy v. Beer Inst., Inc., 491 U.S. 324 (1989); Edgar v. MITE Corp., 457 U.S. 624, 642–43, (1982) ("The Commerce Clause also precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State.").

7 While pharmacy benefit managers (PBMs) are not the focus of this publication, they have regularly cited both categories to derail state efforts to curb prescription drug prices. For example, a federal district court recently ruled that an Arkansas law prohibiting PBMs from operating pharmacies in the state violated the Dormant Commerce Clause by both discriminating against and unduly burdening interstate commerce. Express Scripts, Inc. v. Richmond, No. 4:25-CV-00520-BSM, 2025 WL 2111057 *2-3 (E.D. Ark. July 28, 2025).

8 *See. e.g.*, Rocky Mountain Ass'n of Recruiters v. Moss, 541 F. Supp. 3d 1247, 1254 (D. Colo. 2021) ("The Tenth Circuit has recognized that state statutes may violate the Dormant Commerce Clause in three ways."); Ass'n for Accessible Medicines v. Ellison, 140 F.4th 957, 960 (8th Cir. 2025)("The third way of violating the dormant Commerce Clause—the extraterritoriality doctrine—is at issue here."); Freedom Holdings, Inc. v. Spitzer, 357 F.3d 205, 216 (2d Cir. 2004).

9 Pharm. Rsch. & Mfrs. of Am. v. Walsh, 538 U.S. 644 (2003).

10 *Id.* at 669.

11 Maryland HB 631. Prohibition Against Price Gouging for Essential Off-Patent or Generic Drugs. https://mgaleg.maryland.gov/2017RS/chapters_noln/Ch_818_hb0631E.pdf.

12 Ass'n for Accessible Medicines v. Frosh, 887 F.3d 664, 671 (4th Cir. 2018).

13 *Id*. The panel did so over a dissent from Judge Wynn emphasizing that the panel should have followed Maryland's rules of statutory construction when construing the scope of the Maryland's law. Following this presumption against extraterritoriality in Maryland, Judge Wynn wrote, would "support rejecting the majority opinion's broad interpretation of the statute's extraterritorial reach."

14 Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 371 (2023).

15 *Id.* at 376 note 1.

16 *Id.* (emphasis added).

17 *Id.* at 374.

18 *Id.*

19 Healy v. Beer Inst., 491 U. S. 324 (1989); Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U. S. 573 (1986); and Baldwin v. G. A. F. Seelig, Inc., 294 U. S. 511 (1935).

20 *Nat'l Pork Producers*, 598 U.S. at 371–72.

21 Pharm. Rsch. & Manufacturers of Am. v. Fitch, No. 1:24-CV-160-HSO-BWR, 2024 WL 3277365 (S.D. Miss. July 1, 2024).

22 Brendan Pierson, Lawsuits pile up over state laws on discounts for hospitals' contract pharmacies. Reuters. June 3, 2024. https://www.reuters.com/legal/government/lawsuits-pile-up-over-state-laws-discounts-hospitals-contract-pharmacies-2024-06-03/.

23 Fitch, 2024 WL 3277365, at *12 (emphasis by the court).

24 *Id*. at *12-13 (citing *Tattis v. Karthans*, 215 So. 2d 685, 689 (Miss. 1968) for the proposition that "a Court interpreting Mississippi law applies a 'presumption [ ] that [a] statute is intended to have no extraterritorial effect'" and concluding that "a statute is prima facie operative only as to persons or things within the territorial jurisdiction of the lawmaking power which enacted it").

25 Ass'n for Accessible Medicines v. Ellison, 140 F.4th 957 (8th Cir. 2025).

26 Andrew Twinamatsiko, A Setback for Prescription Drug Pricing: Eighth Circuit Rolls Back Minnesota Drug Price-Gouging Law. O'Neill Institute Expert Column. July 8, 2025. https://oneill.law.georgetown.edu/a-setback-for-prescription-drug-pricing-eighth-circuit-rolls-back-minnesota-drug-price-gouging-law/.

27 *Ellison*, 140 F.4th at, 960.

28 Ass'n for Accessible Medicines v. Bonta, 766 F. Supp. 3d 1020, 1035 (E.D. Cal. 2025) ("AB 824 on its face does not include a limitation to California sales.").

29 *Id*. at 1032.

30 *Frosh*, 887 F.3d at 674.

31 Online Merchants Guild v. Cameron, 995 F.3d 540 (6th Cir. 2021).

32 *Id.* at 553 (internal quotations omitted).

33 COMPLAINT, ¶92, Amgen Inc. et al. v. Mizner et al. 1:24-cv-00810, https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/03/Amgen_2024.03.22_COMPLAINT.pdf.

34 *Id.*

35 Amgen Inc. v. Mizner, No. 24-CV-00810-NYW-SBP, 2025 WL 947474, at *6 (D. Colo. Mar. 28, 2025).

36 *Id*. at *6-7.