

PREEMPTING DRUG PRICE REFORM

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Over the past decade, a number of states have attempted to lower prescription drug costs. State efforts to regulate drug prices range from price gouging laws to drug importation, pharmacy benefit manager regulations, and price transparency efforts. Prescription Drug Affordability Boards (PDABs) in particular have recently become popular, with at least twelve states having enacted PDAB legislation and seventeen more now considering the same. PDABs are state-established entities that assess the affordability of high-cost prescription drugs, and some have authority to set upper payment limits (UPLs) on those drugs. However, most of the costliest drugs that are subject to PDAB review enjoy patent and FDA market exclusivities afforded by federal law. As such, the UPLs set by PDABs have triggered concerns about preemption by the federal patent and drug regulatory regimes.

In 2024, Amgen, the manufacturer of ENBREL, a drug selected for review by the Colorado PDAB, challenged the constitutionality of the Colorado PDAB. Amgen presented patent preemption as one of its key arguments, arguing that permitting a state to limit the prices of patented drugs impermissibly interferes with the design and objectives of federal patent law. While the district court dismissed the challenge for lack of standing, the case is currently on appeal to the Federal Circuit. This case presents the Federal Circuit with a rare opportunity to revisit its interpretation of the scope of patent preemption from a prior holding—*Biotechnology Industry Organization v. District of Columbia* (*BIO v. D.C.*), in which the court held that a D.C. law that prohibited the sale of patented prescription drugs at an “excessive price” was preempted because it created an unconstitutional obstacle to the rewards and incentives established by Congress under the Patent Act.

This Article argues that PDABs are currently the strongest state-level intervention to address the public health crisis precipitated by high prescription drug prices—and are therefore essential. Unlike the law at issue in *BIO v. D.C.*, PDABs afford drug manufacturers opportunities to participate in the affordability review process, and are thus intended to facilitate important public health discussion and negotiation with drug manufacturers. Additionally, because patents do not confer upon patentees the affirmative right to make, use, or sell the subject invention, much less the right to recoup a particular profit, UPLs do not conflict with the objectives

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and purposes of the Patent Act. States have traditionally wielded powers to protect the health, safety, and welfare of their citizens, and therefore must have the power to rectify market failures that lead to excessive drug prices in a way that can be reconciled with federal authority over patents and the national drug market. At a time when federal funding for healthcare has been all but gutted, policymakers must consider how to avoid preempting drug price reform at the state level.

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INTRODUCTION

The exorbitant prices of prescription drugs in the United States are nothing short of a public health crisis. On average, Americans spend twice as much on prescription drugs compared to other high-income countries.¹ With three out of ten American adults reporting that they cannot afford to take their medication as prescribed, many patients, especially those with chronic conditions, are forced to miss doses, ration their prescriptions, or delay filling prescriptions.² This, in turn, can lead to significant health complications, and in some cases, even death.³

1. Nisha Kurani, Dustin Cotliar & Cynthia Cox, *How Do Prescription Drug Costs in the United States Compare to Other Countries?*, PETERSON-KFF HEALTH SYS. TRACKER (Feb. 8, 2022), <https://www.healthsystemtracker.org/chart-collection/how-do-prescription-drug-costs-in-the-united-states-compare-to-other-countries/> [https://perma.cc/Y2RK-MLGG].

2. See Grace Sparks, Ashley Kirzinger, Alex Montero, Isabelle Valdes & Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices*, KFF (Oct. 4, 2024), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/> [https://perma.cc/8LC9-JUNN].

3. See, e.g., Bram Sable-Smith, *Insulin's High Cost Leads to Lethal Rationing*, NPR (Sep. 1, 2018, at 08:35 ET), <https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing> [https://perma.cc/EP4V-3FUY]. According to a 2021 National Health Interview Survey,

The underlying causes of our high prescription drug costs include well-documented market failures, such as a lack of price transparency, misaligned financial incentives for stakeholders, and opportunities to game the patent system and drug regulatory regime through anticompetitive behavior.⁴ Such tactics include evergreening, patent thickening, product hopping, and pay-for-delay agreements—all of which are compounded by a lack of regulatory oversight to remedy such market failures.⁵ A 2021 Department of Health and Human Services (HHS) report, written in response to former President Biden’s Executive Order on Promoting Competition in the American Economy, advocates for “bold legislative action,” such as legislation to speed the entry of generics and biosimilars, slow price increases on existing drugs, and prohibit pay-for-delay agreements and other anticompetitive practices.⁶ Such federal reform, however, requires robust bipartisan support, which seems unlikely with increasing congressional gridlock.

In recent years, the federal government has taken steps to address the high cost of drugs by designing various policies such as the Medicaid Drug Rebate Program,⁷ the 340B Program,⁸ the Federal Supply Schedule

around 16.5% of participants taking insulin reported rationing the drug in the past year due to its high price. See Brenna Miller, *1.3 Million Americans Forced to Ration Insulin, New Study Estimates*, LOWN INST. (Nov. 8, 2022), <https://lowninstitute.org/1-3-million-americans-forced-to-ration-insulin-new-study-estimates/> [<https://perma.cc/4UP2-BQL4>]. The study also found that one-third of American adults without health insurance reported rationing insulin. *Id.*

4. See XAVIER BECERRA, U.S. DEP’T OF HEALTH & HUM. SERVS., A REPORT IN RESPONSE TO THE EXECUTIVE ORDER ON LOWERING PRESCRIPTION DRUG COSTS FOR AMERICANS 5 (2023), <https://innovation.cms.gov/data-and-reports/2023/eo-rx-drug-cost-response-report> [<https://perma.cc/NG2C-C2N6>]; XAVIER BECERRA, U.S. DEP’T OF HEALTH & HUM. SERVS., COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES 6–7 (2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf [hereinafter ASPE REPORT].

5. *Id.*

6. ASPE REPORT, *supra* note 5, at 2.

7. See *Medicaid Drug Rebate Program (MDRP)*, MEDICAID.GOV (Nov. 10, 2025), <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program> [<https://perma.cc/7B84-Y38T>]; Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, KFF (Nov. 12, 2019), <https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program> [<https://perma.cc/LFS5-LENV>].

8. See *340B Drug Pricing Program*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa> [<https://perma.cc/7RAG-TD73>] (last visited Jan. 31, 2026); *340B Drug Pricing Program Overview*, 340B HEALTH, <https://www.340bhealth.org/members/340b-program/overview/> [<https://perma.cc/RT7Q-KUYL>] (last visited Jan. 31, 2026).

for Pharmaceuticals Program,⁹ and more recently, the Medicare Drug Price Negotiation Program established under the Inflation Reduction Act (IRA).¹⁰ While these programs partially closed some gaps in access to medicine, many of these successes have been rolled back by one of the “biggest cut[s] to our social safety net in history”: the 2025 Budget Reconciliation Act (also known as the “One Big Beautiful Bill Act”).¹¹ The Act includes \$1 trillion in spending cuts to health care through 2034, including devastating cuts to Medicaid and Medicare, and is estimated to leave up to fifteen million additional Americans without health insurance in 2034.¹² The resulting uninsurance, underinsurance, and overburdened state systems will inevitably exacerbate gaps in access to prescription drug costs. There is a need for comprehensive prescription drug price reform, and swift action cannot reasonably be expected from the current federal administration.

Against this backdrop, states began exploring reforms to address the high costs of prescription drugs. States bear these costs as they purchase pharmaceuticals for Medicaid beneficiaries, state employees, higher education constituents, and individuals who are incarcerated in state correctional facilities.¹³ Over the past decade, a number of states have taken steps to stem the inflation of prescription drug prices through various mechanisms, including drug price transparency laws, price gouging laws, out-of-pocket caps for specific drugs (such as insulin), drug importation programs, and pharmacy benefit manager (PBM)

9. See *Pharmaceutical Prices*, U.S. DEP'T OF VETERANS AFFS. (Jan. 23, 2026), <https://www.va.gov/opal/nac/fss/pharmprices.asp> [<https://perma.cc/PE3Z-FQKT>].

10. For more information about the program, see *Medicare Drug Price Negotiation Program*, CMS.GOV (May 12, 2025, at 14:50 CT) <https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program> [<https://perma.cc/KN7Z-X68B>], and Juliette Cubanski, *FAQs About the Inflation Reduction Act's Medicare Drug Price Negotiation Program*, KFF (Jan. 23, 2025), <https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/> [<https://perma.cc/6J63-DF92>].

11. Aliza Rozen, *How New Federal Legislation Will Affect Health Care Costs and Access for Americans*, JOHN HOPKINS BLOOMBERG SCH. OF PUB. HEALTH (July 30, 2025), <https://publichealth.jhu.edu/2025/the-changes-coming-to-the-aca-medicare-and-medicare>.

12. *By the Numbers: Harmful Republican Megabill Will Take Health Coverage Away from Millions of People and Raise Families' Costs*, CTR. ON BUDGET & POL'Y PRIORITIES (Aug. 27, 2025), <https://www.cbpp.org/research/health/by-the-numbers-republican-reconciliation-law-will-take-health-coverage-away-from>.

13. NAT'L ACAD. FOR STATE HEALTH POL'Y, STATES AND THE RISING COST OF PHARMACEUTICALS: A CALL TO ACTION 3 (2016), <https://nashp.org/wp-content/uploads/2016/10/Rx-Paper.pdf> [<https://perma.cc/6EFJ-3P4J>].

regulations.¹⁴ These efforts are catalogued and compared in Section I.A of this Article.

In 2017, the National Academy for State Health Policy (NASHP), a nonprofit organization comprised of policymakers developing state health policy innovations, published model legislation outlining another potential mechanism for reining in drug prices: Prescription Drug Affordability Boards (PDABs).¹⁵ PDABs are state entities that assess high-cost prescription drugs, and if necessary, set upper payment limits (UPLs) to make those medications more affordable for consumers.¹⁶ While the precise structure of a PDAB may vary, the NASHP model bill proposes a board operating independently of the executive and legislative branches and comprised of experts in health policy, healthcare economics, or clinical medicine appointed by the Governor and confirmed by the senate.¹⁷ Section II.B describes the mechanics of PDABs, including how members of a PDAB are selected, how drugs are selected for negotiation, how UPLs are set, and how PDAB structures may vary across states.

Maryland was the first state to adopt such PDAB legislation, passing House Bill 768 in April 2019.¹⁸ The bill created a five-person drug affordability board with the power to set UPLs on certain pharmaceuticals, including brand-name drugs with an initial cost of \$30,000 or more per course of treatment, brand-name drugs whose price increases by \$3,000 or more per year, and generic drugs priced at \$100 or more and whose price increases by 200 percent or more per year.¹⁹ In its original form, the board would have had the power to set UPLs on all

14. *2025 State Legislation to Lower Prescription Drug Costs*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Aug. 8, 2025) [hereinafter *2025 NASHP Tracker*], <https://nashp.org/state-tracker/2025-state-legislation-to-lower-prescription-drug-costs> [https://perma.cc/WX8X-X4W3].

15. Drew Gattine & Kris Vallecillo, *NASHP Releases Model State Legislation to Lower the Cost of Prescription Drugs*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Nov. 7, 2022), <https://nashp.org/nashp-releases-model-state-legislation-to-lower-the-cost-of-prescription-drugs/> [https://perma.cc/FZ3L-P2KY].

16. *Id.*

17. NAT'L ACAD. FOR STATE HEALTH POL'Y, AN ACT TO REDUCE THE COST OF PRESCRIPTION DRUGS BY ESTABLISHING A PRESCRIPTION DRUG AFFORDABILITY BOARD 3 (2022) [hereinafter *NASHP MODEL LEGISLATION*], https://eadn-wc03-6094147.nxedge.io/wp-content/uploads/2022/08/2022-PDAB-Model-Act_Form_080222.pdf [https://perma.cc/Q33J-BDQY].

18. Prescription Drug Affordability Board Act, H.B. 768, 2019 Leg., 439th Sess. (Md. 2019); *Maryland Passes Nation's First Prescription Drug Affordability Board Legislation*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Apr. 16, 2019), <https://nashp.org/maryland-passes-nation%C2%92s-first-prescription-drug-affordability-board-legislation/> [https://perma.cc/2JYE-N2XX].

19. Md. H.B. 768.

health plans in the state.²⁰ But certain delegates expressed concerns that such “pricing control” would result in drug rationing, with Delegate Matthew Morgan (R-MD) stating that “[f]rom a logical standpoint from the company, [drug manufacturers] would sell it to 49 other states before selling it to us.”²¹ Thus, the state legislature eventually limited UPLs to drugs purchased by health plans that serve employees of the state and county governments.²² However, in May 2025, Maryland Governor Wes Moore signed a bill expanding the PDAB’s authority to set UPLs for drugs bought by all residents in the state.²³

In the years that followed, multiple states followed Maryland’s lead. Indeed, as of June 2025, twelve states have enacted PDAB legislation²⁴ and seventeen more are now considering the same.²⁵ In Section I.B, I compare PDABs to the previously described state schemes and conclude that PDABs are one of the strongest—if not the strongest—measure that states have currently enacted to curb the high costs of prescription drug prices. This Section also unpacks some of the policy critiques that have been lobbed against PDABs by the pharmaceutical industry and other stakeholders, including concerns about drug rationing and patchwork legislation.

While PDABs are continuing to gain popularity with state legislatures, opponents of these efforts have sought to derail PDABs through litigation. In 2021, Colorado enacted legislation to establish a PDAB with the authority to set UPLs that would apply to the fully insured market, state and local government, and self-funded plans that opt in.²⁶

20. Bruce Depuyt, *House Panel Drastically Scales Back Prescription Drug Affordability Bill*, MD. MATTERS (Mar. 22, 2019, at 17:47 CT), <https://marylandmatters.org/2019/03/22/house-panel-drastically-scales-back-prescription-drug-affordability-bill/>.

21. *Id.*

22. *Id.*

23. See Prescription Drug Affordability Board - Authority and Stakeholder Council Membership (Lowering Prescription Drug Costs for All Marylanders Now Act), S.B. 357, 2025 Leg., 447th Sess. (Md. 2025); see also Ed Silverman, *Maryland Governor Signs Law to Expand Powers of the State’s Prescription Drug Affordability Board*, STAT (May 20, 2025), <https://www.statnews.com/pharmalot/2025/05/20/pharmaceuticals-biotech-medicines-pharma-maryland-prices-affordable-diabetes-amgen-colorado/> [<https://perma.cc/VK8B-TJPR>] (describing Maryland’s new PDAB law and noting that “[t]he move was hailed by consumer advocates”).

24. *State Laws Passed to Lower Prescription Drug Costs: 2017–2025*, NAT’L ACAD. FOR STATE HEALTH POL’Y (Jan. 15, 2026), <https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2025/> [<https://perma.cc/2ST3-5BCJ>].

25. See 2025 NASHP Tracker, *supra* note 14.

26. Jennifer Reck & Hemi Tewarson, *District Court Dismisses Challenge to Colorado’s Prescription Drug Affordability Board*, NAT’L ACAD. FOR STATE HEALTH

The PDAB reviewed a number of high-cost drugs and found that three biologic drugs—Novartis’s Cosentyx (secukinumab),²⁷ Janssen’s Stelara (ustekinumab),²⁸ and Amgen’s Enbrel (etanercept)²⁹—were unaffordable within the state.³⁰

On March 22, 2024, Amgen—manufacturer of Enbrel, an injectable biologic approved for the treatment of rheumatoid arthritis and psoriatic arthritis—sued in federal court challenging the constitutionality of Colorado’s PDAB law.³¹ One of the primary arguments advanced by Amgen was that the PDAB’s pricing mechanisms conflicted with federal patent laws and was therefore preempted.³² Amgen argued that UPLs established by PDABs impermissibly overrode the legislative balance struck by Congress in order to “reward[] pharmaceutical innovation with a period of market exclusivity and the ability to charge prices that allow for further investment and innovation during that period,” “strip[ping] away the very rights and economic incentives that Congress sought to create in enacting the patent laws.”³³ While the district court dismissed the challenge for lack of standing, the case is currently on appeal to the Federal Circuit.³⁴ This case presents the Federal Circuit with a rare opportunity to revisit its interpretation of the scope of patent preemption from a prior holding—*Biotechnology Industry Organization v. District of Columbia*³⁵ (*BIO v. D.C.*), in which the court held that a D.C. price-setting law that prohibited the sale of patented prescription drugs at an “excessive price” was preempted because it created an unconstitutional obstacle to the rewards and incentives established by Congress under the Patent Act.³⁶ Section II.C summarizes this litigation.

On October 3, 2025, the Colorado PDAB set the nation’s first UPL on Enbrel.³⁷ Relying on the “maximum fair price” for the same drug that

POL’Y (Mar. 31, 2025), <https://nashp.org/district-court-dismisses-challenge-to-colorados-prescription-drug-affordability-board/> [<https://perma.cc/UWW6-T66L>].

27. COSENTYX, <http://www.cosentyx.com> [<https://perma.cc/8MBN-C4YZ>] (last visited Jan. 31, 2026).

28. STELARA (Nov. 2025), <http://www.stelarainfo.com> [<https://perma.cc/LPQ8-YS5W>].

29. ENBREL, <http://www.enbrel.com> [<https://perma.cc/UTR9-HC34>] (last visited Jan. 31, 2026).

30. Reck & Tewarson, *supra* note 26.

31. Complaint at 3, 8, *Amgen v. Mizner*, No. 24-cv-00810 (D. Colo. Mar. 22, 2024) [hereinafter *Amgen* Complaint].

32. *Id.* at 5–6.

33. *Id.*

34. *Amgen v. Mizner*, No. 24-cv-00810, 2025 WL 947474, at *9 (D. Colo. Mar. 28, 2025), *appeal docketed*, No. 25-1641 (Fed. Cir. Apr. 14, 2025).

35. 496 F.3d 1362 (Fed. Cir. 2007).

36. *Id.* at 1365, 1374.

37. *Id.*

Amgen negotiated for at the federal level under the IRA, the UPL for Enbrel was set at \$31,000 per year, in comparison to over \$50,000 on average under the average insurance plan in 2023.³⁸ Because Colorado's PDAB is furthest along in its process, this case is likely to serve as a test case for future litigation against PDABs in other states—particularly Maryland, Minnesota, and Washington, whose PDABs also have authority to set UPLs. Thus, it is essential for those states and other states considering PDAB legislation to consider whether federal patent law prevents states from enacting measures to lower the cost of prescription drugs. At a time when federal cuts to Medicaid and Medicare threaten access to healthcare across the country, state regulation of healthcare costs is more important than ever.

This Article considers how patent preemption applies to UPLs set by PDABs. Part II unpacks the urgent question at the heart of this public health debate: whether federal patent law prevents states from enacting measures to lower the cost of prescription drugs. Section II.A provides an overview of patent preemption doctrine, and Section II.B reviews the most relevant case on point—*BIO v. D.C.*—and its flaws. In Section II.C, I examine the doctrine of patent exhaustion as an effective defense against claims of patent preemption asserted by drug manufacturers. Patent preemption prevents drug manufacturers from controlling subsequent sales after the first authorized sale of a patented drug.³⁹ Indeed, this may be a rare instance in which the complex network of drug distribution, which has historically been used by the pharmaceutical industry and its associated middlemen to obfuscate and inflate prices, works in favor of the drug price reform.

In Part III, I consider possible paths forward. If PDABs are not preempted, I predict that the proliferation of PDABs may influence drug manufacturers to shift to a direct-to-consumer sales model. I also catalogue possible solutions if the Federal Circuit (or eventually, the U.S. Supreme Court) finds that UPLs are preempted by federal patent law and map out possible strategies to reform PDABs to overcome preemption and other constitutional hurdles. In doing so, this Article aims to set out the first attempt at a fulsome analysis of PDABs, compare them to other state efforts to reform prescription drug prices, and consider patent preemption as the key issue at the heart of PDAB litigation. States must be permitted to experiment with innovative drug pricing and negotiation schemes in order to create a roadmap for replication and scaling of successful policies at the federal level. Preserving the role of states as

38. Sara Wilson, *Colorado Becomes First State to Cap Price of Prescription Drug*, COLO. NEWSLINE (Oct. 7, 2025, at 14:05 CT), <https://coloradonewsline.com/2025/10/07/colorado-first-state-cap-price-prescription-drug/>.

39. *See Impression Prods. v. Lexmark Int'l*, 581 U.S. 360, 366–68 (2017).

laboratories of democracy may be the key to developing scalable national solutions to the drug pricing crisis.

I. PRESCRIPTION DRUG AFFORDABILITY BOARDS

Over the past decade, states have grown increasingly active in innovating legislative and policy solutions to address the rising cost of prescription drugs, experimenting with a range of policy tools to improve affordability and transparency. This Part frames PDABs within the evolving landscape of state drug pricing reforms and explains why stakeholders should be watching PDABs (and litigation challenging them) closely. The first section examines the breadth of state-level strategies aimed at curbing pharmaceutical costs, with special attention to three prominent examples. The second turns to PDABs, describing their core structure and variation in how states have implemented them. The final section compares PDABs to other state efforts and argues that PDABs represent one of the most ambitious and potentially most impactful approaches in the current wave of state innovation.

A. Surveying State Efforts

Over the past decade, a number of states have attempted to lower prescription drug costs,⁴⁰ with the NASHP Center for State Rx Drug Pricing at the helm of many of these efforts.⁴¹ Some of these efforts include out-of-pocket price caps,⁴² generic price gouging laws,⁴³ and

40. NAT'L ACAD. FOR STATE HEALTH POL'Y, *supra* note 24.

41. *Prescription Drug Pricing: Drug Pricing Center*, NAT'L ACAD. FOR STATE HEALTH POL'Y, <https://nashp.org/policy/health-costs-and-value/prescription-drug-pricing/> [<https://perma.cc/358K-QXTG>] (last visited Jan. 31, 2026).

42. Out-of-pocket price caps restrict the amount that health insurance plans can require patients to pay out of pocket for certain drugs at the point of sale by restricting deductibles and other consumer cost-sharing mechanisms. Maureen Hensley-Quinn & Zoe Torrey, *State Legislatures Pursue Policies to Address High Health Care Prices*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Jan. 27, 2025), <https://nashp.org/state-legislatures-pursue-policies-to-address-high-health-care-prices/> [<https://perma.cc/N8RD-RLMC>]. Most of these laws target essential, commonly used generic or biosimilar drugs and medical devices, such as insulin, prescription inhalers, and epinephrine autoinjectors (EpiPens). See *2025 NASHP Tracker*, *supra* note 14 (“Out-of-Pocket Caps” dropdown).

43. Price gouging laws penalize significant increases in the prices of generic drugs, which are not justified by supply chain changes or shortages. For a discussion of generic price gouging laws and litigation challenging them, see Shweta Kumar, *Formulating Public Pharma*, 110 CORN. L. REV. (forthcoming 2026) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4993865. See *2025 NASHP Tracker*, *supra* note 14 (“Price Gouging” dropdown). Note that the Eighth Circuit recently affirmed a district court’s decision to strike down Minnesota’s generic drug price

consumer cost-sharing efforts.⁴⁴ This Section includes a deep dive into three of these efforts that have been particularly popular amongst states and discussed as weapons in the arsenal of state efforts to reform drug prices: drug price transparency programs, drug importation programs, and pharmacy benefit manager regulations.

1. Drug Price Transparency Programs

Prescription drug price transparency laws aim to shed light on drug pricing practices by manufacturers, PBMs, and insurers. Most price transparency laws require manufacturers to report a Wholesale Acquisition Cost (WAC), which is the list price set by the manufacturer before any discounts, rebates, or negotiations, for certain drugs with high launch prices or significant price increases (often 10 percent or more over twelve months).⁴⁵ Other states impose broader reporting obligations. For example, California's law requires manufacturers to provide advance notice and justification for certain price increases,⁴⁶ while Oregon's law mandates annual reporting on both drug prices and cost drivers across the supply chain.⁴⁷ Still other states extend reporting obligations to other entities in the supply chain, including insurers, pharmacy benefit managers, pharmacy service administrative organizations, and wholesale distributors.⁴⁸ As of June 2025, approximately twenty-three states have passed drug price transparency laws.⁴⁹ Encouragingly, states that have enacted such price transparency laws report fewer WAC increases, although launch prices continue to rise.⁵⁰

gouging law, finding that it violated the Dormant Commerce Clause. *Ass'n for Accessible Meds. v. Ellison*, 140 F.4th 957, 958–59 (8th Cir. 2025).

44. Consumer cost sharing efforts require insurers, health maintenance organizations, PBMs, and others to reduce patient out-of-pocket spending by accounting for rebates or savings accrued through price negotiation by a PBM. *See 2025 NASHP Tracker*, *supra* note 14 (“Consumer Cost Sharing” dropdown).

45. *See* Johanna Butler, *Drug Price Transparency Laws Position States to Impact Drug Prices*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Jan. 10, 2022), <https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/> [<https://perma.cc/VD7D-RT2B>].

46. S.B. 17, 2017 Leg., Reg. Sess. (Cal. 2017).

47. OR. REV. STAT. § 646A.683 (2025).

48. Butler, *supra* note 45.

49. Heath R. Ingram, Matt Wetzel & Avi Strauss, *State Drug Transparency Laws – 2025 Update*, GOODWIN (June 2, 2025), <https://www.goodwinlaw.com/en/insights/publications/2025/06/alerts-lifesciences-state-drug-transparency-laws> [<https://perma.cc/L6VD-PFDA>].

50. Butler, *supra* note 45 (noting a 79 percent decline in the total number of drugs reaching a 15 percent price increase per year); *see also* NUMI LEE GRIFFITH & ANTONIO VARGAS, DEP'T OF CONSUMER & BUS. SERVS., *PRESCRIPTION DRUG PRICE TRANSPARENCY RESULTS AND RECOMMENDATIONS – 2020*, at 31 (2020), <https://dfr>.

Of course, price transparency laws are not without their shortcomings. While WAC is the most readily available benchmark for pricing,⁵¹ it is not the actual price paid by payers or patients, and thus critics argue that it can paint a misleading picture of drug affordability and cost trends. Because WAC does not reflect rebates negotiated by PBMs or discounts offered to insurers, reporting based on WAC may overstate the cost burden to some payers while underrepresenting pricing dynamics for others. Furthermore, manufacturers may manipulate the timing or magnitude of WAC changes to avoid triggering reporting thresholds. As a result, these laws often raise awareness but do not directly constrain pricing behavior. A 2019 analysis of state drug price transparency laws found that no state legislation required release of real transaction prices at each stage of the pharmaceutical distribution process, a necessary prerequisite for policymakers seeking effective solutions.⁵²

There are also some concerns that price transparency programs may facilitate price signaling among competitors. By publicly disclosing WAC increases and justifications, transparency laws may inadvertently allow drug manufacturers to coordinate pricing strategies without explicit communication—raising concerns about tacit collusion or price fixing.⁵³ This concern is especially salient in markets where the number of sellers is small and barriers to entry for new firms is high, such as the pharmaceutical market.⁵⁴ However, there are reasons to believe that health care is distinct from other industries in which efforts to promote price transparency have led to collusion.⁵⁵ While transparency may create

oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2020.pdf [https://perma.cc/Z7UN-8VDD] (noting a 70 percent decline in the number of drugs facing yearly price increases above the state's reporting threshold).

51. See Anna Hung & Sean Dickson, *A Primer on Prescription Drug Pricing Benchmarks in the United States*, 31 J. MANAGED CARE & SPECIALTY PHARMACY 1326, 1327 (2025).

52. MARTHA RYAN & NEERAJ SOOD, USC LEONARD D. SCHAEFFER CTR. FOR HEALTH POL'Y & ECON., STATE DRUG PRICING TRANSPARENCY LAWS; NUMEROUS EFFORTS, MOST FALL SHORT 1 (2019), https://schaeffer.usc.edu/wp-content/uploads/2024/10/State_Drug_Transparency_White_Paper_FINAL.pdf [https://perma.cc/7AXY-NYLM].

53. See, e.g., ROBERT F. GRABOYES & JESSICA MCBIRNEY, MERCATUS CTR. AT GEO. MASON UNIV., PRICE TRANSPARENCY IN HEALTHCARE: APPLY WITH CAUTION 2 (2020), <https://www.mercatus.org/system/files/graboyes-price-transparency-mercatus-research-v1.pdf> [https://perma.cc/33U6-SF5V].

54. *Id.* at 5–6.

55. KATHERINE L. GUDIJKEN, SAMUEL M. CHANG & JAIME S. KING, CAL. HEALTH CARE FOUND., THE SECRET OF HEALTH CARE PRICES: WHY TRANSPARENCY IS IN THE PUBLIC INTEREST 11–12 (2019), https://portal.ct.gov/-/media/ohs/healthcare-cabinet/2021-meetings/march-9/gudiksen_secret-of-health-care-prices_chcf.pdf [https://perma.cc/4U59-QA87].

opportunities for collusion in the generic market, transparency may also be the best tool for identifying and validating suspected anticompetitive conduct that might otherwise go unnoticed.⁵⁶

Legal challenges brought by the pharmaceutical industry have also created uncertainty for the future of price transparency laws. In *Pharmaceutical Research & Manufacturers of America v. Stolfi*,⁵⁷ a pharmaceutical industry trade group, PhRMA, challenged Oregon's drug price transparency statutes (H.B. 4005 and H.B. 2658), arguing that they compelled speech in violation of the First Amendment and effected a taking under the Fifth Amendment under a broad "public interest" exception that permits the state to publish submitted information, including trade secret information, if it determines that disclosure is in the public interest.⁵⁸ The U.S. District Court for the District of Oregon agreed, issuing a declaratory judgment holding that the annual price-increase reporting mandate violated free-speech principles and that "the public-interest exception violated the Fifth Amendment."⁵⁹ On appeal, the Ninth Circuit reversed, ruling that the required disclosures were commercial speech that the state could require under intermediate scrutiny, reinstating Oregon's authority to enforce its drug price transparency law.⁶⁰

Finally, while transparency laws aim to hold drugmakers accountable and generate public pressure against unjustified price increases, they are only the first step in curbing high drug prices. By increasing visibility without directly lowering prices, price transparency laws help policymakers identify drugs that place a high burden on the healthcare system, but such laws have no real "teeth" to penalize excessive prices or price hikes. NASHP notes that transparency laws are often intended not only to inform policymakers and the public but also to serve as a foundation for more aggressive cost-containment measures in the future, such as PDABs.⁶¹

2. Drug Importation Programs

Meanwhile, several states have looked outside the United States, establishing programs to import prescription drugs from Canada, where prices are typically much lower than prices in the U.S. Under section

56. *Id.* at 11.

57. 724 F. Supp. 3d 1174 (D. Or. 2024).

58. *Id.* at 1183, 1185–86, 1197.

59. *Id.* at 1183–84.

60. *Pharm. Rsch. & Mfrs. of Am. v. Stolfi*, 153 F.4th 795, 819–20, 840 (9th Cir. 2025).

61. Butler, *supra* note 45.

804 of the Federal Food, Drug, and Cosmetic Act, states may seek FDA approval to import select prescription drugs from Canada.⁶² To obtain approval, sponsors must demonstrate that the importation program will result in a significant reduction in the cost of eligible prescription drugs without posing any additional risk to the public's health and safety.⁶³ In January 2024, Florida became the first state to receive conditional FDA approval for its importation program, granting a two-year pilot limited to Medicaid, county health departments, prisons, and the Department of Health's central pharmacy—targeting drugs like those treating HIV/AIDS, diabetes, and mental health conditions.⁶⁴ Since then, multiple other states—including Colorado, Maine, New Mexico, and Vermont—have also enacted enabling legislation or filed Section 804 Importation Program (SIP) proposals with the FDA.⁶⁵

While state drug importation programs offer a possible solution to leverage lower prices in Canada, critics warn of potential risks. Although the program mandates FDA-certified laboratory testing and adherence to the Drug Supply Chain Security Act, Canadian law allows “transshipment” of drugs sourced from third-party countries, including those with lower regulatory standards, undermining traceability and safety.⁶⁶ This, in turn, poses novel questions about liability for mass torts resulting from defective drug products.⁶⁷ Furthermore, experts have noted that Canada's drug market, at 2 percent of global pharmaceutical

62. 21 U.S.C. § 384.

63. 21 C.F.R. § 251 (2026).

64. See FLA. STAT. § 381.02035 (2024); *FDA Authorizes Florida's Drug Importation Program*, FDA (Jan. 5, 2024), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-floridas-drug-importation-program>; Shawn Radcliffe, *Florida Can Now Import Prescription Drugs from Canada, Will That Lower Prices?*, HEALTHLINE (Jan. 9, 2024), <https://www.healthline.com/health-news/florida-can-now-import-prescription-drugs-from-canada-will-that-lower-prices>.

65. *State Drug Wholesale Importation Programs*, NAT'L CONF. OF STATE LEGISLATURES (May 7, 2024), <https://www.ncsl.org/health/state-drug-wholesale-importation-programs>.

66. Nisha Quasba & Elliot Vice, *What Should Prescribers and Policy Makers Know About US Drug Importation?*, 26 AMA J. ETHICS 295, 296–68 (2024); *FDA Authorizes Florida's Drug Importation Program*, *supra* note 64; see also Lauren Massaro, *Florida Drug Importation Program Faces Nationwide Opposition from Pharmacy Organizations*, DRUG TOPICS (Jan. 18, 2024), <https://www.drugtopics.com/view/florida-drug-importation-program-faces-nationwide-opposition-from-pharmacy-organizations> [<https://perma.cc/HZ3L-5H3J>] (noting that over seventy pharmacy groups voiced concerns about Florida's drug importation program, including uncertainty about quality and origin of foreign-made drugs and the impact on the U.S. drug supply chain).

67. See *Mass Tort Implications of FDA's First of its Kind State Drug Importation Program*, DECHERT (Feb. 22, 2024), <https://www.dechert.com/knowledge/onpoint/2024/2/mass-tort-implications-of-fda-s-first-of-its-kind-state-drug-imp.html> [<https://perma.cc/DV7B-XA97>].

consumption, is not nearly large enough to fill U.S. demand (at 44 percent of the global market).⁶⁸ To compound this shortcoming, Canada's ongoing drug shortages—affecting approximately 33 percent of all medications in 2019 and 2,700 drugs in 2022 to 2023—raise worries that U.S. importation might exacerbate supply instability.⁶⁹ Thus, many Canadian officials have opposed such importation programs, cautioning that excessive exports from Canada could undermine the Canadian drug supply.⁷⁰ Similarly, American politicians must consider how relying on Canadian importation for essential drugs could undermine the stability and quality of the U.S. drug supply chain.

Additionally, state programs face significant operational costs and delays. Florida, despite FDA approval, has not yet launched the program due to unresolved logistics, pending coordination with Canadian manufacturers, and potential trade-tariff complications.⁷¹ Finally, analysts question whether cost reductions will meaningfully reach patients. Initial savings estimates often omit critical overhead—like state administrative spending and lab testing—and fail to account for market dynamics or supply restraints.⁷² A study from 2004 found that if imported drugs include a sizable share of new prescriptions, drugmakers may preserve or even increase profits, diminishing projected consumer savings.⁷³

Regardless of how drug importation programs might sidestep the unwillingness of the U.S. federal government to regulate drug prices, it

68. *Canada Can't Solve America's Drug Pricing Problem*, ONPOINT ANALYTICS (Jan. 14, 2020) <https://onpointanalytics.com/pharma/canada-cant-solve-america-s-drug-pricing-problem/> [<https://perma.cc/4KF2-K2P9>].

69. *Drug Shortages in Canada: Fiscal Year 2022 to 2023 in Review*, GOV'T OF CAN. (Nov. 6, 2023), <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/2022-2023-review.html>.

70. See Allison Martell, *Exclusive: Canada Warns U.S. Against Drug Import Plans, Citing Shortage Concerns*, REUTERS (July 18, 2019, at 21:20 CT), <https://www.reuters.com/article/world/exclusive-canada-warns-us-against-drug-import-plans-citing-shortage-concerns-idUSKCN1UD2LJ/>; Health Canada, *Statement from Health Canada on FDA Decision on Florida Bulk Drug Importation*, GOV'T OF CAN. (Jan 8, 2024), <https://www.canada.ca/en/health-canada/news/2024/01/statement-from-health-canada-on-fda-decision-on-florida-bulk-drug-importation-plan.html>.

71. Phil Galewitz, *Florida Gov. DeSantis' Canadian Drug Import Plan Goes Nowhere After FDA Approval*, KFF HEALTH NEWS (Nov. 22, 2024), <https://kffhealthnews.org/news/article/florida-gov-desantis-canadian-drug-import-plan-goes-nowhere-after-fda-approval> [<https://perma.cc/7ZLZ-MWYX>].

72. See *Would Prescription Drug Importation Reduce U.S. Drug Spending?*, CONG. BUDGET OFF. (Apr. 29, 2004), <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf>.

73. ALAN SAGER & DEBORAH SOCOLAR, *DO DRUG MAKERS LOSE MONEY ON CANADIAN IMPORTS?* DATA BRIEF NO. 6, at 1, 8 (Apr. 15, 2004), https://www.bu.edu/sph/files/2015/05/Canadian_importing_break-even_14_Apr-04_FINAL.pdf.

is clear that drug importation is not a long-term solution to secure access to drugs in the United States.

3. Pharmacy Benefit Manager Regulations

Pharmacy benefit managers have also been the target of increasing political scrutiny in recent years. PBMs are third parties in the drug distribution chain that manage prescription drug benefits on behalf of health insurers, employers, and other payers.⁷⁴ Among other things, PBMs use their purchasing power to negotiate rebates and discounts from drug manufacturers, with critics arguing that PBMs fail to pass these savings on to consumers. For instance, PBMs may engage in “spread pricing”—charging insurers more for a particular drug than what is reimbursed to the pharmacy, with PBMs retaining the difference as profit.⁷⁵ PBMs also manage formularies, or lists of prescription drugs covered by the insurance companies they contract with, which can facilitate formulary management practices that favor certain drugs over others based on rebate size, rather than clinical efficacy.⁷⁶

At the federal level, bipartisan concern about the role of PBMs in inflating drug pricing has led to multiple congressional hearings on PBM practices.⁷⁷ In 2025, the Pharmacy Benefit Manager Transparency Act was introduced in Congress, expanding a prior version of the bill introduced in 2023.⁷⁸ The Act aims to hold PBMs accountable by prohibiting spread pricing and unfair rebate clawbacks from pharmacies, facilitates transparency by mandating reporting of particular data to the FTC and HHS, and enables enforcement through civil penalties.⁷⁹ The bill is currently pending in committee.⁸⁰

74. Kristi Martin, *What Pharmacy Benefit Managers Do, and How They Contribute to Drug Spending*, COMMONWEALTH FUND (Mar. 17, 2025), <https://www.commonwealthfund.org/publications/explainer/2025/mar/what-pharmacy-benefit-managers-do-how-they-contribute-drug-spending>.

75. *Id.*

76. *Id.*

77. *See, e.g.*, Susanna Vogel & Rebecca Pifer, *PBMs Battle Bipartisan Scrutiny as Lawmakers Eye Reforms*, BIOPHARMA DIVE (July 24, 2024), <https://www.biopharmadive.com/news/pharmacy-benefits-manager-congress-hearing-drug-costs/722272/> [<https://perma.cc/K6Z7-KJTC>]; Press Release, Comm. on Energy & Com., Subcommittee on Health Holds Hearing to Scrutinize Abusive PBM Practices (Feb. 27, 2025), <https://energycommerce.house.gov/posts/subcommittee-on-health-holds-hearing-to-scrutinize-abusive-pbm-practices> [<https://perma.cc/5JYL-87TJ>].

78. Pharmacy Benefit Manager Transparency Act of 2025, S. 526, 119th Cong. (2025).

79. *Id.*

80. *See id.*

The PBM industry is highly concentrated, with the “Big 3”—CVS Caremark, Express Scripts, and OptumRx (owned by UnitedHealth Group)—accounting for 80 percent of all prescription claims.⁸¹ In recent years, vertical integration has allowed PBMs to steer patients to their affiliated pharmacies by favoring them in reimbursement rates and formulary placement, while disadvantaging independent pharmacies.⁸² In 2022, the FTC launched an investigation into the practices of six major PBMs.⁸³ The FTC found, among other things, that (1) PBMs and brand pharmaceutical manufacturers may enter agreements to exclude generic drugs and biosimilars from particular formularies in exchange for higher rebates;⁸⁴ (2) between 2017 and 2022, the Big 3 marked up several specialty generic drugs at affiliated pharmacies, allowing the PBMs and their affiliated pharmacies to generate more than \$7.3 billion of revenue in excess of the drugs’ acquisition costs;⁸⁵ and (3) affiliated pharmacies earned significantly higher reimbursements than unaffiliated pharmacies—in the case of two specialty cancer generics, twenty to forty times the standard acquisition cost for those drugs.⁸⁶

PBM legislation is also popular among states. According to the 2025 NASHP Tracker, it is the most widely adopted category of state legislation to lower prescription drug costs.⁸⁷ State regulation typically focuses on requiring licensure, mandating fiduciary duties to plan sponsors, limiting spread pricing, and enhancing transparency regarding rebate practices.⁸⁸ Arkansas’s Act 900, for instance, prohibits PBMs from providing discriminatory reimbursements to unaffiliated

81. Martin, *supra* note 74; FED. TRADE COMM’N, SPECIALTY GENERIC DRUGS: A GROWING PROFIT CENTER FOR VERTICALLY INTEGRATED PHARMACY BENEFIT MANAGERS 1 (2025) [hereinafter SECOND INTERIM STAFF REPORT], https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf [<https://perma.cc/24DQ-UK72>].

82. See FED. TRADE COMM’N, PHARMACY BENEFIT MANAGERS: THE POWERFUL MIDDLEMEN INFLATING DRUG COSTS AND SQUEEZING MAIN STREET PHARMACIES 32 (2024) [hereinafter FIRST INTERIM STAFF REPORT], https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf [<https://perma.cc/P7CH-SPAC>]; SECOND INTERIM STAFF REPORT, *supra* note 81, at 15.

83. Press Release, Fed. Trade Comm’n, FTC Launches Inquiry into Prescription Drug Middlemen Industry (June 7, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry> [<https://perma.cc/LVY8-U98X>].

84. FIRST INTERIM STAFF REPORT, *supra* note 82, at 66–70.

85. SECOND INTERIM STAFF REPORT, *supra* note 81, at 19–22.

86. *Id.* at 1–2.

87. 2025 NASHP Tracker, *supra* note 14 (“Pharmacy Benefit Manager” dropdown).

88. *Id.*

pharmacies and requires PBMs to reimburse pharmacies for generic drugs at or above the acquisition costs for that drug.⁸⁹

In 2020, the U.S. Supreme Court upheld Act 900 in light of an ERISA preemption challenge brought by the Pharmaceutical Care Management Association (PCMA), a major trade association representing pharmacy benefit managers.⁹⁰ The Employment Retirement Income Security Act (ERISA) includes an express preemption clause, which states that ERISA “shall supersede any and all State laws insofar as they . . . relate to any employee benefit plan.”⁹¹ Since PBMs often administer prescription drug benefits for ERISA-covered plans, PCMA argued that Act 900 would force ERISA-covered plans to adopt a particular reimbursement structure and was thus preempted.⁹² The Court disagreed, emphasizing that the Act regulates prices, not plan structures or benefit designs and emphasized that states have long regulated healthcare costs, including pharmacy reimbursement, and doing so does not interfere with ERISA’s core purposes—namely, uniform plan administration.⁹³

More than forty states have recently adopted or considered legislation aimed at curbing PBM practices that reduce transparency or harm independent pharmacies.⁹⁴ These efforts vary in approach but reflect a growing consensus that PBMs must be held accountable for their role in drug pricing. Notably, the pharmaceutical industry has not shied away from using PBMs as a scapegoat for high drug prices (and vice versa).⁹⁵ While comprehensive prescription drug price reform undoubtedly calls for PBM regulation, such regulation does not address the core issue of high list prices and price hikes for which the pharmaceutical industry is responsible. Nevertheless, state efforts to regulate PBMs remain a key step in addressing the crisis of high drug prices.

89. ARK. CODE ANN. § 17-92-507 (2025).

90. *Rutledge v. Pharm. Care Mgmt. Ass’n*, 141 S. Ct. 474, 478 (2020).

91. 29 U.S.C. § 1144(a).

92. *Rutledge*, 141 S. Ct. at 479–80.

93. *Id.* at 480–81.

94. *2025 NASHP Tracker*, *supra* note 14 (“Pharmacy Benefit Manager” dropdown).

95. *See, e.g.*, Greg Slabodkin, *PBMs and Big Pharma Play Blame Game for Inflated Prescription Drug Prices*, BIOSPACE (July 12, 2024), <https://www.biospace.com/policy/pbms-and-big-pharma-play-blame-game-for-inflated-prescription-drug-prices> [<https://perma.cc/JUF8-N5CK>] (PBMs and pharmaceutical companies blaming one another); Zoey Becker, *PBMs Call Out Big Drugmakers for Setting High Drug Prices in New Digital Ads*, FIERCE PHARMA (Apr. 24, 2025, at 10:09 CT), <https://www.fiercepharma.com/marketing/pbms-pcall-out-big-drugmakers-setting-high-drug-prices-new-digital-ads> (PBMs blaming pharmaceutical companies).

B. Basic Mechanism of PDABs

In this Section, I describe the mechanics of PDABs, including how members of a PDAB are selected, how drugs are selected for negotiation, how UPLs are set, and how PDAB structures may vary across states.

In 2017, NASHP, published model legislation proposing PDABs as a potential mechanism for reining in drug prices.⁹⁶ A PDAB is a public entity established by the state legislature to help lower the prices of prescription drugs.⁹⁷ PDABs are entrusted with evaluating the cost of prescription drugs, assessing the affordability of the drugs in the state, and setting payment or reimbursement limits for drugs dispensed in the state.⁹⁸ They evaluate the prices of some of the most expensive drugs and recommend methods for lowering prices, such as by setting UPLs.⁹⁹

While the composition of a PDAB may vary state to state, the NASHP model bill proposes a PDAB comprised of five members who are experts in health policy, healthcare economics, clinical medicine, and/or other relevant topics.¹⁰⁰ The Bill states that members would be appointed by the governor and confirmed by the state senate, but the board would operate independently of the executive and legislative branches.¹⁰¹ For instance, Maryland's PDAB includes the former Secretary of the Maryland Department of Health and Mental Health, a professor at the University of Maryland School of Pharmacy, a retired orthopedic surgeon, a professor at John Hopkins School of Public Health, and the executive director of the American Public Health Association.¹⁰²

Establishing a UPL typically proceeds in three stages: (1) conducting an eligibility review; (2) conducting an affordability review; and (3) establishing an "upper payment limit."¹⁰³ The boards consider various factors in determining the drugs that are eligible for review, with price being a chief factor. For example, Maryland has established that a

96. Drew Gattine & Kris Vallecillo, *NASHP Releases Model State Legislation to Lower the Cost of Prescription Drugs*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Nov. 7, 2022), <https://nashp.org/nashp-releases-model-state-legislation-to-lower-the-cost-of-prescription-drugs/> [https://perma.cc/MQ99-3ZSL].

97. Mary Kate Barnauskas, *PDABs and UPLs: What They Are and Why They Matter for Drug Pricing Policy*, MULTISTATE (May 15, 2025), <https://www.multistate.us/insider/2025/5/15/pdabs-and-upls-what-they-are-and-why-they-matter-for-drug-pricing-policy> [https://perma.cc/N99U-A8LM].

98. *Id.*

99. *Id.*

100. NASHP MODEL LEGISLATION, *supra* note 17, § 3(2).

101. *Id.*

102. *Meet the Board*, MD. PRESCRIPTION DRUG AFFORDABILITY BD., <https://pdab.maryland.gov/Pages/meettheboard.aspx> [https://perma.cc/RF49-AZ2T] (last visited Jan. 31, 2026).

103. *See* NASHP MODEL LEGISLATION, *supra* note 17.

brand-name drug or biologic that has “a launch wholesale acquisition cost of \$30,000 or more per year or course of treatment” or whose acquisition cost increases by at least \$3,000 in a year may be eligible for review.¹⁰⁴ Boards may also consider how often a particular drug is dispensed, total annual insurance coverage spending on the drug, increases in insurance expenditure from year-to-year, out-of-pocket costs for patients, and impacts on insurance premiums by rebates or other benefits by drug manufacturers to health insurers.¹⁰⁵

If a drug is selected for review, the PDAB determines whether it is affordable. In assessing whether the cost of the drug is sustainable for consumers and the healthcare system, affordability determinations consider a number of factors that overlap with those for eligibility review, including out-of-pocket costs for patients, the average cost of the drug relative to its therapeutic value, the presence of other competitors in the market, the drug’s projected revenue, the drug’s cost-effectiveness relative to therapeutic alternatives, off-label use, the cost of manufacturing the drug, and consumer assistance provided by the drug manufacturer.¹⁰⁶ If the board determines that a drug is unaffordable, it may set a UPL for the drug, which is limited to transactions within the state.¹⁰⁷ UPLs are established while considering a number of statutorily prescribed factors, including the cost of administering and delivering the drugs (considering wholesale acquisition costs, discounts, rebates, and so forth), the difference in pricing for sales in other countries, the status of the drug on the FDA’s drug shortage list, and more.¹⁰⁸

Maryland was the first state to adopt such PDAB legislation, passing House Bill 768 in April 2019.¹⁰⁹ The bill created a five-person drug affordability board with the power to set UPLs on certain pharmaceuticals, including brand-name drugs with an initial cost of \$30,000 or more per course of treatment, brand-name drugs whose price increases by \$3,000 or more per year, and generic drugs priced at \$100 or more and whose price increases by 200 percent or more per year.¹¹⁰ In its original form, the board would have had the power to set UPLs on all health plans in the state.¹¹¹ But certain delegates expressed concerns that such “price control” would result in drug rationing, with Delegate Matthew Morgan (R) stating that “[f]rom a logical standpoint from the

104. MD. CODE ANN., HEALTH-GEN. § 21-2C-08(c) (West 2025).

105. NASHP MODEL LEGISLATION, *supra* note 17, § 4(3).

106. *Id.* § 6(2).

107. *Id.* § 7(2), (7).

108. *Id.* § 7(3).

109. H.B. 768, 2019 Leg., 439th Sess. (Md. 2019).

110. *Id.*

111. Depuyt, *supra* note 20.

company, [drug manufacturers] would sell it to 49 other states before selling it to us.”¹¹² Thus, the state legislature eventually limited UPLs to drugs purchased by health plans that serve employees of the state and county governments.¹¹³ However, Maryland Governor Wes Moore eventually expanded the PDAB’s authority to set UPLs.¹¹⁴

In the years that followed, multiple states followed Maryland’s lead. Indeed, as of June 2025, 12 states have enacted PDAB legislation¹¹⁵ and seventeen more are now considering the same.¹¹⁶ While some states grant PDABs the authority to set UPLs (*e.g.*, Colorado, Maryland, Minnesota, and Washington), most have limited their roles to conducting affordability reviews and making recommendations (*e.g.*, Oregon).¹¹⁷

Of the four state-level reforms discussed, PDABs stand apart as the strongest state-level effort to directly control escalating prescription drug prices. Unlike broader transparency laws or limits on specific PBM practices, PDABs with authority to set UPLs can play a significant role in capping what payers and patients can be charged.¹¹⁸ This direct pricing intervention is a significant step toward addressing systemic drug affordability issues that have persisted in the U.S. despite decades of research, policy, and legislative proposals to rein in high drug prices. Although the White House recently released an executive order aiming to set “most-favored-nation price targets [for] pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations,”¹¹⁹ experts have expressed skepticism about the efficacy of the proposal—including its weak enforcement mechanisms and potential for easy gaming¹²⁰—borne out by the fact that

112. *Id.*

113. *Id.*

114. Prescription Drug Affordability Board - Authority and Stakeholder Council Membership (Lowering Prescription Drug Costs for All Marylanders Now Act), S.B. 357, 2025 Leg., 447th Sess. (Md. 2025); *see also* Silverman, *supra* note 23 (describing bill expanding PDAB’s authority to set UPLs).

115. *State Laws Passed to Lower Prescription Drug Costs: 2017–2025*, *supra* note 24.

116. *Id.*

117. *See* Barnauskas, *supra* note 97.

118. *See* RYAN & SOOD, *supra* note 52, at 1 (finding that no state has seen results from transparency laws); *Delinking PBM Compensation From Drug List Prices Could Unleash Major Savings*, USC LEONARD D. SCHAEFFER INST. FOR PUB. POL’Y & GOV’T SERV. (July 24, 2025), <https://schaeffer.usc.edu/research/pbm-delinking-drug-cost-savings/> [<https://perma.cc/MD8B-W949>] (criticizing limits on PBM practices); Barnauskas, *supra* note 97 (supporting that UPLs can cap drug prices).

119. Exec. Order No. 14,297, 90 Fed. Reg. 20749 (May 12, 2025).

120. *See, e.g.*, Darius Lakdawalla & Dana Goldman, ‘*Most-Favored Nation’ Drug Pricing Has Three Significant Problems*, USC LEONARD D. SCHAEFFER INST. FOR PUB. POL’Y & GOV. SERV. (Apr. 14, 2025), <https://schaeffer.usc.edu/research/most-favored-nation-drug-pricing-has-three-significant-problems/> [<https://perma.cc/7SUD->

pharmaceutical stock indexes rose the day after the announcement.¹²¹ By taking a proactive role in regulating drug prices, PDABs curb market excesses and protect consumers from unpredictable and often exorbitant drug expenses.

Nevertheless, PDABs face critiques, particularly from the industry, which argues that government price-setting puts vital healthcare decisions in the hands of “politicians” and “bureaucrats,” thereby risking patient access to medicine and stifling innovation.¹²² These concerns echo broader debates about balancing cost while maintaining incentives for pharma research and development. However, such critiques overlook the persistent market failures in the pharmaceutical sector—limited competition, opaque pricing, and misaligned incentives—that justify state intervention.¹²³ By recognizing prescription drugs as essential goods with unique market dynamics, PDABs offer a tailored regulatory model to correct systemic inefficiencies and promote equal access to medicines.

However, efforts to rein in drug costs through PDABs have not gone unchallenged. As state PDABs progress through affordability reviews to establish UPLs, industry resistance has also escalated. The case of *Amgen v. Colorado Prescription Drug Affordability Review Board (Amgen v. Colorado PDAB)*¹²⁴ tests the boundaries of a state’s authority to regulate drug prices.

FNM2] (listing important shortcomings of most favored nation pricing proposals, including the fact that it can easily be gamed).

121. Daniel Payne, *White House Unveils Sweeping Plan to Try to Lower U.S. Drug Prices*, STAT (May 12, 2025), <https://www.statnews.com/2025/05/12/trump-drug-prices-executive-order-most-favored-nation-prescription-pricing/> [https://perma.cc/L2TR-8G9M].

122. *Government Price Setting*, PHRMA, <https://phrma.org/police-issues/government-price-setting> [https://perma.cc/L9Z3-RJMY] (last visited Jan. 31, 2026); see also Brad Watts, *Newly Announced Price Controls Hurt Medical Innovation and Limit Patient Access*, U.S. CHAMBER OF COM. (Aug. 15, 2024), <https://www.uschamber.com/intellectual-property/newly-announced-price-controls-hurt-medical-innovation-and-limit-patient-access-to-new-treatments> [https://perma.cc/SXS5-8M5U] (advancing similar arguments about the IRA, arguing that it “giv[es] unelected federal bureaucrats the authority to set arbitrary price controls on lifesaving medicines”).

123. Rena Conti, Richard G. Frank & Jonathan Gruber, *Addressing the Trade-off Between Lower Drug Prices and Incentives for Pharmaceutical Innovation*, BROOKINGS INST. (Nov. 15, 2021), <https://www.brookings.edu/articles/addressing-the-trade-off-between-lower-drug-prices-and-incentives-for-pharmaceutical-innovation/> [https://perma.cc/8LEA-Q9FC].

124. *Amgen v. Mizner*, No. 24-cv-00810 (D. Colo. Mar. 28, 2025), *rev’d sub nom.*, *Amgen v. Colo. Prescription Drug Affordability Rev. Bd.*, No. 25-1641 (Fed. Cir. Apr. 14, 2025).

C. Amgen v. Colorado PDAB

In 2021, Colorado's PDAB reviewed cost, utilization, and budget impact data for a number of high-cost drugs and found that three biologics used to treat autoimmune conditions—Novartis's Cosentyx (secukinumab), Janssen's Stelara (ustekinumab), and Amgen's Enbrel (etanercept)—were unaffordable for Coloradans.¹²⁵ Cosentyx, used to treat conditions such as plaque psoriasis and psoriatic arthritis, cost about \$47,000 per patient in 2022, and the Board found that about 80 percent of patients surveyed indicated they had trouble affording it.¹²⁶ Stelara, used to treat plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis, cost the average patient over \$150,000 in 2022, and its wholesale acquisition cost has increased nearly 200 percent since its approval in 2009.¹²⁷ Enbrel, a blockbuster drug approved to treat rheumatoid arthritis and psoriatic arthritis, has undergone consistent price hikes since it was approved in 1998, with Amgen raking in \$21 billion in revenue from these hikes from 2011 to 2021.¹²⁸ After making this determination, the Colorado PDAB has continued to work towards setting a UPL for these drugs and is currently on track to establish the nation's first UPL.¹²⁹ Under Colorado's PDAB law, UPLs are maximum amounts that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado.¹³⁰

125. Reck & Tewarson, *supra* note 26.

126. Ed Silverman, *Colorado Board Decides a Pricey Novartis Medicine Is Unaffordable*, STAT (June 14, 2024), <https://www.statnews.com/pharmalot/2024/06/14/colorado-novartis-cosentyx-amgen-enbrel-jnj-medicines-affordable-price/> [<https://perma.cc/Q6YZ-Z8DB>].

127. Zoey Becker, *Colorado Drug Review Board Finds J&J's Stelara Unaffordable, Teeing Up Potential Statewide Price Cap*, FIERCE PHARMA (June 11, 2024, at 09:05 CT), <https://www.fiercepharma.com/pharma/colorado-drug-affordability-review-board-votes-jjs-stelara-unaffordable-teeing-potential>; *Ustekinumab Injection*, CLEVELAND CLINIC, <https://my.clevelandclinic.org/health/drugs/18088-ustekinumab-injection> [<https://perma.cc/X89X-H7QB>] (last visited Jan. 31, 2026).

128. Gregg Girvan, *The Impact of Amgen's Price Increases for Enbrel on Pharmaceutical Innovation*, FREOPP: BLOG (Oct. 21, 2022), <https://freopp.org/the-impact-of-amgens-price-increases-for-enbrel-on-pharmaceutical-innovation> [<https://perma.cc/V6WJ-KK3H>]; *FDA Accepts Amgen's Supplemental Biologics License Application for the Expanded Use of Enbrel (Etanercept) to Treat Pediatric Patients with Chronic Severe Plaque Psoriasis*, AMGEN (Mar. 10, 2016), <https://www.amgen.com/newsroom/press-releases/2016/03/fda-accepts-amgens-supplemental-biologics-license-application-for-the-expanded-use-of-enbrel-etanercept-to-treat-pediatric-patients-with-chronic-severe-plaque-psoriasis> [<https://perma.cc/RRP3-5PKU>].

129. Reck & Tewarson, *supra* note 26.

130. Defendants' Combined Cross-Motion for Summary Judgment and Memorandum in Support and Response in Opposition to Plaintiffs' Motion for Summary Judgment at 9–10, *Amgen v. Mizner*, No. 24-cv-00810 (D. Colo. Aug. 9, 2024).

In response, Amgen, the manufacturer of Enbrel, filed a lawsuit in the U.S. District Court for the District of Colorado, challenging the constitutionality of Colorado’s PDAB law.¹³¹ In its lawsuit, Amgen advanced three central arguments.¹³² First, the PDAB violates due process because it lacks standards and procedural protections to guide the Board’s decision-making in determining what drugs are unaffordable or when setting a UPL, it and therefore fails to provide drug manufacturers with a meaningful opportunity to be heard and fails to protect them against erroneous deprivations of property.¹³³ Second, Amgen alleged that UPLs violate the Dormant Commerce Clause by regulating commercial transactions that take place entirely outside of Colorado, such as initial sales from the drug manufacturer to wholesalers.¹³⁴ Third, Amgen argued that the PDAB’s authority to set UPLs is preempted by federal patent law, including the Patent Act and the Hatch-Waxman Act.¹³⁵ Amgen argued that UPLs impermissibly override the legislative balance struck by Congress in order to “reward[] pharmaceutical innovation with a period of market exclusivity and the ability to charge prices that allow for further investment and innovation during that period,” “strip[ping] away the very rights and economic incentives that Congress sought to create in enacting the patent laws.”¹³⁶ While the district court dismissed the challenge for lack of standing and thus did not reach the substance of any of these arguments, the case is currently on appeal to the Federal Circuit.¹³⁷ Part III of this Article delves into the third argument (patent preemption), so I first preview the Dormant Commerce Clause and procedural due process claims here.

In briefing, the state responded to Amgen’s due process arguments by emphasizing the procedural protections built into the PDAB framework. The state argued that the PDAB process includes public meetings, notice of proposed decisions, and opportunities for written and

[hereinafter Defendants’ MSJ] (citing S.B. 21-175, 73d Gen. Assemb., Reg. Sess. (Colo. 2021); COLO. CODE REGS. § 702-9:4.2.C (2023)).

131. *Amgen v. Mizner*, slip. op. at 4.

132. Amgen also argued that the PDAB was preempted from applying UPLs to federal payors such as Medicare. *Amgen* Complaint, *supra* note 31, at 31–33. However, the Board and state Attorney General explicitly disclaimed such applications in guidance documents, stating that UPLs would not apply to Medicare or self-funded plans subject to ERISA that did not opt-in. *Id.* at 7 n.1; Defendants’ MSJ, *supra* note 130, at 39–42.

133. *Amgen* Complaint, *supra* note 31, at 29–31.

134. *Id.* at 33–36.

135. *Id.* at 26–29.

136. *Id.* at 5–6.

137. *Amgen v. Mizner*, No. 24-cv-00810 (D. Colo. Mar. 28, 2025), *rev’d sub nom.*, *Amgen v. Colo. Prescription Drug Affordability Rev. Bd.*, No. 25-1641 (Fed. Cir. Apr. 14, 2025).

oral input from stakeholders, including manufactures like Amgen.¹³⁸ Indeed, the state pointed out that Amgen had in fact submitted written comments and participated in such public meetings, demonstrating that it had meaningful opportunities to engage.¹³⁹ The state also highlighted the detailed, 500-plus page affordability review report as evidence of the Board’s thorough and transparent deliberative process.¹⁴⁰ Finally, the state contended that the Board’s preliminary determination of unaffordability is not final agency action, but rather a threshold step that triggers the possibility of initiating rulemaking and setting a UPL—not a binding obligation.¹⁴¹ These safeguards, Colorado argued, satisfy and exceed the requirements of due process.

To evaluate how such due process arguments would fare against the Colorado PDAB, it is instructive to consider similar claims brought in litigation challenging the Medicare Drug Negotiation Program under the IRA. In the IRA litigation, drug manufacturers argued that the program deprived them of property without due process by imposing coercive price-setting mechanisms without meaningful procedural protections.¹⁴² However, Andrew Twinamatsiko and Zachary Baron of the O’Neill Institute have observed that these arguments conflate ordinary regulatory disagreements with constitutional deprivations, relying on a strained theory that participation in a voluntary federal benefits program constitutes a protected property interest in existing pricing structures.¹⁴³ These claims appear to rely on *Michigan Bell Telephone Co. v. Engler*¹⁴⁴—a case cited in Amgen’s briefing as well¹⁴⁵—in which the Sixth Circuit found that telephone companies were likely to prevail on a claim that rate-setting legislation for telephones violated due process rights.¹⁴⁶

However, as Twinamatsiko and Baron point out, *Michigan Bell* stands for the proposition that “the constitution protects [public] utilities

138. Defendants’ MSJ, *supra* note 130, at 36–37.

139. *Id.*

140. *Id.* at 15, 36–37.

141. *Id.* at 20–21.

142. HANNAH-ALISE ROGERS, CONG. RSCH. SERV., R47682, CONSTITUTIONAL CHALLENGES TO THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM 8 (Oct. 10, 2024).

143. Andrew J. Twinamatsiko & Zachary L. Baron, *Policy Dispute Masquerading as Constitutional Theory? Due Process Attacks on Medicare Drug Negotiation Program*, O’NEILL INST. (Aug. 17, 2023), <https://oneill.law.georgetown.edu/policy-dispute-masquerading-as-constitutional-theory-due-process-attacks-on-medicare-drug-negotiation-program/> [https://perma.cc/56EW-CU98].

144. 257 F.3d 587 (6th Cir. 2001).

145. Plaintiffs’ Combined Reply in Support of Plaintiffs’ Motion for Summary Judgment and Opposition to Defendants’ Cross-Motion for Summary Judgment at 22–24, *Amgen v. Mizner*, No. 24-cv-00810 (D. Colo. Sep. 6, 2024).

146. *Michigan Bell Telephone Co.*, 257 F.3d at 596.

from being limited to a charge for their property serving the public which is so unjust as to be confiscatory.”¹⁴⁷ Public utilities are legally compelled to provide services to the public, while drug manufacturers are voluntary participants in a private market. Although “price control is unconstitutional . . . if arbitrary, discriminatory, or demonstrably irrelevant to the policy under a due process analysis,” “the Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases. . . . The right to conduct a business, or to pursue a calling, may be conditioned by regulation of such activity.”¹⁴⁸ Recent decisions rejecting such due process claims against the IRA’s negotiation program reflect a similar logic: Manufacturers have no vested property right in prevailing market prices, and participation in Medicare remains voluntary (just as participation in a state’s drug market is voluntary).¹⁴⁹ These rulings reinforce Colorado’s argument that UPLs—so long as procedurally fair—are presumptively valid under the Due Process Clause.

Amgen also argued that the Colorado PDAB violates the Dormant Commerce Clause, referring to the principle that state laws must not discriminate against or unduly burden interstate commerce. Specifically, the extraterritoriality principle of the Dormant Commerce Clause prohibits a state from enacting laws that regulate commerce occurring entirely outside its borders.¹⁵⁰ In *National Pork Producers Council v. Ross*,¹⁵¹ the Supreme Court clarified the scope of the Dormant Commerce Clause, upholding California’s animal welfare laws even though they had upstream effects on out-of-state producers.¹⁵² A majority of Justices rejected a per se extraterritoriality rule, emphasizing that upstream effects on interstate commerce are not enough for courts to find a violation of the Dormant Commerce Clause—there must be direct regulation of out of state prices or conduct.¹⁵³

In 2025, the Eighth Circuit affirmed a lower court decision granting a preliminary injunction against a Minnesota generic drug price gouging

147. Twinamatsiko & Baron, *supra* note 143 (emphasis omitted).

148. *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440, 456 (S.D. Ohio 2023) (cleaned up); *see also Fishman v. Est. of Wirtz*, 807 F.2d 520, 538 n.16 (7th Cir. 1986) (noting that “[a] patent is not a natural monopoly in the same sense as is a franchise for the provision of electric power”).

149. *Boehringer Ingelheim Pharms., Inc. v. U.S. Dep’t of Health & Hum. Servs.*, No. 23-cv-01103, 2024 WL 3292657, at *19 (D. Conn. July 3, 2024); *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413, at *5 (D.N.J. July 31, 2024); *AstraZeneca Pharms. v. Becerra*, 719 F. Supp. 3d 377, 393–97 (D. Del. 2024).

150. *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989).

151. 143 S. Ct. 1142 (2023).

152. *Id.* at 1153–55.

153. *Id.*

law for violating the Dormant Commerce Clause.¹⁵⁴ The Minnesota law prohibited manufacturers from imposing or causing “to be imposed an excessive price increase” on “generic or off-patent drugs sold, dispensed, or delivered to any consumer in the state.”¹⁵⁵ The district court granted Association for Accessible Medicines’ motion for a preliminary injunction, reasoning that the broad language of the Act suggested that the initial “sale” regulated by the Act need not occur within Minnesota—upstream sales by the manufacturer occurring wholly outside of the state could cause “excessive” price increases to be imposed on sales within the state in violation of the law.¹⁵⁶ The court also found significant that the Act penalized manufacturers who would try to avoid liability under the Act by prohibiting their drugs from being sold or distributed in Minnesota, noting that “the Act is fundamentally at odds with Dormant Commerce Clause jurisprudence, which often relies on the principle that anyone who wishes to avoid being subject to a state’s economic regulation can simply avoid doing business in that state.”¹⁵⁷ The Eighth Circuit affirmed the injunction, distinguishing *Pork Producers* by concluding that the law amounted to regulation of a sale that occurred in another state simply because the product eventually made its way into Minnesota.¹⁵⁸

While the decision is a blow to Minnesota’s drug price gouging law, Colorado’s PDAB law only prohibits certain entities in the state from purchasing or reimbursing drugs for distribution within the state. Thus, the PDAB regulates in-state payors, not manufacturers and upstream sales which may occur wholly out-of-state. Additionally, the application of UPLs to state employee plans and Medicaid is more akin to state procurement law than a price control. In such applications, the market participation exception may apply: Where the state is acting as a participant in the private market, it may set limits on what it is willing to pay for drugs on the private market.¹⁵⁹ As will be discussed further, state

154. *Ass’n for Accessible Meds. v. Ellison*, 140 F.4th 957, 958–59 (8th Cir. 2025).

155. MINN. STAT. § 62J.842 (2025).

156. *Ass’n for Accessible Meds. v. Ellison*, 704 F. Supp. 3d 947, 952–54 (D. Minn. 2023).

157. *Id.* at 956–57 (citing *Nat’l Pork Producers Council v. Ross*, 143 S. Ct. 1142, 1161–62 (2023) (plurality opinion)).

158. *Ass’n for Accessible Meds.*, 140 F.4th at 961–62.

159. *See, e.g., Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 806–10 (1976) (establishing the market participant doctrine and upholding a Maryland law that provided subsidies to in-state scrap processors, finding that the state was acting as a purchaser in the market); *Reeves, Inc. v. Stake*, 447 U.S. 429, 436–40 (1980) (upholding South Dakota’s policy of restricting its sales of state-produced cement to in-state residents under the market participant exception); *White v. Mass. Council of Constr. Emps., Inc.*, 460 U.S. 204, 205 n.1, 214–15 (1983) (upholding a Boston executive order requiring

regulation of intrastate commerce is part and parcel of a state's inherent and historic powers.

Amgen's final argument relies on the doctrine of patent preemption. This case presents the Federal Circuit with a rare opportunity to revisit its interpretation of the scope of patent preemption from a prior holding—*BIO v. D.C.*, in which the court held that a D.C. price-setting law that prohibited the sale of patented prescription drugs at an "excessive price" was preempted because it created an unconstitutional obstacle to the rewards and incentives established by Congress under the Patent Act.¹⁶⁰

II. PATENT PREEMPTION LANDSCAPE

To evaluate the scope of federal patent law's preemption of UPLs, I begin with an overview of U.S. Supreme Court and Federal Circuit precedent on patent preemption. I then consider whether and why the Federal Circuit has jurisdiction to strike down state laws that purportedly preempt federal patent law, compare the law at issue in *BIO v. D.C.* to PDAB UPLs, and finally consider the role of patent exhaustion in the claims that Colorado's is preempted by federal patent law.

A. An Overview of Patent Preemption

In the United States, the Constitution and federal laws may invalidate, or "preempt," state laws that conflict with federal law. The constitutional authority for preemption is derived from the Supremacy Clause of the Constitution, which states:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.¹⁶¹

Thus, any state law which conflicts with federal law, either expressly or implicitly, must be invalidated, or "preempted," under the Supremacy Clause.

publicly funded construction projects to be performed by a workforce consisting of at least 50 percent city residents under the market participant doctrine).

160. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

161. U.S. CONST. art. VI, cl. 2.

The Patent Act and other federal intellectual property laws were enacted pursuant to Congress's powers under the Intellectual Property Clause, which holds: "The Congress shall have 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."¹⁶² As an exercise of its Article I powers, Congress has enacted a series of laws governing patents, including the Patent Act, the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the Hatch-Waxman Act),¹⁶³ and the Biologics Price Competition and Innovation Act of 2009 (BPCIA).¹⁶⁴ The Patent Act grants an inventor the right to exclude others from making, using, offering for sale, selling, or importing into the U.S. the subject invention.¹⁶⁵

There are two forms of preemption: express and implied. If a federal statute contains language that explicitly affirms Congress's intent to preempt state law, any conflicting state law is expressly preempted. At the same time, courts tasked with deciding express preemption cases must still determine "the substance and scope of Congress' displacement of state law."¹⁶⁶ The federal patent laws do not expressly preempt state laws, and the Federal Circuit has recognized as much.¹⁶⁷ Thus, if the Patent Act preempts a state law, it must be under implied preemption.

Under implied preemption, congressional intent to preempt state law may be inferred from the structure and purpose of a federal statute. Implied preemption is further subdivided into field preemption and conflict preemption. Field preemption occurs when federal law creates a regulatory scheme that is so pervasive as to "occupy the field" in that area of the law that courts will infer congressional intent to preempt state law, even when the relevant state law does not directly conflict with, but only supplements federal law.¹⁶⁸ If so, courts will conclude that Congress "intend[s] to 'foreclose any state regulation in the area,' irrespective of

162. U.S. CONST. art. I, § 8, cls. 1, 8.

163. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in part at 35 U.S.C. § 156).

164. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 804 (2010).

165. 35 U.S.C. § 271.

166. *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008).

167. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) ("There is no express provision in the patent statute that prohibits states from regulating the price of patented goods; indeed, 'the federal patent laws do not create any affirmative right to make, use, or sell anything.'" (quoting *Leatherman Tool Grp., Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997))).

168. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

whether state law is consistent or inconsistent with ‘federal standards.’”¹⁶⁹

Professor Robin Feldman and others have concluded that it is unlikely that field preemption would apply to state drug payment rate regulation.¹⁷⁰ However, states cannot create their own patent systems or grant patents or patent-like rights that conflict with federal patent law.¹⁷¹ For instance, in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,¹⁷² the U.S. Supreme Court struck down a Florida state law that prohibited copying unpatented boat hull designs, finding that such a law partially duplicated and was therefore preempted by the federal patent scheme.¹⁷³ The Court held that the Florida law disrupted the balance between the federal patent law’s objective of promoting progress and that law’s critical assumption “that free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception.”¹⁷⁴

For other patent-adjacent claims, the Federal Circuit has held that “there is no field preemption of state unfair competition claims that rely on a substantial question of federal patent law,” placing importance on the fact that unfair competition and patent law have historically coexisted as independent bodies of law.¹⁷⁵ Similarly, in *Kewanee Oil Co. v. Bicron Corp.*,¹⁷⁶ the U.S. Supreme Court held that state trade secret protection, which protects against improper acquisition and use of secret information, was not preempted by federal patent law.¹⁷⁷ On the other hand, in *Amgen, Inc. v. Sandoz, Inc.*,¹⁷⁸ the Federal Circuit found that the BPCIA field preempted state law unfair competition claims related to the BPCIA’s “patent dance,”¹⁷⁹ finding that biosimilar patent litigation

169. *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015) (emphasis omitted).

170. Robin Feldman, Betty Chang Rowe, Rabiah Oral, Amu Gu & Katherine Gudiksen, *Federalism, Patents, and the Constitutionality of State Pharmaceutical Regulation*, in U.C. HASTINGS COLL. OF THE L. LEGAL. STUD. RSCH. PAPER SERIES, at 1, 13 (RsCh. Paper No. 311, 2018).

171. See Camilla A. Hrды, *Getting Patent Preemption Right*, 24 J. INTELL. PROP. L. 305, 307 (2017).

172. 489 U.S. 141 (1989).

173. *Id.* at 144.

174. *Id.* at 151.

175. *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1333–35 (Fed. Cir. 1998), *overruled on other grounds by, Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1318, 1333 (Fed. Cir. 1999) (concluding that “there is no reason to believe that the clear and manifest purpose of Congress was for federal patent law to occupy exclusively the field pertaining to state unfair competition law”).

176. 416 U.S. 470 (1974).

177. *Id.* at 474–75.

178. 877 F.3d 1315 (Fed. Cir. 2017).

179. *Biologics, Biosimilars, and the Biologics Price Competition and Innovation Act (“BPCIA”): A Short Primer*, GOODWIN: BIG MOLECULE WATCH (May 29, 2015), <https://www.bigmoleculewatch.com/2015/05/29/2-biologics-biosimilars-and-the->

was not a field which the states have traditionally occupied.¹⁸⁰ PDAB laws do not attempt to create “patent-like rights,” such as the state law at issue in *Bonito Boats*, and as will be discussed further, patent laws do not set minimum prices for or guarantee profits from the sale of patented products.¹⁸¹ States have also historically regulated the prices of certain essential goods and services—patented or not—and such regulations have traditionally coexisted with patent rights. Thus, courts are unlikely to find PDAB laws invalid by field preemption.

The second variety of implied preemption is conflict preemption.¹⁸² The conflict may arise when it is impossible to comply with both the state and federal regulations (impossibility preemption),¹⁸³ or when the state law imposes an obstacle to the accomplishment of the full purposes and objectives of Congress (obstacle preemption).¹⁸⁴ Although the U.S. Supreme Court has ruled on a number of impossibility preemption cases in the context of FDA law,¹⁸⁵ impossibility preemption rarely arises in the context of patents, and it is not the type of preemption at issue with PDABs; it is not practically impossible for a pharmaceutical company to comply with any requirements under federal patent law and the UPLs set by PDABs.

Thus, if patent law is to preempt the existence of UPLs established by PDABs, it must be due to obstacle preemption. Indeed, this was the

biologics-price-competition-and-innovation-act-bpcia-a-short-primer/ [https://perma.cc/XD6N-V6J9].

180. *Amgen, Inc. v. Sandoz, Inc.*, 877 F.3d at 1327–28.

181. See Feldman, Rowe, Oral, Gu & Gudiksen, *supra* note 170, at 4.

182. See *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (“[W]e have long recognized that state laws that conflict with federal law are ‘without effect.’” (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981))).

183. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009) (holding that it was not impossible for a drug company to enhance its warning labels to comply with both state and federal law, establishing a high bar for impossibility preemption); *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019) (reaffirming this high bar by holding that a manufacturer must show “clear evidence” that the FDA would have rejected a label change that would bring a label into compliance with state law in order to successfully make out a case for impossibility preemption).

184. See, e.g., *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 352 (2011).

185. The Court has ruled on a number of cases concerning the issue of whether drug labeling requirements under the Food, Drug & Cosmetics Act preempted conflicting labeling or duties to warn under state regulations. See generally *Wyeth*, 555 U.S. 555 (finding no impossibility preemption when state law required stronger warnings, and FDA regulations allowed manufacturers to unilaterally strengthen warnings); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (finding impossibility preemption where state tort law required stronger warnings, but generic drug manufacturers had no ability to unilaterally change labels); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013) (finding that impossibility preemption barred state law design-defect claims against generic drug manufacturers who could not change the composition or labeling of the drug under FDA law).

type of preemption applied by the Federal Circuit in *BIO v. D.C.* when it held that the D.C. price gouging law stood as an obstacle to the goals and objectives of the Patent Act.¹⁸⁶ The U.S. Supreme Court has held that a state law is preempted if it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”¹⁸⁷ Because preemption displaces the laws of states that retain their own sovereignty, the U.S. Supreme Court has warned that “implied preemption analysis does not justify a ‘freewheeling judicial inquiry into whether a state statute is in tension with federal objectives.’”¹⁸⁸ For that reason, the Court has required that “a high threshold must be met if a state law is to be preempted for conflicting with the purposes of a federal Act.”¹⁸⁹

In *Wyeth v. Levine*,¹⁹⁰ the U.S. Supreme Court emphasized that federal preemption analysis “must be guided by two cornerstones of our pre-emption jurisprudence.”¹⁹¹

First, “the purpose of Congress is the ultimate touchstone in every pre-emption case.” Second, “[i]n all pre-emption cases, and particularly in those in which Congress has ‘legislated . . . in a field which the States have traditionally occupied,’ . . . we ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’”¹⁹²

This is especially true for state legislation that aims to protect public health, which is in the heartland of state sovereignty and police power.¹⁹³ Courts must therefore fully “ascertain the nature of the federal interest” before finding that “a state law conflicts with Congress’ purposes and objectives.”¹⁹⁴

186. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1365 (Fed. Cir. 2007).

187. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

188. *Chamber of Com. v. Whiting*, 563 U.S. 582, 607 (2011) (quoting *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 111 (1992)).

189. *Id.* (quoting *Gade*, 505 U.S. at 112).

190. 555 U.S. 555 (2009).

191. *Id.* at 565.

192. *Wyeth*, 555 U.S. at 565 (alterations in original) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)); see also *Retail Clerks Int’l Ass’n, Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963) (stating that “[t]he purpose of Congress is the ultimate touchstone”).

193. *Medtronic, Inc.*, 518 U.S. at 475 (“Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens.”).

194. *Hillman v. Maretta*, 569 U.S. 483, 491 (2013).

Turning to the first cornerstone, the U.S. Supreme Court has historically recognized three primary objectives of federal patent law:

First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.¹⁹⁵

The Federal Circuit has often cited the first objective—fostering and rewarding innovation—as the principle aim of patent law,¹⁹⁶ and indeed relied upon this principle to strike down D.C.’s price gouging law in *BIO v. D.C.*¹⁹⁷ However, several U.S. Supreme Court cases from the early- to mid-nineteenth century recognized the second objective of disseminating the inventor’s ideas to the public as the most important.¹⁹⁸

195. *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (citing *Kewanee Oil Co. v. Bicron Co.*, 416 U.S. 470, 480–81 (1974)).

196. *See Paulik v. Rizkalla*, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (en banc) (“The exclusive right, constitutionally derived, was for the national purpose of advancing the useful arts—the process today called technological innovation. As implemented by the patent statute, the grant of the right to exclude carries the obligation to disclose the workings of the invention, thereby adding to the store of knowledge without diminishing the patent-supported incentive to innovate. But the obligation to disclose is not the principal reason for a patent system; indeed, it is a rare invention that cannot be deciphered more readily from its commercial embodiment than from the printed patent. The reason for the patent system is to encourage innovation and its fruits: new jobs and new industries, new consumer goods and trade benefits. We must keep this purpose in plain view as we consider the consequences of interpretations of the patent law such as in the Board’s decision.”).

197. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372–73 (Fed. Cir. 2007) (“The fundamental goal of the patent law is spelled out in the Constitution: ‘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.’ Inventors are impelled to invest in creative effort by the expectation that, through procurement of a patent, they will obtain a federally protected ‘exclusive right’ to exclude others from making, using, or selling embodiments of their invention. Patentees value the right to exclude in part because the ability to foreclose competitors from making, using, and selling the invention may allow them an opportunity to obtain above-market profits during the patent’s term. This court has repeatedly recognized as important the pecuniary rewards stemming from the patent right.” (citation omitted)), *reh’g and reh’g en banc denied*, 505 F.3d 1343, 1344 (Fed. Cir. 2007).

198. *See Pennock v. Dialogue*, 27 U.S. 1, 19 (1829) (“While one great object [of the patent laws] was, by holding out a reasonable reward to inventors, and giving them an exclusive right to their inventions for a limited period, to stimulate the efforts of genius; the main object was ‘to promote the progress of science and useful arts’”); *Kendall v. Winsor*, 62 U.S. 322, 327–28 (1858) (“It is undeniably true, that the limited and temporary monopoly granted to inventors was never designed for their exclusive

The second objective is frequently characterized as a *quid pro quo* bargain: In exchange for the right to exclude others from making, using, selling, or importing an invention for a limited period of time, a patentee must fully disclose how to make and use the claimed invention.¹⁹⁹ After the patent expires, the disclosure of this knowledge, and the associated invention, should fall into the public domain. Thus, any preemption analysis of a state law that may conflict with the objectives and purposes of patent law must begin with these objectives.

B. A Flawed Analysis in *BIO v. D.C.*

As previously noted, patent preemption was successfully deployed against the D.C. excessive drug pricing law in *BIO v. D.C.*²⁰⁰ The law at issue in *BIO v. D.C.*—the Prescription Drug Excessive Pricing Act of 2005—prohibited patented drugs from being sold at excessive prices.²⁰¹ Under the law, a drug was presumed to be excessively priced if its wholesale price in D.C. was at least 30 percent higher than its price in the United Kingdom, Germany, Canada, or Australia—high-income countries where drugs enjoy patent protection and other market exclusivities.²⁰² A drug manufacturer, however, could rebut this presumption based on patent policy considerations.²⁰³ Specifically, a manufacturer could show that the drug was not excessively priced based on “demonstrated costs of invention, development and production of the prescription drug, global sales and profits to date, consideration of any government funded research that supported the development of the drug, and the impact of price on access to the prescription drug by residents and the government of the District of Columbia.”²⁰⁴ The law broadly empowered everyone “directly or indirectly affected by excessive prices of patented prescription drugs” to sue drug manufacturers and obtain various remedies, including fines, treble damages, and attorney fees.²⁰⁵

profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly.”).

199. See, e.g., *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989) (“The federal patent system . . . 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.”).

200. *Biotechnology Indus.Org.*, 496 F.3d at 1362.

201. *Id.* at 1365.

202. *Id.* at 1365–66.

203. *Id.* at 1365, 1371.

204. *Id.* at 1365 (quoting D.C. CODE § 28–4554(b) (2007)).

205. *Id.* at 1366.

Shortly after the law was passed, groups of drug manufacturers brought suit, arguing that the law was facially unconstitutional because it conflicted with the purpose and objectives of federal patent laws.²⁰⁶ The Federal Circuit agreed. Although the court acknowledged that D.C. is a federal territory whose laws are forms of federal regulation, principles of federal preemption of state law still applied because D.C. was on the same footing as states in that respect.²⁰⁷

Acknowledging that federal patent statutes neither expressly preempt conflicting state law nor “create any affirmative right to make, use, or sell anything,” the court proceeded to assess whether the D.C. law was invalid by obstacle preemption.²⁰⁸ The court observed that the purpose of patent law was laid out in the Constitution’s Progress Clause and Federal Circuit precedent finding important the pecuniary rewards stemming from the patent right important in encouraging innovation.²⁰⁹ The *BIO v. D.C.* court concluded that these goals were concretized in patent laws that spur innovation by providing patentees the right to exclude others from making, using, or selling the embodiments of the invention, which is valuable to patentees because it keeps competitors out, allowing patentees to “obtain above-market profits” for the duration of the patents.²¹⁰ The court also considered preemption under the Hatch-Waxman Act, the federal law that governs the process by which generic drug manufacturers can challenge brand patents while seeking FDA approval, balancing incentives for both generic and brand pharmaceutical manufacturers.²¹¹ The court concluded that a patentee’s profits were also essential to the balance that Congress struck in the Hatch-Waxman Act based on the Act’s legislative history and statements made by the House Committee on Energy and Commerce: “Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.”²¹²

The court concluded that the D.C. law was in tension with Congress’s balancing of the competing interests of exclusion, free use, and competition. First, the court noted that the D.C. law was not generally applicable to all drugs, but rather specifically “applie[d] only

206. *Id.*

207. *Id.* at 1371–72.

208. *Id.* at 1372.

209. *Id.* at 1372–73.

210. *Id.* at 1372.

211. *Id.* at 1373 (citing Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984)).

212. *Id.* at 1373 (citing H.R. Rep. No. 98-857, at 15, 17 (1984)).

to patented drugs” and was therefore “targeted at the patent right.”²¹³ By targeting patented drugs alone, D.C. recognized that the exclusionary rights of patent owners enabled them to charge high prices for patented drugs, and thus sought to shift the benefits of the patent system from drug manufacturers to consumers by impermissibly rebalancing the federal “statutory framework of rewards and incentives” for new drugs.²¹⁴ The Act also enabled such rebalancing by permitting D.C. to consider evidence that a given prescription drug was not excessively priced, such as the “costs of invention, development and production of the prescription drug, global sales and profits to date, . . . any government funded research that supported the development of the drug, and the impact of price on access to the prescription drug by residents and the government of the District of Columbia.”²¹⁵

To the Federal Circuit, the D.C. law was “a clear attempt to restrain those excessive prices, in effect diminishing the reward to patentees in order to provide greater benefit to [D.C.] drug consumers.”²¹⁶ D.C. had essentially sought to “change federal patent policy within its borders,” even though “the proper balance between innovators’ profit and consumers access to medication” was exclusively within Congress’s purview²¹⁷—an apparently clear application of preemption doctrine.

However, the *BIO v. D.C.* case has drawn sustained critique for its overly broad application of patent preemption.²¹⁸ Most recently, Professor Rebecca Wolitz has argued that congressional inaction on excessive drug pricing has made state-level intervention necessary, even if this option is second-best to federal drug policy reform.²¹⁹ She concludes that, while *BIO v. D.C.* has compromised the ability of states

213. *Id.* at 1373–74; *see also Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 23-CV-00997, 2024 WL 4361597, at *9 (W.D. La. Sep. 30, 2024) (“Here, unlike the D.C. Council’s legislation, Louisiana’s Act 358 does not, on its face, target patent rights or, by its terms, apply only to patented drugs or the price of patented drugs.”).

214. *Biotechnology Indus. Org.*, 496 F.3d at 1373–74.

215. *Id.* at 1365 (citing D.C. CODE § 28–4554(b) (2007)).

216. *Id.* at 1374.

217. *Id.*

218. *See, e.g.,* Rebecca E. Wolitz, *States, Preemption, and Patented Drug Prices*, 52 SETON HALL L. REV. 385, 418 (2021); Christopher Lea Lockwood, Note, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 ALB. L.J. SCI. & TECH. 143, 172–73 (2009); David M.G. Ross, Note, *Biotechnology v. District of Columbia: The Federal Circuit Expands Its Jurisdiction in Order to Extend Preemption Doctrine to State Law Restrictions on Patent Rights*, 10 TUL. J. TECH. & INTELL. PROP. 339, 348–51 (2007); Joshua D. Sarnoff, *BIO v. DC and the New Need to Eliminate Federal Patent Law Preemption of State and Local Price and Product Regulation*, 2007 PATENTLY-O PAT. L.J. 30, 33–35 (2007).

219. Wolitz, *supra* note 218, at 388, 391.

to enact reforms, “states should not be preempted by federal patent law from addressing the urgent problem of excessively priced patented medications.”²²⁰ She critiques *BIO v. D.C.* as misreading preemption doctrine and the objectives of patent law, arguing that the decision treats any attempt at regulating pricing of products that happen to be patented as interference with a patent’s exclusionary power: “The Federal Circuit’s ruling should not preempt, on patent law grounds, state level excessive price regulation that reaches patented medications. . . . States should not be blocked from addressing the urgent problems of prescription drug access and affordability given federal abdication of corrective action. [*BIO v. D.C.*] must be avoided or fixed.”²²¹

Professor Wolitz adds that, because patent law only grants patentees the right to exclude others from making, selling, or using the subject invention, nothing in patent law or congressional intent justifies wholesale preemption of state authority to address high drug prices, undermining the Federal Circuit’s conclusion that state price regulations of patented drugs conflict with the objectives and purposes of federal patent law.²²² This notion is supported by Professor Robin Feldman and others, who add that:

The Patent Act does not regulate the price for any patented product. It does not guarantee or entitle a profit to the inventor at all, and most patent holders never garner any returns from their invention. Although patent holders are free to completely withhold their invention from the market, for those who do choose to sell a product based on that patent, the Patent Act does not guarantee any particular level of profit, and certainly not at the level of a monopolist. In fact, the Supreme Court has held that given the language of the Patent Act, Congress could not have intended “the mere existence of a patent to constitute . . . market power.” In short, patent laws do not touch the issue of pricing or level of return in any manner.²²³

Indeed, in his dissent from the denial of the petition for rehearing in *BIO v. D.C.*, Judge Dyk argued that, as a result of the panel’s overbroad

220. *Id.* at 386.

221. *Id.* at 440.

222. *Id.*

223. Feldman, Rowe, Oral, Gu & Gudiksen, *supra* note 170, at 4 (alteration in original) (footnotes omitted) (quoting *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 42 (2006)); *see also* 35 U.S.C. § 271(d)(4) (stating that “[n]o patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . refused to license or use any rights to the patent”).

holding, “any state law regulating the prices of patented pharmaceutical products would likely be preempted.”²²⁴ In his view, the essential problem with the D.C. Act was that, due to the manner in which it was structured, the Act was field preempted by federal patent law.²²⁵ The Act required D.C. courts, while considering defenses to a presumption of excessive pricing, to determine what price was necessary to spur innovation—a policy determination that Congress made in the Patent Act and thus did not intend to leave to the states.

Instead, he argued that “[d]espite its poor drafting,” the core of the Act was a regulation of price discrimination (in drug prices in the United States and other industrialized countries with drug patent protection), which “presents no conflict with the purpose of the federal patent law.”²²⁶ He noted that the U.S. Supreme Court had previously declined to find that federal price discrimination statutes preempt comparable state-level restrictions based on similar arguments,²²⁷ and patent law was not “designed to confer immunity from antitrust-type regulation” (such as price discrimination regulation).²²⁸ Thus, “sellers of patented products have no special right to fix the price at which the patented products are sold.”²²⁹

Judge Dyk further concluded, as Professor Wolitz, Professor Feldman, and others did in their arguments described previously, that “[a] patent grant is designed not to allow the patent holder to exploit the grant for the maximum profit that the market will bear, but merely to confer a right of exclusivity.”²³⁰ He added that “[t]he Supreme Court has frequently applied this principle to conclude that patent law does not preempt or conflict with state and federal statutes regulating or prohibiting the sale of patented products,” including an 1880 U.S. Supreme Court case finding that a state tax was not preempted as applied to the sale of patented products and an 1878 case holding that a state ban on a patented product due to safety concerns was permissible.²³¹

224. *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1348 (Fed. Cir. 2007) (Dyk, J., dissenting from denial of rehearing en banc).

225. *Id.* at 1349 (Dyk, J., dissenting from denial of rehearing en banc).

226. *Id.* (Dyk, J., dissenting from denial of rehearing en banc).

227. *Id.* at 1350 (Dyk, J., dissenting from denial of rehearing en banc) (citing *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 131 (1978)).

228. *Id.* (Dyk, J., dissenting from denial of rehearing en banc).

229. *Id.* (Dyk, J., dissenting from denial of rehearing en banc) (citing *United States v. Gen. Elec. Co.*, 272 U.S. 476, 493–94 (1926) (collecting cases)); *see also id.* at 1350–51 (citing *Standard Sanitary Mfg. Co. v. United States*, 226 U.S. 20, 49 (1912) (finding that patent rights do not preempt price-fixing restrictions under the Sherman Act)).

230. *Id.* at 1350. (Dyk, J., dissenting from denial of rehearing en banc).

231. *Id.* (Dyk, J., dissenting from denial of rehearing en banc) (first citing *Webber v. Virginia*, 103 U.S. 344, 347–48 (1880) (upholding a state tax as applied to

Even if correctly decided, the *BIO v. D.C.* decision was unique in several ways. First, *BIO v. D.C.* did not seek to clarify the contours of federal patent laws vis-a-vis state drug pricing laws writ large. Rather, it dealt with a specific, limited question—whether federal patent statutes preempted the D.C. Prescription Drug Excessive Pricing Act of 2005.²³² As Judge Gajarsa, who authored the panel opinion in *BIO v. D.C.*, later noted in his concurrence in the opinion denying a petition for rehearing, “[w]hether future efforts of states to regulate drug prices, which for example did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right, would also be preempted is a question that remains for another day.”²³³ He added that *BIO v. D.C.* does not require “the preemption of ‘any state law regulating the prices of patented pharmaceutical products.’”²³⁴ A state regulation that affects a patentee’s profits does not per se undermine federal patent protections.²³⁵

While PDABs may share the same objective of lowering prescription drug costs, its mechanism of action is very different. The D.C. law singled out patent rights, applied only to patented drugs, and sought to evaluate drug manufacturers pecuniary interests based on metrics that were tied to patent frameworks, including those of foreign countries. The D.C. law was essentially a parallel “patent policy” that empowered “the D.C. courts to determine what price is necessary to spur innovation.”²³⁶ PDABs, on the other hand, apply uniformly to all prescription drugs. Any drug—patented or not—may be selected for affordability review according to a list of criteria set out by statute or regulation, and any drug subsequently determined to be unaffordable may be assigned an UPL.²³⁷ Indeed, Professor Feldman and others advise that any state regulation attempting to rein in drug costs may be able to avoid obstacle preemption with such a strategy.²³⁸

sale of patented products); then citing *Patterson v. Kentucky*, 97 U.S. 501, 501 (1878) (upholding state statute banning the sale of a particular patented burning oil, finding that patent rights were subordinate to state statute governing safety requirements for lighting oil)).

232. *Id.* at 1348 (Gajarsa, J., concurring in the denial of the petition for rehearing en banc).

233. *Id.* (Gajarsa, J., concurring in the denial of the petition for rehearing en banc).

234. *Id.* (Gajarsa, J., concurring in the denial of the petition for rehearing en banc).

235. *Id.* at 1346 n.1 (Gajarsa, J., concurring in the denial of the petition for rehearing en banc).

236. *Id.* at 1345 (Gajarsa, J., concurring in the denial of the petition for rehearing en banc).

237. See Feldman, Rowe, Oral, Gu & Gudiksen, *supra* note 170, at 3, 6.

238. *Id.* at 6–7.

Finally, the D.C. law imposed such broad liability as to be unwieldy, empowering anyone directly or indirectly affected by excessive prices to sue drug manufacturers and obtain remedies.²³⁹ Since any patient could be injured by prices deemed excessive under the statute and seek individual remedies against drug manufacturers, the statute could prove to create a flood of litigation against drug manufacturers. Because UPLs set by a PDAB are state regulations without private rights of action, they do not create the risk of expansive litigation against the pharmaceutical industry.

The limited scope of the *BIO v. D.C.* decision notwithstanding, the threat of preemption continues to haunt state efforts to address excessive prices of prescription drugs. This is especially so because the Federal Circuit has held that its own law governs whether federal patent law preempts state laws or other federal statutes.²⁴⁰ A preliminary question at the outset of this inquiry might be why the Federal Circuit has jurisdiction to strike down state laws. After all, the Federal Circuit is a court of limited jurisdiction under 28 U.S.C. § 1295, with jurisdiction “in any civil action arising under, or in any civil action in which a party has asserted a compulsory counterclaim arising under, any Act of Congress relating to patents or plant variety protection.”²⁴¹

In *Midwest Industries, Inc. v. Karavan Trailers, Inc.*,²⁴² the Federal Circuit explained why it does not defer to the law of regional circuits for questions of patent preemption:

[W]e conclude that the rigid division between substantive patent law issues and all other substantive and procedural issues, which was the basis for the court’s choice-of-law ruling in the Cable Electric case, no longer represents this court’s approach to choice-of-law questions in patent cases. Rather, [precedential cases from the Federal Circuit] make clear that our responsibility as the tribunal having sole appellate responsibility for the development of patent law requires that we do more than simply apply our law to questions of substantive patent law. In order to fulfill our obligation of promoting uniformity in the field of patent law, it is equally important to apply our construction of patent law to the questions whether and to what extent patent law preempts or

239. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1366 (Fed. Cir. 2007).

240. *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1357 (Fed. Cir. 1999) (en banc).

241. 28 U.S.C. § 1295(a)(1).

242. 175 F.3d 1356 (Fed. Cir. 1999) (en banc).

conflicts with other causes of action. Otherwise, we will be forced into the awkward posture of holding that, with respect to cases coming to us from district courts in some circuits, patent law forecloses certain other causes of action, but with respect to cases coming to us from district courts in other circuits, it does not. We hold that our responsibility to decide what patent law permits and prohibits requires that we apply our own law to such cases.²⁴³

In *Christianson v. Colt Industries Operating Corp.*,²⁴⁴ the U.S. Supreme Court held that the Federal Circuit did not have jurisdiction over a case where the plaintiff's antitrust and tort claims could be supported without resolving any patent issues.²⁴⁵ The Court found that a case "arises under" patent law only if the plaintiff's well-pleaded complaint establishes that patent law is a necessary element of the claim or the plaintiff's right to relief "necessarily depends on resolution of a substantial question of federal patent law."²⁴⁶ Since the plaintiff's claims could be resolved on non-patent grounds, the case did not arise under patent law, and thus federal jurisdiction was lacking.²⁴⁷ Conceivably, the Federal Circuit did not have jurisdiction in *BIO v. D.C.*, since patent preemption was just one of many claims asserted against the D.C. law. Indeed, some commentators have argued that the Federal Circuit should not have had jurisdiction over the case under *Christianson*, but the U.S. Supreme Court did not have an opportunity to review the Federal Circuit's assertion of jurisdiction.²⁴⁸

243. *Id.* at 1360–61; *see also BearBox LLC v. Lancium LLC*, 125 F.4th 1101, 1111 (Fed. Cir. 2025) ("Federal Circuit law governs whether federal patent law preempts a state law claim, a question we review de novo."); *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1325 (Fed. Cir. 2017) ("We apply our own law to determine whether the BPCIA [Biologics Price Competition & Innovation Act] preempts the state law claims."); *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999) ("[W]e apply our law in deciding . . . whether . . . Exzec's state unfair competition claim [based on tortious interference with contract predicated on patentee's alleged misrepresentations of infringement made in the marketplace] is preempted by the patent or antitrust laws.").

244. 486 U.S. 800 (1988).

245. *Id.* at 809.

246. *See id.* at 808–09.

247. *See id.* at 809.

248. *See, e.g., Ross, supra* note 218, at 349–50 ("Here, the plaintiffs' lawsuit sought only to strike the statute and alleged several legal theories by which the Excessive Drug Pricing Act might be held unconstitutional: (1) that the Act violated the Dormant Commerce Clause of Article I, Section 8, Clause 3 of the Constitution; (2) that the Act violated the Foreign Commerce Clause of Article I, Section 8, Clause 3 of the Constitution; and (3) that federal patent law preempted the statute. If upheld by the court, any one of the plaintiffs' arguments arguably would have the effect the plaintiffs desired. Only the preemption argument involved an issue of patent law. Accordingly, the holding

As a result of *BIO v. D.C.*, some states have limited their law to generic drugs to avoid preemption issues. For example, Maryland and Minnesota have limited their drug pricing laws to “off-patent or generic” prescription drugs.²⁴⁹ While the decision to avoid price regulations of patented drugs is not explicitly attributed to *BIO v. D.C.*, it has been surmised that it is because of the preemption concerns and the *BIO v. D.C.* decision.²⁵⁰ Even though *BIO v. D.C.* has had a chilling effect on state regulation of patented drug prices, its scope is overemphasized. By setting UPLs on drugs selected for review that happen to be incidentally patented, Colorado’s PDAB does not undermine the objectives and purposes of federal patent law.

The U.S. Supreme Court has also cautioned against lightly finding preemption in areas traditionally regulated by states. Under the Tenth Amendment, the powers not delegated to the federal government by the Constitution, nor prohibited to the states by the same, are reserved for states.²⁵¹ According to the second cornerstone of preemption,

[i]n all pre-emption cases, and particularly in those in which Congress has “legislated . . . in a field which the States have traditionally occupied,” [courts] “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”²⁵²

in *Christianson* suggests that the Commerce Clause allegations in the noted case were ‘reasons completely unrelated’ to the patent laws by which the plaintiff could recover, which arguably should have precluded Federal Circuit jurisdiction under § 1295(a)(1). If the Federal Circuit did indeed extend its jurisdiction to all multiple-theory-for-relief cases that include one well-pleaded claim under the patent laws, then the court has sanctioned a mechanism by which a party could forum-shop on appeal. Arguably, in any future lawsuit, a plaintiff need only plead one claim or theory for relief under the patent laws to establish appellate jurisdiction in the Federal Circuit. In such a case, the appellant arguably now has the choice to either appeal the case to the trial court’s home circuit court of appeals, or to transfer the case to the Federal Circuit.” (footnotes omitted).

249. See MD. CODE ANN., HEALTH-GEN. § 2-802(a) (West 2025); MINN. STAT. § 62J.84 (2025).

250. *Ass’n for Accessible Meds. v. Ellison*, 704 F. Supp. 3d 947, 951 n.1 (D. Minn. 2023) (“The record does not seem to reflect why the Minnesota Legislature targeted only generic and off-patent drugs, and not all drugs. One possible explanation is that the Federal Circuit has previously held that a similar price-control law directed at patented drugs was preempted by federal patent law.”); see also Wolitz, *supra* note 218, at 429 (describing *BIO v. D.C.*’s chilling effect on state efforts to regulate patented drug prices drug, with states instead shifting their efforts to focus on generic drugs).

251. U.S. CONST. amend. X.

252. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citation omitted).

On a state's police power, the U.S. Supreme Court has noted that a definition or attempt to define its scope is "fruitless," but "[p]ublic safety, public health, morality, peace and quiet, law and order . . . are some of the more conspicuous examples of the traditional application of the police power to municipal affairs."²⁵³

PDABs implicate at least two categories of state police powers: the protection of public health and consumer welfare. PDABs protect public health by regulating drug affordability to (1) ensure access to medically necessary treatments, (2) prevent disruptions to care due to cost, and (3) maintain a stable healthcare delivery system. U.S. Supreme Court precedent has variously upheld state vaccination mandates,²⁵⁴ state decisions regarding physician-assisted suicide,²⁵⁵ and state programs conditioning Medicaid benefits on manufacturers providing rebates.²⁵⁶ These goals fall squarely within the health and welfare aspects of a state's police power.

States have also traditionally enacted consumer protection laws, including the regulation of prices consumers pay for certain essential goods and services—patented or not.²⁵⁷ While the FTC has authority to indirectly regulate market prices through antitrust enforcement and to protect consumers through unfairness doctrine, the Federal Trade Commission Act (FTCA) does not expressly or implicitly preempt state

253. *Berman v. Parker*, 348 U.S. 26, 32 (1954).

254. *Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905) (upholding a Massachusetts smallpox vaccination mandate as a legitimate public health measure under the state's police power). Similarly, a state should be able to regulate in-state payors to ensure access to life-saving medications for vulnerable populations within their borders.

255. *Gonzalez v. Oregon*, 546 U.S. 243, 274–75 (2006) (holding that the federal government could not override Oregon's medical decisions regarding physician-assisted suicide, reaffirming that states have primary authority over the regulation of medical practice and healthcare). If true, states also have the authority to regulate the cost structure for prescription drugs provided to their residents.

256. *See generally Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003) (upholding a Maine program conditioning Medicaid sales on drug manufacturers providing rebates, finding no unreasonable burdens, and therefore no conflict with, federal Medicaid law). The Court cited the "presumption against federal pre-emption of a state statute designed to foster public health" and concluded that "Maine's interest in protecting the health of its uninsured residents also provides a plainly permissible justification for a prior authorization requirement that is assumed to have only a minimal impact on Medicaid recipients' access to prescription drugs." *Id.* at 666. Thus, states should have discretion to experiment with cost-containment models that promote access to prescription drugs.

257. *Ferguson v. Skrupa*, 372 U.S. 726, 730–31 (1963) ("States 'have power to legislate against what are found to be injurious practices in their internal commercial and business affairs, so long as their laws do not run afoul of some specific federal constitutional prohibition, or some valid federal law.'" (quoting *Lincoln Fed. Lab. Union v. Nw. Iron & Metal Co.*, 335 U.S. 525, 536 (1949))).

consumer protection law unless it conflicts with the FTCA.²⁵⁸ To this day, such laws continue to coexist alongside federal consumer protection regulation.²⁵⁹

For instance, the U.S. Supreme Court has upheld state laws relating to minimum wage,²⁶⁰ rent control,²⁶¹ and food and other essential goods during emergencies.²⁶² While many states also prohibit price gouging—defined as price increases of 15 percent above normal rates—of essential goods during emergencies, including medical supplies, such laws typically take effect during prototypical disasters, such as hurricanes, wildfires, pandemics, or terrorist attacks.²⁶³ While the access to medicine crisis has frequently been characterized as a public health crisis,²⁶⁴ price gouging laws likely do not provide standalone precedent for drug price regulation in other circumstances.²⁶⁵

PDABs promote economic and consumer welfare by ensuring fair markets and preventing financial exploitation of patients in the drug market, where consumers have little to no bargaining power when seeking prescription drugs, which are classic inelastic goods subject to monopolistic pricing as a result of patent protection. High prices lead to

258. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 423 n.5 (1992) (Stevens, J., dissenting) (“The FTCA does not, by its own force, pre-empt state prohibitions of unfair and deceptive trade practices. Thus, unless a state prohibition conflicts with a Federal Trade Commission rule, state laws and regulations are not pre-empted.”).

259. See CAROLYN CARTER, NAT’L CONSUMER L. CTR., CONSUMER PROTECTION IN THE STATES: A 50-STATE EVALUATION OF UNFAIR AND DECEPTIVE PRACTICES LAWS 1-3 (2018), https://www.nclc.org/wp-content/uploads/2022/09/UDAP_rpt.pdf [<https://perma.cc/X28Q-8WCJ>].

260. See generally *W. Coast Hotel v. Parrish*, 300 U.S. 379 (1937) (upholding a Washington state minimum wage law for women).

261. See generally *Block v. Hirsh*, 256 U.S. 135 (1921) (upholding D.C. emergency rent control law during a post-war housing crisis).

262. *Pennell v. City of San Jose*, 485 U.S. 1, 11 (1988) (“[W]e have recognized that the government may intervene in the marketplace to regulate rates or prices that are artificially inflated as a result of the existence of a monopoly or near monopoly.”).

263. See, e.g., Hannah Hilst, *Price Gouging Laws by State*, FINDLAW (Jan. 30, 2025), <https://www.findlaw.com/consumer/consumer-transactions/price-gouging-laws-by-state.html>; *Price Gouging State Statutes*, NAT’L CONF. OF STATE LEGISLATURES (Jan. 21, 2025), <https://www.ncsl.org/financial-services/price-gouging-state-statutes>.

264. U.S. SEN. COMM. ON HOMELAND SEC. & GOV. AFF., A PRICE TOO HIGH: COST, SUPPLY, AND SECURITY THREATS TO AFFORDABLE PRESCRIPTION DRUGS 2 (2019), https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/191206_Report_APriceTooHigh.pdf [<https://perma.cc/FS4N-J9ZZ>].

265. See also PUBLIC CITIZEN, PUBLIC CITIZEN GUIDE TO FIGHTING PRICE GOUGING DURING THE COVID-19 PANDEMIC EMERGENCY 1 (2020), <https://www.citizen.org/wp-content/uploads/PC-Guide-to-Fighting-Price-Gouging.pdf> [<https://perma.cc/T2XP-U8BC>] (advocating for a federal price gouging law to ensure access to essential goods during the COVID-19 pandemic).

non-adherence to courses of treatment, especially among low-income patients. PDABs aim to prevent these price-driven health disparities, and are thus well within the police power of states. As Judge Dyk noted in his dissent, while the *BIO v. D.C.* panel did not offer much discussion of state police powers, in his view, “[i]t is clear that, to the extent that the D.C. Act prohibits price discrimination to ensure public access to important medications, it falls within the core of the states’ traditional powers, triggering a strong presumption against preemption.”²⁶⁶ Similar types of price regulation by federal agencies have been found to be constitutional by the U.S. Supreme Court.²⁶⁷

An analogous type of state legislation exemplifies why states should have the ability to regulate the prices of patented goods: right to repair laws. As of today, all fifty states have introduced right to repair legislation, which “requires manufacturers to allow consumers and independent businesses to access parts, tools and documentation needed to repair a range of electronic products,” and twenty-four states have passed such laws.²⁶⁸ To comply with these laws, Apple recently announced that it would begin selling repair parts for iPads to the public.²⁶⁹ However, as *404 Media* reports, Apple is selling these repair parts for exorbitant prices, selling new iPad charge ports for \$250 (with third-party suppliers offering them for \$20) and digitizers for \$200 (the third-party cost being \$50).²⁷⁰ According to the National Conference of State Legislatures, many of these right to repair laws require companies to sell repair parts to the public on “fair and reasonable terms.”²⁷¹ While none of these laws specify particular price points to meet this standard,²⁷²

266. *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1351 (Fed. Cir. 2007) (Dyk, J., dissenting from denial of rehearing en banc).

267. *See, e.g., Fed. Power Comm’n v. Hope Nat. Gas Co.*, 320 U.S. 591, 602–03 (1944) (holding that utility rate regulation does not violate the Constitution so long as resulting rates are “just and reasonable”); *Permian Basin Area Rate Cases*, 390 U.S. 747, 774 (1968) (same).

268. Nathan Proctor, *RELEASE: All 50 States Now Have Filed Right to Repair Legislation over Last 8 Years*, PIRG (Feb. 24, 2025), <https://pirg.org/media-center/release-all-50-states-now-have-filed-right-to-repair-legislation-over-last-8-years/>.

269. *Apple Launches Self Service Repair for iPad, Expands Repair Program*, APPLE (May 28, 2025), <https://www.apple.com/newsroom/2025/05/apple-launches-self-service-repair-for-ipad-expands-repair-programs/> [<https://perma.cc/SSA9-PSR5>].

270. Jason Koebler, *Apple Is Selling iPad Repair Parts for Astronomical Prices*, 404 MEDIA (July 31, 2025, at 09:46 CT), <https://www.404media.co/apple-is-selling-ipad-repair-parts-for-astronomical-prices/?ref=daily-stories-newsletter> [<https://perma.cc/C83V-3Z5L>].

271. *See Right to Repair 2023 Legislation*, NAT’L CONF. STATE LEGISLATURES (Nov. 1, 2023), <https://www.ncsl.org/technology-and-communication/right-to-repair-2023-legislation>.

272. *See generally id.* (listing state right to repair laws, none of which includes a specific price point).

prohibiting states from regulating the prices of electronic repair parts, many of which may be patented, would effectively gut state right to repair laws. If tech companies like Apple are permitted to sell patented repair parts for any price point, without restriction, they would be able to set prices high enough to dissuade consumers from repairing these goods at all—pushing consumers to instead fully replace broken tech products.

Considering all of the above, it is clear that Colorado’s PDAB law should not conflict with the objectives and purposes of federal patent laws, not least of all because patent laws do not confer an affirmative right to make, use, sell, or extract a particular profit from sales of the subject invention. It is also apparent that Colorado has a legitimate interest in exercising its police powers to protect consumer welfare and public health by regulating the prices of prescription drugs that the Board deems unaffordable for the majority of Coloradans—thus, the Federal Circuit must consider the presumption against preemption of a state’s exercise of its historic police powers. Drug manufacturers are invited to participate in the process of setting the UPL. Unlike the law at issue in *BIO v. D.C.*, Colorado’s PDAB law is narrowly tailored, crafted neutrally to apply to all drugs, patented or not, and does not provide a private right of action.

C. Patent Exhaustion

In the alternative, the doctrine of patent exhaustion provides another strong defense for the Colorado PDAB. Under this longstanding principle of patent law, once a patented product is sold in a sale authorized by the patent holder, the patentee’s exclusive rights to control the use or resale of that product are exhausted. This means that the patentee cannot use the patent to restrict downstream sales, pricing, or other uses of the product after it has been lawfully sold.²⁷³ The U.S. Supreme Court reaffirmed and clarified this principle in the 2017 case, *Impression Products, Inc., v. Lexmark International, Inc.*²⁷⁴ In *Lexmark*, a patentee attempted to enforce post-sale restrictions on printer cartridges it had sold, including resale bans and refill prohibitions, claiming that such restrictions were enforceable under patent law.²⁷⁵ The Court rejected this argument, emphasizing that once a patentee sells a product—whether

273. See *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 666 (1895) (holding that once a patented article is sold by the patent owner, the buyer has the right to use or resell it without assumed restriction); see also *Motion Picture Pats. Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 518–19 (1917) (holding that a patentee cannot enforce post-sale restrictions on the use of a patented product through their exclusive rights).

274. 581 U.S. 360 (2017).

275. See *id.* at 367–68.

domestically or internationally—it relinquishes any further rights to control that item through patent law.²⁷⁶

This reasoning supports the validity of the Colorado PDAB’s regulation of drug reimbursement or pricing *after* a patented drug has entered the market. Due to the complexity of the national drug distribution network, drug manufacturers rarely sell directly to patients. Sahil Agrawal, Melissa Barber, Amy Kapczynski & Trudel Pare have described this complexity in the context of public pharmaceutical distribution.²⁷⁷ Manufacturers sell drugs to a wholesaler, which may then distribute the drug to a pharmacy, which disburses the drug to patients.²⁷⁸ The pharmacy, in turn, may negotiate discounts with PBMs and health plans.²⁷⁹ In other words, in most circumstances, there is at least one middleman who buys and resells the drug (most likely outside of the state) before it ever reaches the patient.

Under the patent exhaustion doctrine, so long as the initial sale is authorized—whether to a wholesaler, pharmacy, or state Medicaid program—the drug manufacturer has no remaining right under patent law to dictate downstream pricing or reimbursement terms.²⁸⁰ Courts have consistently held that post-sale price controls or resale regulations do not infringe a patentee’s rights once exhaustion applies.²⁸¹ Therefore, even if a PDAB imposes a UPL or caps the reimbursement price for a patented drug after it enters the market, it does not intrude on federal patent rights because those rights were extinguished once the product was voluntarily introduced upstream in the stream of commerce.

This first sale is not necessarily regulated by the Colorado PDAB law—which only applies to sales within the state (such as sales to an in-state pharmacy, hospital, or physician)—since most drug manufacturers are headquartered and incorporated outside of the state.²⁸² Exhaustion was set forth as one of the state’s key arguments—the first authorized sale of the patented drug did not occur in-state; therefore, the drug manufacturer cannot control downstream sales and has no standing to

276. *See id.* at 377.

277. *See generally* Sahil Agrawal, Melissa Barber, Amy Kapczynski & Trudel Pare, *Drug Dealing: Making Public Pharma Work*, 103 WASH. U. L. REV. 49 (2025) (discussing challenges posed by the U.S. pharmaceutical industry).

278. Defendants’ MSJ, *supra* note 130, at 2–3 (quoting *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 44 F.4th 959, 965 (10th Cir. 2022)).

279. *See id.* at 4–5.

280. *Id.* at 24.

281. *See, e.g., Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 666 (1895); *Motion Picture Pats. Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 518–19 (1917).

282. *See* COLO. REV. STAT. § 10-16-1403(1)(a) (2025).

challenge the Colorado PDAB law.²⁸³ Although the Colorado district court did not reach the merits of the argument, it did dismiss for lack of standing, finding merit in the exhaustion argument and holding that UPLs do not directly apply to that first authorized sale.²⁸⁴

Patent exhaustion has been used to justify Florida's Section 804 drug importation program—formally known as the Canadian Prescription Drug Importation Program—which is the first state-certified initiative under section 804 of the FD&C Act.²⁸⁵ This provision authorizes the importation of prescription drugs from Canada by states, wholesalers, or pharmacists, provided HHS certifies that such importation poses no additional risk to public health and results in significant cost savings.²⁸⁶ Under Florida's program, eligible prescription drugs—those approved in both Canada and the U.S., excluding controlled substances, biologics, and certain injectables—may be imported in bulk, relabeled and tested for safety, and dispensed through participating state-run programs, such as Medicaid or correctional facilities.²⁸⁷ If the drugs imported under Florida's program were originally sold in Canada by or with the authorization of the patent holder, then those sales may exhaust the U.S. patent rights, allowing their subsequent importation and resale without infringement liability. Thus, if authorized by the FDA, a patentee has no ability to exclude the importation of drugs that were first sold abroad by the patentee or its licensee(s).

In short, UPLs, such as the one facilitated by the Colorado PDAB law, should not be preempted by federal patent law, and drug manufacturers have exhausted their patent rights. Of course, if the Federal Circuit adopts the expansive reading of patent preemption that was implicit, but not confirmed, in *BIO v. D.C.*, it would become necessary to consider possible paths forward if the Federal Circuit upholds or strikes down the Colorado PDAB law. Part III considers these possibilities.

III. PATHS FORWARD

If the Federal Circuit upholds the Colorado PDAB law, the aforementioned middlemen—pharmacies, wholesalers, and PBMs—may attempt to challenge the law on grounds other than patent preemption. These stakeholders, who play a central role in the pharmaceutical

283. See Defendants' MSJ, *supra* note 130, at 23–31.

284. See *Amgen Inc. v. Mizner*, No. 24-cv-00810, at 12–16, 18–19 (D. Colo. Mar. 28, 2025).

285. 21 U.S.C. § 384.

286. See § 384(b)–(c).

287. See FLA. STAT. § 381.02035(5), (7), (10) (2025).

distribution chain, have financial incentives to oppose any regulation that potentially reduces their profit margins. The exhaustion doctrine is an effective defense against claims of patent preemption brought by drug manufacturers, but by and large, middlemen are not licensees of the patent rights to the drugs they buy and sell, and therefore have no standing to challenge UPLs. The middlemen involved in the drug distribution chain sell pharmaceuticals within the state, and are therefore directly affected by UPLs. Thus, they could challenge the Colorado PDAB law under other theories, such as due process rights and the Dormant Commerce Clause. In particular, PBMs may argue that UPLs interfere with contractual freedom or disrupt reimbursement mechanisms governed by federal programs such as Medicaid and Medicare Part D.

In addition, if the Federal Circuit upholds the PDAB law on the grounds of patent exhaustion, there is a possibility that the pharmaceutical industry may shift its strategy in order to develop pathways to provide drugs directly to consumers (“DTC sales”). Drug manufacturers have been experimenting with DTC sales in the context of GLP-1 drugs, such as semaglutide, which are used for the treatment of diabetes and weight management.²⁸⁸ These efforts are facilitated by the rise of telehealth platforms, mail-order pharmacies, and vertically integrated delivery models.²⁸⁹ While the pharmaceutical industry has long blamed PBMs and other middlemen for inflating drug prices, UPLs could force the pharmaceutical industry to innovate in drug distribution, such as by establishing a DTC sales pipeline. By eliminating intermediaries, manufacturers may argue that the final sale to the consumer constitutes the first authorized sale, thus allowing them to sidestep the patent exhaustion doctrine in jurisdictions with PDABs that can set UPLs.²⁹⁰

If the Federal Circuit finds the Colorado PDAB preempted by federal patent law, the ideal path would be for the U.S. Supreme Court to grant certiorari and reverse the decision, thereby overruling

288. See Sally Pipes, *Drugmakers Are Embracing Direct-to-Consumer Sales. That's Fantastic News for Patients.*, FORBES (Aug. 08, 2025, at 15:38 ET), <https://www.forbes.com/sites/sallypipes/2025/08/08/drugmakers-are-embracing-direct-to-consumer-sales-thats-fantastic-news-for-patients/>.

289. See *id.*

290. See, e.g., Katie Palmer, *Senators Reveal How Much Lilly, Pfizer Paid Telehealth Companies*, STAT (July 17, 2025), <https://www.statnews.com/2025/07/17/senators-investigate-pharma-telehealth-payments-for-possible-kickbacks/> [<https://perma.cc/7WSA-EQDT>]; see also Peter Loftus, *Bristol-Myers and Pfizer to Offer Blockbuster Blood Thinner at Discount*, WALL ST. J. (July 17, 2025, at 06:30 ET), <https://www.wsj.com/health/pharma/bristol-myers-pfizer-eliquis-discount-3c0513ef> (reporting that Bristol-Myers Squibb and Pfizer will sell Eliquis directly to patients at a reduced cash price through a direct-to-consumer program).

or distinguishing *BIO v. D.C.*²⁹¹ Over the past three decades, the Court has overturned many of the Federal Circuit’s overexpansive interpretations of patent rights. In cases such as *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*,²⁹² *Amgen Inc. v. Sanofi*,²⁹³ and *Impression Products, Inc., v. Lexmark International, Inc.*,²⁹⁴ the Court has narrowed the scope of patent-eligible subject matter, clarified that disclosure in a patent must match broad claims, and emphasized limits on patent enforcement, respectively.²⁹⁵

Additionally, given this Court’s recent federalism jurisprudence, it would be anomalous for it to invalidate a state healthcare reform initiative. In cases such as *Dobbs v. Jackson Women’s Health Organization*²⁹⁶ and *United States v. Skrametti*,²⁹⁷ the Court has highlighted state autonomy in matters of public health and welfare.²⁹⁸ Striking down PDABs would place the Court at odds with its alleged commitment to state sovereignty and power to regulate complex policy areas involving health and welfare.

Another possible path forward may be federal legislation to clarify the scope of patent preemption in the context of drug prices. Such legislation could expressly preserve state authority to implement affordability mechanisms for patented drugs. However, legislative action is likely to be politically fraught. While the Trump administration has promoted most favored nation pricing for Medicare, its focus was largely nationalist, stating that the United States has too long been “subsidizing low prices in the rest of the world,” arguing that most favored nation pricing will “ensure foreign nations can no longer use price controls to

291. It would also be possible for the Federal Circuit to reconsider *BIO v. D.C. en banc* if the procedural requirements of the relevant federal practice rule are met. See FED. R. APP. P. 40(b)(2).

292. 569 U.S. 576 (2013).

293. 143 S. Ct. 1243 (2023).

294. 581 U.S. 360 (2017).

295. *Ass’n for Molecular Pathology*, 569 U.S. at 580 (“[A] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated”); *Amgen Inc. v. Sanofi*, 143 S. Ct. at 1254 (“If a patent claims an entire class of . . . compositions of matter, the patent’s specification must enable a person skilled in the art to make and use the entire class.”); *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 581 U.S. 360, 366 (2017) (“[A] patentee’s decision to sell a product exhausts all of its patent rights in that item, regardless of any restrictions the patentee purports to impose or the location of the sale.”).

296. 142 S. Ct. 2228 (2022).

297. 145 S. Ct. 1816 (2025).

298. *Dobbs*, 142 S. Ct. at 2279 (“[T]he authority to regulate abortion must be returned to the people and their elected representatives.”); *Skrametti*, 145 S. Ct. at 1837 (“[W]e leave questions regarding [the State’s] policy to the people, their elected representatives, and the democratic process.”).

free ride on American innovation.”²⁹⁹ The Biden administration successfully pushed reform through the Inflation Reduction Act, which empowers Medicare to negotiate drug prices for certain high-cost drugs.³⁰⁰ Yet, congressional appetite for broader structural reforms—especially those enhancing state regulatory authority—remains limited.³⁰¹

If the Federal Circuit finds Colorado’s PDAB to be preempted by federal patent law, states might reform the design and legal framing of PDABs to avoid triggering preemption concerns. One strategy could involve targeting the reimbursement rates PBMs negotiate with drug manufacturers, rather than capping prices at the consumer or pharmacy level. This indirect approach would exert downward pressure on drug prices without directly regulating the price of patented goods. Such mechanisms could be justified under the state’s traditional authority to regulate insurance and healthcare markets.

UPLs might also be replaced with variable taxes on drugs that kick in if the sticker price of a drug exceeds a particular amount. While most states have historically exempted prescription drugs from sales taxes,³⁰² states may be able to levy corporate income taxes on drugs identified as unaffordable and whose manufacturers refuse to engage in negotiation with the PDAB. The taxes collected could then be used to subsidize state purchases of the drug. While such an initiative may be challenged as an excessive fine under the Eighth Amendment, similar arguments brought by the pharmaceutical industry against the Medicare drug price negotiation provisions of the Inflation Reduction Act have not succeeded in courts.³⁰³ This is supported by U.S. Supreme Court precedent—in

299. See, e.g., *Fact Sheet: President Donald J. Trump Announces Largest Developments to Date in Bringing Most-Favored-Nation Pricing to American Patients*, WHITE HOUSE (Dec. 19, 2025), <https://www.whitehouse.gov/fact-sheets/2025/12/fact-sheet-president-donald-j-trump-announces-largest-developments-to-date-in-bringing-most-favored-nation-pricing-to-american-patients/>; Exec. Order No. 14297, 90 Fed. Reg. 20749–51 (May 15, 2025).

300. See Cubanski, *supra* note 10.

301. See Rebecca Robbins & Margot Sanger-Katz, *Trump Seeks to Lower Drug Prices Through Medicare and Some Imports*, N.Y. TIMES (Apr. 15, 2025), <https://www.nytimes.com/2025/04/15/health/trump-executive-order-prescription-drug-pricing.html>.

302. See Robert Dumas, *Sales Tax on Prescription Drugs & Over-the-Counter Medicine*, TAX CONNEX (Apr. 8, 2025), <https://www.taxconnex.com/blog-/prescription-drugs-and-sales-tax> [https://perma.cc/BLZ6-WPMV].

303. See Zachary Baron & Andrew Twinamatsiko, *Medicare Drug Price Negotiation Program: A Litigation Status Check*, HEALTH AFFS. (July 18, 2025), <https://www.healthaffairs.org/content/forefront/medicare-drug-price-negotiation-program-litigation-status-check>; see also *Medicare Drug Price Negotiation*, O’NEILL INST.: HEALTH CARE LITIG. TRACKER, <https://litigationtracker.law.georgetown.edu/issues/medicare-drug-price-negotiation/> [https://perma.cc/C27B-JUML] (last visited Feb 1, 2026) (collecting cases challenging Medicare drug price negotiation).

Webber v. Virginia,³⁰⁴ the Court held that patented products may be taxed.³⁰⁵ This suggests that a price-linked tax mechanism, if carefully structured, could survive constitutional scrutiny.

As a last resort, states could turn their attention to generic drugs, which are not protected by active patents or FDA exclusivities.³⁰⁶ Many states have passed price gouging statutes targeting generics, citing sudden, unexplained price increases as evidence of market failure.³⁰⁷ Although some of these statutes have been struck down on Dormant Commerce Clause grounds—as in *Ass’n for Accessible Medicines v. Frosh*³⁰⁸—others have survived.³⁰⁹ At the same time, federal antitrust enforcement has increased scrutiny of generic drug manufacturers, particularly in cases involving price-fixing cartels.³¹⁰

Finally, states should continue to pursue complementary drug policy reforms in parallel with PDABs. These include transparency laws requiring disclosure of cost structures and pricing justifications, stricter PBM regulations to curb spread pricing and rebate abuses, and the creation of state-run drug purchasing cooperatives to pool bargaining power. Such measures, though indirect, reinforce the larger project of lowering drug costs without triggering preemption challenges. If PDABs ultimately fail in court, these alternatives will become even more critical as states attempt to mitigate the harms of excessive drug prices through constitutionally permissible means.

CONCLUSION

Prescription Drug Affordability Boards represent a novel and increasingly vital tool in the states’ arsenal to combat the rising cost of prescription medications. As laboratories of democracy, states have long exercised their police powers to protect the health and economic well-being of their residents—regulating everything from utility rates to

304. 103 U.S. 344 (1880).

305. *Id.* at 347–48 (upholding a state tax as applied to sale of patented products).

306. See Tony Pistilli, *Pharmaceutical Patent Regulation in the United States*, ACTUARY (Feb. 2021), <https://www.theactuarmagazine.org/pharmaceutical-patent-regulation-in-the-united-states/> [<https://perma.cc/V9T6-DGKF>].

307. *State Laws Passed to Lower Prescription Drug Costs: 2017–2025*, *supra* note 24.

308. 887 F.3d 664 (4th Cir. 2018).

309. See, e.g., *Online Merchs. Guild v. Cameron*, 995 F.3d 540, 559–60 (6th Cir. 2021).

310. See, e.g., Press Release, U.S. Dep’t of Just., Major Generic Drug Companies to Pay Over Quarter of a Billion Dollars to Resolve Price-Fixing Charges and Divest Key Drug at the Center of Their Conspiracy (Feb. 6, 2025), <https://www.justice.gov/archives/opa/pr/major-generic-drug-companies-pay-over-quarter-billion-dollars-resolve-price-fixing-charges>.

hospital billing practices. PDABs fit squarely within this tradition, leveraging transparent, evidence-based processes to address a market failure with profound public health consequences: the unaffordability of lifesaving drugs.

Yet the intersection of PDAB authority with federal patent protections has generated legal uncertainty, culminating in Amgen's challenge to Colorado's PDAB. This Article has shown that the constitutional framework—particularly the doctrines of obstacle preemption and patent exhaustion—does not support a broad reading of federal law that would bar states from setting reimbursement limits. To the contrary, once a patented drug has been sold into the marketplace, the patent owner's rights are exhausted, and state regulation of prices in downstream distribution channels does not pose an impermissible conflict with the objectives of the Patent Act.

Even if the Federal Circuit ultimately revives a more expansive view of patent preemption, PDABs remain adaptable. States may modify their statutes to avoid direct pricing mandates on manufacturers, target reimbursement rates among payers, or integrate affordability determinations into purchasing and coverage decisions—measures that fall even more clearly within the ambit of state police powers. Moreover, should courts narrow the permissible scope of PDABs, such outcomes will only underscore the urgent need for congressional action to restore balance in a pharmaceutical market distorted by monopoly protections and opaque pricing.

In short, PDABs reflect a constitutionally sound and democratically accountable response to the escalating crisis of drug pricing. Rather than intruding upon federal patent law, they reinforce core principles of federalism and consumer protection. As legal challenges unfold, it is imperative for courts to recognize both the limits of patent exclusivity and the enduring role of states in safeguarding the public's health and economic security.