OLIGOPOLY SQUARED: FEDERALISM AND THE NEW LEGAL LANDSCAPE TACKLING THE DARK WEB OF DRUG PRICING

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The pharmaceutical industry's billion-dollar practice of inflating drug prices and shielding itself from accountability has brought immense public outcry and inspired a profusion of legal reforms. But the precise dynamics that enable this ongoing crisis remain obscure, impeding effective resolution. This Article examines the interplay between legislative, regulatory, and new governance approaches emerging at both the federal and state levels. It exposes how a seemingly singular problem of high drug costs unfolds as a complex series of mergers, collusions, and restrictive strategies throughout the healthcare supply chain.

The poster child of big pharma greed is insulin, the lifesaving drug of diabetics. This Article presents insulin as a case study in analyzing how a drug discovered long ago evolved, through product hopping and patent evergreening, into multiple brand-name products still under patent. It further illustrates how market concentration in each link of the drug delivery chain has substantially increased with impunity, spanning from big pharma to pharmacy benefit management ("PBM") intermediaries that broker deals between drug manufacturers, insurers, and pharmacies. The compounding effects of horizontal and vertical

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*integration of powerful industry actors—what this Article calls "*oligopoly squared*"—have enabled collusive deals, including formulary exclusion, secret rebates, spread pricing, and preferred pharmacy status, each designed to artificially inflate insulin prices.*

Moving from the expository and descriptive to the analytical and prescriptive, this Article then presents an equally multifaceted framework to address these harmful effects, combining cost control and transparency laws, PBM regulation, patent law and U.S. Food and Drug Administration generics approval reforms, and antitrust enforcement. This Article explains why federal law should not be interpreted as preempting state regulation of pharmaceutical supply chains. This Article further analyzes efforts using cutting-edge theories of competition law in light of broader recent developments in adjudicating market power and collusion. Most importantly, this Article examines the newest approaches emerging in the landscape of market and legal levers—direct-to-consumer transparent pharmacies and the public production of drugs—and argues that these new governance models have the greatest potential to disrupt the concentrated market. By analyzing and integrating these diverse efforts through the lens of legal theory and practical impact, this Article not only charts the course of pharmaceutical drug industry reform but also offers broader implications for regulating complex industries.

INTRODUCTION

Escalating prescription drug prices have sparked an unprecedented wave of law and policy initiatives, with numerous lawsuits and legislative reforms emerging at both the federal and state levels. These efforts aim to tackle not only the exorbitant cost of prescription medications but also the opaque and entrenched practices in each link of a complex drug delivery chain.[1]

The sheer scope and diversity of new legal reforms—spanning price controls, transparency mandates, patent law and generic drug approval reforms, antitrust enforcement, and, most recently, public drug production and direct-to-patient delivery—signal a seismic shift in the understanding of how legal frameworks can be deployed to disrupt concentrated markets and protect consumers. The breadth of legal actions provides a model for studying competition and industry regulation more broadly. This Article analyzes the contemporary momentum in which policymakers simultaneously leverage legislation, regulation, litigation, and market strategies to tackle a billion-dollar industry's harmful practices. It shows how myriad efforts to directly regulate drug prices have stalled, proven ineffective, or been challenged in courts, including in a current case in which the Supreme Court recently denied certiorari.[2] Analyzing the split circuit adjudication on federal preemption of such state reforms, this

[1] See infra Parts III–IV.

[2] Pharm. Care Mgmt. Ass'n v. Mulready, 78 F.4th 1183 (10th Cir. 2023), *cert. denied*, 145 S. Ct. 2843 (2025) (mem.).

Article argues that the Court should have resolved the split by holding that state regulation of pharmaceutical supply chains is not preempted by federal law. The complex structure of the pharmaceutical industry presents a test case wherein federalism offers opportunities for democratic experimentalism and new multilevel governance reforms.[3] Preemption should be narrowly tailored to allow state laws designed to protect patients and enhance consumer welfare. Even more critically, this Article argues that the novel path of public drug manufacturing and delivery is an essential lever to directly disrupt this complex concentrated market.

Insulin is the poster child for high drug costs in the United States. Insulin prices in the United States have spiked shockingly high compared to those in other developed countries.[4] A 2024 RAND report found that the price of insulin in the United States is more than *nine times higher* than the price of insulin in thirty-three comparison nations combined.[5] Even when accounting for rebates and discounts, U.S. net prices are still, on average, 2.3 times higher than those in other countries.[6] Examining insulin as a case study for addressing skyrocketing drug prices reveals the need for the multifaceted framework presented in this Article. There are three manufacturers who make nearly all insulin sold in the United States:

[3] On new governance theory and practice, see Orly Lobel, The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought, 89 Minn. L. Rev. 342, 404–07 (2004) [hereinafter Lobel, The Renew Deal] (describing the paradigm shift in legal process from command and control to more collaborative participatory regulation); Orly Lobel, New Governance as Regulatory Governance, *in* The Oxford Handbook of Governance 65, 65 (David Levi-Faur ed., 2012) (explaining how new governance theory provides lessons for government and market stakeholders on how to collaborate toward shared goals); Orly Lobel, National Regulation in a Global Economy: New Governance Approaches to 21st Century Work Law, *in* 2 Labor and Employment Law and Economics 630, 640–41 (Kenneth G. Dau-Schmidt, Seth D. Harris & Orly Lobel eds., 2009) (applying new governance theory to workplace regulation); Orly Lobel, Setting the Agenda for New Governance Research, 89 Minn. L. Rev. 498, 499–502 (2004) (describing next steps in the developments of new governance theory and practice).

[4] Andrew W. Mulcahy & Daniel Schwam, RAND Corp., Comparing Insulin Prices in the United States to Other Countries 17 (2024) ("Compared with other countries, and in each insulin category, the United States had dramatically higher gross prices. The average U.S. manufacturer price per 100 IUs across all insulins was $22.68, compared with $3.75 in Canada, $2.20 in the United Kingdom, $2.79 in Mexico, and $2.37 across all non-U.S. OECD countries combined . . . .").

[5] Id. at v.

[6] Id.

Eli Lilly, Novo Nordisk, and Sanofi.[7] These three dominant pharmaceutical manufacturers frequently engage in practices like product hopping and patent evergreening whereby they introduce slightly modified versions of brand-name drugs—often just before patent expiration—and aggressively market them to shift patients to the newly patented formulations.[8] Although insulin was discovered more than a century ago, these practices prevent generic drugs from entering the market and competing with lower drug prices. Still, if drug manufacturers alone were engaging in anticompetitive tactics, reforming intellectual property law and generic drug approval could be a straightforward and effective solution. Unfortunately, the reality is far more complex. The American insulin industry is not simply an oligopoly; it represents what this Article terms an "*oligopoly squared*" market—the compounded effect of both market consolidation and restrictive tactics across complex supply chains.

Big pharma colludes with another highly concentrated industry that has largely operated under the radar: pharmacy benefit managers ("PBMs").[9] PBMs, while surprisingly understudied in legal scholarship, are the powerful middlemen who shape prescription drug delivery.[10] PBMs determine *formularies*, the lists that dictate the prescription drugs that a health insurance plan covers.[11] Three PBMs—CVS Caremark, Express Scripts, and Optum Rx—control this key intermediary role in the market.[12] The three lead manufacturers of insulin control more than ninety percent of the drug by value globally, and three PBMs control more than eighty percent of the prescription-management market.[13] Furthermore, for

[7] Judith A. Johnson, Cong. Rsch. Serv., IF11026, Insulin Products and the Cost of Diabetes Treatment 2 (2018).

[8] See infra Part I.

[9] See infra Section II.B.

[10] See infra Section II.B.

[11] See infra Section II.B.

[12] See Adam J. Fein, The Top Pharmacy Benefit Managers of 2024: Market Share and Key Industry Developments, Drug Channels Inst. (Mar. 31, 2025), https://www.drugchannels.net/2025/03/the-top-pharmacy-benefit-managers-of.html [https://perma.cc/XY38-T4BH] ("[Drug Channels Institute] estimates that for 2024, about 80% of all equivalent prescription claims were processed by three companies: the Caremark business of CVS Health, the Express Scripts business of Cigna, and the Optum Rx business of UnitedHealth Group.").

[13] Claudia Martínez, Camille Romero & Natalia Sánchez Villalobos, Access to Med. Found., What Are Pharma Companies Doing to Expand Access to Insulin—and How Can Efforts Be Scaled Up? 4 (2022); Off. of Pol'y Plan., U.S. Fed. Trade Comm'n, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street

decades, PBMs have been engaging in both vertical and horizontal integration, further concentrating the market by purchasing other key players in the healthcare supply chain, including pharmacies and health insurance providers.[14] As this Article illustrates, the combined oligopolistic structure of the industry, alongside the complex regulatory scheme for pharmaceuticals and health care, has enabled the three leading insulin producers and three dominant PBM players to exploit legal loopholes, manipulate markets, and broker collusive deals, all while aggressively and continuously increasing the price of insulin and other drugs.

Public outcry over insulin prices has prompted congressional hearings, legislative and regulatory action, and pending litigation at both the state and federal levels. At the federal level, Congress enacted the Inflation Reduction Act of 2022, empowering Medicare to negotiate drug prices and capping out-of-pocket insulin costs at thirty-five dollars per month for Medicare patients.[15] In 2024 alone, dozens of new bills were introduced in Congress to address the high costs of pharmaceutical drugs.[16] A 2025 bipartisan bill, the Patients Over Profit Act, seeks to prevent the increasing vertical integration in health care, where insurance companies acquire provider practices, labs, specialty practices, and outpatient clinics—although in its current form, the bill leaves intact the consolidation between PBMs and pharmacies.[17] At the state level, this Article produces an original, comprehensive, and up-to-date mapping of the twenty-nine states, plus the District of Columbia, that have passed legislation to cap insulin prices, analyzing the potential benefits and risks of such direct price controls.[18] Over the past few years, each of the fifty

Pharmacies 2 (2024). The six largest PBMs manage nearly ninety-five percent of all prescriptions filled in the United States. Id. at 5.

[14] See discussion infra Section II.D.

[15] Bisma A. Sayed et al., Off. of the Assistant Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Hum. Servs., Insulin Affordability and the Inflation Reduction Act: Medicare Beneficiary Savings by State and Demographics 1 (2023), https://aspe.hhs.gov/sites/default/files/documents/bd5568fa0e8a59c2225b2e0b93d5ae5b/aspe-insulin-affordibility-datapoint.pdf [https://perma.cc/TL9A-QWJU]; Tami Luhby, More Americans Can Now Get Insulin for $35, CNN, https://www.cnn.com/2024/01/01/politics/insulin-price-cap/index.html [https://perma.cc/6TAR-FBEV] (last updated Jan. 2, 2024, 5:34 PM); Jay-Donavin Ved, The Inflation Reduction Act of 2022: Addressing Prescription Drug Coverage, 32 Annals Health L. Advance Directive 131, 131 (2023).

[16] See infra Part III.

[17] Patients Over Profit Act, S. 2836, 119th Cong. (2025).

[18] See infra Section III.B, Figure IV, Table I.

states has also enacted legislation to tackle the PBMs' behaviors, through measures such as prohibiting PBMs' exclusion of nonaffiliated pharmacies from health plans.[19] The validity of these state reforms is uncertain in light of a circuit split regarding whether they are preempted by federal law. Moreover, in the past few years, and accelerating in 2024, state attorneys general across the country, as well as the Federal Trade Commission ("FTC"), have filed lawsuits against the major insulin manufacturers and PBMs, alleging anticompetitive practices and price-fixing.[20] In 2023, those states filed *In re Insulin Pricing Litigation*, the consolidated multidistrict litigation centering on the allegations that major insulin manufacturers—such as Eli Lilly, Novo Nordisk, and Sanofi—colluded with PBMs—like CVS Caremark, Express Scripts, and Optum Rx—to artificially and fraudulently inflate the price of insulin.[21] Since 2023, the number of states in the multistate litigation has grown to include seventeen U.S. states and territories.[22] Drawing on antitrust principles, this Article presents the first scholarly analysis of this sea of new lawsuits and contends that the pharmaceutical companies and pharmacy managers have conspired to artificially inflate drug prices, thereby exploiting the vulnerability of millions of patients.

California's approach to high insulin prices is broader than most state reforms, the majority of which have focused solely on direct price controls. California's legislation to cap the price of insulin was initially

[19] T. Joseph Mattingly II, Maisie Lewis, Mariana P. Socal & Ge Bai, State-Level Policy Efforts to Regulate Pharmacy Benefit Managers (PBMs), 18 Rsch. Soc. & Admin. Pharmacy 3995, 3995, 3999 (2022).

[20] Many of these actions—including those by Arkansas, Illinois, Kansas, Mississippi, Montana, California, Louisiana, Puerto Rico, Hawaii, Arizona, Texas, Utah, Missouri, as well as by unions and local governments—have been consolidated. Docket, In re Insulin Pricing Litig., No. 3080 (J.P.M.L. May 9, 2023). The FTC filed its own complaint against PBMs, alleging violation of Section 5 of the FTC Act, 15 U.S.C. § 45, in September 2024. Complaint, In re Caremark Rx, LLC, No. 9437 (F.T.C. Sept. 20, 2024) [hereinafter FTC Complaint]. Class actions have also been filed by patients against insurers for paying PBMs inflated drug costs. Daniel Wiessner, Wells Fargo Sued Over Employee Prescription Drug Costs, Reuters (July 30, 2024), https://www.reuters.com/legal/wells-fargo-sued-over-employee-prescription-drug-costs-2024-07-30/ [https://perma.cc/7MM5-VF5N].

[21] First Amended Complaint at 6, Arkansas ex rel. Rutledge v. Eli Lilly & Co., No. 22-cv-00549 (E.D. Ark. Aug. 8, 2022); Complaint at 6, Illinois ex rel. Raoul v. Eli Lilly & Co., No. 2022CH11699 (Ill. Cir. Ct. Dec. 2, 2022); Petition at 6, Kansas ex rel. Schmidt v. Eli Lilly & Co., No. 2022-cv-000735 (Kan. Dist. Ct. Dec. 2, 2022); Third Amended Complaint at 5, Mississippi ex rel. Fitch v. Eli Lilly & Co., No. 21-cv-00674 (S.D. Miss. Feb. 17, 2022).

[22] These states and territories are Arizona, Arkansas, California, Hawaii, Illinois, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Ohio, Pennsylvania, Puerto Rico, Texas, Utah, and West Virginia. Docket, *In re Insulin Pricing Litig.*, No. 3080.

vetoed by Governor Gavin Newsom, though such caps were enacted in 2025.[23] In the wake of Newsom's original veto, the state instead enacted a revolutionary state-produced insulin initiative. In 2023, California announced a contract with a nonprofit drugmaker, Civica Rx, to produce government-funded, affordable insulin. Named CalRx, the public program aims to develop, produce, and distribute generic drugs at low costs, starting with insulin.[24] This novel approach to public drug production has the potential to disrupt not just the diabetes medication market, but healthcare delivery more broadly. The next drug on the agenda is naloxone, a drug used to reverse opioid overdoses that the U.S. Food and Drug Administration ("FDA") recently approved as an over-the-counter generic.[25] Other states, as well as a federal bill, are looking to emulate this public intervention. In parallel, market initiatives such as Transparency-Rx and Mark Cuban's Cost Plus are emerging to bypass the dominant PBMs and directly disrupt the concentrated market of drug delivery.[26]

The high cost of insulin and other essential medications is often framed as a straightforward, single-issue problem: drug prices are simply inflated by their sellers.[27] However, this reductive view obscures the intricate web

[23] See Lexington Souers, State Legislation Provides Hope for Rising Insulin Costs, Council of State Gov'ts (Mar. 31, 2023), https://www.csg.org/2023/03/31/state-legislation-provides-hope-for-rising-insulin-costs/ [https://perma.cc/6R4D-7937] (contrasting the legislation that Governor Newsom initially vetoed with insulin price cap legislation in eleven other states); Jess Berthold, CA Governor Just Vetoed Price Caps on Insulin. Now What?, Univ. of Cal. S.F. (Oct. 11, 2023), https://www.ucsf.edu/news/2023/10/426351/ca-governor-just-vetoed-price-caps-insulin-now-what [https://perma.cc/8MPV-MT6D] (explaining California's alternative plan to produce its own insulin for thirty dollars per vial); see also infra note 237 (detailing California's newly enacted insulin price cap legislation).

[24] S.B. 852, 2020 Leg., Reg. Sess. (Cal. 2020).

[25] Lynn La, California Will Buy Cheaper Naloxone to Stop Fentanyl Deaths, CalMatters (Apr. 30, 2024), https://calmatters.org/newsletter/california-fentanyl-deaths-naloxone/ [https://perma.cc/KS48-3QPT]; see also Kristen Hwang, Newsom Committed California to Making Its Own Insulin. It's at Least a Year Behind His Schedule, CalMatters (Jan. 15, 2025), https://calmatters.org/health/2025/01/insulin-production-gavin-newsom/ [https://perma.cc/K9FR-NX92] (detailing the ties between the state's efforts to make both insulin and naloxone more affordable).

[26] See infra Section V.A.

[27] See, e.g., Lev Facher, It's the Insulin, Stupid: How Drug Pricing's Simplest Case Study Became a Top Issue for 2020 Democrats, STAT News (Jan. 28, 2020), https://www.statnews.com/2020/01/28/insulin-pricing-becomes-top-issue-for-democrats [https://perma.cc/GB8L-EVKQ] ("Even in a primary dominated by broader health care issues, insulin has emerged as particularly alluring campaign fodder for Democrats. Unlike more perplexing topics like health insurance reform or the cost of drug research, candidates have a plain and simple rallying cry for insulin: That it's corporate profiteering.").

of market dynamics and regulatory vulnerabilities that sustain and exacerbate the crisis. The source of the illness lies in the inscrutable structures of the pharmaceutical market, characterized by concentrated but convoluted supply chains, opaque pricing mechanisms, and a labyrinth of middlemen whose incentives are misaligned with public health goals. This Article explains how the compounded structure of multiple oligopolies enables actors to leverage legal loopholes, exploit patent laws, and engage in explicit and tacit collusions that further entrench market dominance and stifle competition. What appears to be a straightforward economic issue is, upon closer examination, a systemic pathology supported by an inadequate legal landscape. This Article argues that it is precisely the reality of *oligopoly squared* that has resisted traditional regulation. Most importantly, by offering a rigorous analysis of the new legal landscape, this Article explains the comparative advantages and interplay between federal and state law and policy, uncovering why complex market structures require an antidote of equally robust legal innovation.

This Article makes three major contributions. First, it demonstrates that the high cost of drugs is not the result of a single problem but instead has emerged through a series of anticompetitive practices throughout the healthcare industry. Mining through the profusion of new congressional reports, governmental investigations, lawsuits, and interdisciplinary research, this Article presents the multiple ways in which key actors in the pharmaceutical supply chain engage in anticompetitive and unfair business practices that artificially inflate the costs of prescription drugs.

This Article's second contribution is its timely, novel analysis of the ongoing court challenges to state law reforms aiming to address healthcare industry anticompetitive practices. In 2025, the Supreme Court denied a petition to help resolve *Pharmaceutical Care Management Ass'n v. Mulready*.[28] The case presented the Court with a circuit split on whether state laws regulating PBMs are preempted by the federal Employee Retirement Income Security Act ("ERISA") and Medicare Part D. The circuit decision was also in tension with a recent Supreme Court case, *Rutledge v. Pharmaceutical Care Management Ass'n*, wherein the Court unanimously upheld a state law regulating PBMs.[29] Through an analysis of the preemption issues and long-standing case law balancing uniformity

[28] 78 F.4th 1183 (10th Cir. 2023).
[29] 141 S. Ct. 474 (2020).

and federalism, this Article explains why the Court should have granted certiorari and ruled that the states clearly have the authority to regulate PBMs.

Third, this Article shows how the perfect storm of public outcry, new state and federal legislation, and escalating court battles presents a unique opportunity to study the comparative advantages of and interactions between legal approaches: legislative, regulatory, adjudicative, and public-private governance.[30] In particular, it classifies the law reforms into three emerging frontiers: (1) reforming patent law and drug approval regulations to prevent product hopping and encourage generic competition, as well as direct price caps and price transparency; (2) preventing horizontal and vertical collusions in the drug delivery chain, including by addressing the role of PBMs in brokering unfair formulary and rebate deals systems; and (3) launching innovative models for drug production and distribution, including transparent pharmacies and public manufacturing initiatives. This Article argues that among the many paths of law reform, the third category has the most revolutionary potential.

This Article proceeds in five parts. Part I presents insulin as a prominent example of a drug that was discovered long ago and has evolved into a variety of brand-name products that are still patented today because of big pharma's manipulative product hopping and patent evergreening practices. Part II turns to the structure of the pharmaceutical and pharmacy benefit management markets, explaining how market concentration is compounded when each link in the drug delivery chain is dominated by powerful actors. It further describes the collusive practices among these actors that artificially inflate drug prices, including formulary exclusion, rebates, spread pricing, convoluted fees, and preferred pharmacy status. Part III documents and classifies the recent law reforms at both the state and federal levels, including cost control and cost transparency laws, PBM regulation, and antitrust lawsuits. This Part also analyzes the split circuit case law on federal preemption and argues that such preemption should be narrowly tailored to allow for democratic experimentalism. Part IV examines the dozens of new lawsuits by state attorneys general and the FTC that use antitrust and unfair competition law to put a stop to the range of collusive practices and deals between pharmaceutical manufacturers and PBMs. This Part analyzes frontiers of

[30] On public-private governance theory and practice, see Lobel, The Renew Deal, supra note 3, at 344–45.

competition law and doctrine in relation to new enforcement efforts. Finally, Part V introduces the most novel approaches emerging in the landscape of market and legal levers: alternative public production and delivery of drugs.

The interplay between market realities and legal innovation described in this Article comes at a pivotal moment in the evolution of healthcare governance. This Article concludes by arguing that the emerging framework lends itself to examining more broadly the rich landscape of legal levers on consumer welfare, equitable access, and market competition. By analyzing this breadth of efforts through the lens of legal theory and practical impact, this Article aims not only to chart the course for pharmaceutical drug industry reforms, but also to explore broader implications for regulating complex concentrated industries.

I. FROM PUBLIC GOODS TO EVERGREEN PATENTED BRANDS: INSULIN AS PHARMA'S GREED POSTER CHILD

"Insulin is the poster child of [a] broken drug pricing system."

- FTC 2024 Complaint[31]

A. The Century-Old $1 Patent

Diabetes care has simply become unaffordable for too many patients. Diabetes is a vast and growing medical condition, afflicting over 800 million individuals worldwide.[32] These patients span all countries, ages, ethnicities, and genders. As of 2021, the global prevalence of diabetes is over six percent of the world population, and diabetes is among the top causes of death and disability.[33] The prevalence of Type 1 and Type 2 diabetes is projected to double by 2050, meaning 1.3 billion people will be living with the condition.[34] As in other countries, millions of children

[31] FTC Complaint, supra note 20, ¶ 8.

[32] World Health Org., Urgent Action Needed as Global Diabetes Cases Increase Four-Fold over Past Decades (Nov. 13, 2024), https://www.who.int/news/item/13-11-2024-urgent-action-needed-as-global-diabetes-cases-increase-four-fold-over-past-decades [https://perma.cc/FR9S-UWYL].

[33] Kanyin Liane Ong et al., Global, Regional, and National Burden of Diabetes from 1990 to 2021, with Projections of Prevalence to 2050: A Systematic Analysis for the Global Burden of Disease Study 2021, 402 Lancet 203, 207 (2023) [hereinafter GBD 2021 Report].

[34] Id. at 216.

and adults in the United States live with diabetes. These numbers are only rising.

Diabetic patients need insulin to survive. Specifically, all Type 1 diabetics and about one-third of Type 2 diabetics need daily doses of insulin.[35] Insulin has been used to treat diabetes for over a century, yet the price of insulin has skyrocketed over the last two decades. Although relatively inexpensive to produce—approximately ten dollars per dose—some insulin products have a list price above two hundred dollars.[36] Patients pay thousands of dollars per year for insulin simply to stay alive.[37] Despite the fact that the United States represents just fifteen percent of the global insulin market by volume, it constitutes nearly half of the insulin industry's total revenue in global sales.[38] Alarmingly, the high costs force one out of every six American patients living with diabetes to ration their insulin.[39] Diabetes is the most expensive chronic condition in the United States—people with diabetes account for one of every four dollars spent on U.S. health care and roughly one-third of Medicare drug spending.[40] According to one national study, improving

[35] Insulin Routines, Am. Diabetes Ass'n, https://diabetes.org/health-wellness/medication/insulin-routines [https://perma.cc/2BQ2-5297] (last visited Oct. 8, 2025); Press Release, Univ. of Tex. Sw. Med. Ctr., Weekly Insulin Found Safe, Effective for Type 2 Diabetes (July 12, 2023), https://www.utsouthwestern.edu/newsroom/articles/year-2023/july-weekly-insulin-found-safe.html [https://perma.cc/584Y-LJ9Z] ("About a third of people with Type 2 diabetes require insulin injections to keep their blood sugar within a healthy range . . . .").

[36] Dylan Scott, Insulin Is Way Too Expensive. California Has a Solution: Make Its Own., Vox (Feb. 7, 2023, 11:06 PM), https://www.vox.com/policy-and-politics/23574178/insulin-cost-california-biden-medicare-coverage.

[37] See Rebecca Myerson, State-Level Insulin Copayment Caps—Who Benefits, and What Is Next?, JAMA Network Open, Aug. 14, 2024, at 1, 1, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2822225 [https://perma.cc/A8Y9-89F2] (articulating the scale of insulin-rationing among insulin users in the United States); Katie Thomas, Drug Discounts Often Elude the Poor, N.Y. Times, Jan. 21, 2025, at D1.

[38] Frederick M. Abbott & Padmashree Gehl Sampath, U.N. Dev. Programme, A Competition Law Approach to Accessing Insulin 27 (Dec. 2022) (unpublished manuscript), https://uniatf.who.int/docs/librariesprovider22/default-document-library/undp-a-competition-law-approach-to-accessing-insuling-a-working-paper.pdf?sfvrsn=ab888fa3_1 [https://perma.cc/9867-HFDR].

[39] Adam Gaffney, David U. Himmelstein & Steffie Woolhandler, Prevalence and Correlates of Patient Rationing of Insulin in the United States: A National Survey, 175 Annals Internal Med. 1623, 1624 (2022).

[40] Press Release, Am. Diabetes Ass'n, New American Diabetes Association Report Finds Annual Costs of Diabetes to Be $412.9 Billion (Nov. 1, 2023) [hereinafter Press Release, Am. Diabetes Ass'n] (citing Emily D. Parker et al., Economic Costs of Diabetes in the U.S. in 2022, 47 Diabetes Care 26, 26 (2024)), https://diabetes.org/sites/default/files/2023-11/6AM_2023%20Economic%20Report%20News%20Release%20%285%29.pdf [https://perma.cc/KH

diabetes care in the United States would prevent nearly 700,000 emergency department visits and 341,000 hospitalizations, as well as save $4.7 billion annually.[41] The exponential growth of the patient population suffering from diabetes has highlighted the disparities in access to diabetes care, including those along socioeconomic, racial, and ethnic lines.[42]

A century ago, the discovery of insulin was one of medicine's most significant achievements, transforming what was once a fatal diagnosis into a manageable chronic condition. Before scientists discovered how to manufacture insulin artificially, a diagnosis of Type 1 diabetes amounted to a death sentence.[43] The condition, in which the pancreas ceases to produce insulin, inevitably led to rapid health decline and death as patients' bodies lost the ability to process glucose.[44]

In 1922, the landscape of diabetes treatment changed dramatically with the groundbreaking discovery of animal-derived insulin therapy.[45] In a decision that stands in stark contrast to modern pharmaceutical practices, researchers assigned their patent rights to the University of Toronto for a

4W-QC25]; Letter from Lisa Murdock, Chief Advoc. Officer, Am. Diabetes Ass'n, to Kevin McCarthy, Speaker of the House, Chuck Schumer, Senate Majority Leader, Mitch McConnell, Senate Minority Leader & Hakeem Jeffries, House Minority Leader (Sept. 8, 2023), https://diabetes.org/sites/default/files/2023-10/ADA-PBM-Leadership-Letter-Sept-2023.pdf [https://perma.cc/5BGZ-3XWS].

[41] Ashish K. Jha, Ronald E. Aubert, Jianying Yao, J. Russell Teagarden & Robert S. Epstein, Greater Adherence to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly $5 Billion Annually, 31 Health Affs. 1836, 1836 (2012).

[42] GBD 2021 Report, supra note 33, at 216–19 (discussing disparities in access to diabetes treatment and preventative care).

[43] Howard E. LeWine, People with Type 1 Diabetes Are Living Longer, Harv. Health Online (Jan. 8, 2015), https://www.health.harvard.edu/blog/people-type-1-diabetes-living-longer-201501087611 [https://perma.cc/UR6P-GDLB] ("Ninety years ago, type 1 diabetes was a death sentence: half of people who developed it died within two years; more than 90% were dead within five years.").

[44] Jordyn Imhoff, 100 Years of Insulin, Mich. Med. (Nov. 11, 2021, 4:18 PM), https://www.michiganmedicine.org/health-lab/100-years-insulin [https://perma.cc/VY6R-K3WZ] ("However, people with diabetes of any type, have difficulty keeping their blood sugar stable because [an] insufficient amount of insulin [is] secreted from their pancreas, sugar stays in the blood instead of entering cells. When the sugar stays in the blood and blood sugar levels remain high over a period of time, this can cause serious health issues and increase a patient's risk of heart disease, kidney disease, eye disease, other organs' damage and importantly premature death.").

[45] See Michael Bliss, The Discovery of Insulin 84 (25th-anniversary ed. 2007) (describing the path to discovery and commercialization of insulin in the 1920s).

mere dollar each.[46] The researchers' reasoning reflected a profound commitment to public health over profit; they believed that once the preparation method was published, anyone would be able to produce the extract, which would prevent any entity from establishing a profitable monopoly.[47] Frederick Banting, one of insulin's primary inventors, famously declared that "insulin does not belong to me, it belongs to the world."[48]

Banting won the Nobel Prize in Medicine in 1923, sharing the award with John James Richard MacLeod, for their contributions to the discovery of insulin.[49] Both insulin inventors shared their prize money with others who they collaborated with in the months leading up to the discovery; Banting shared with Charles Best, and MacLeod shared with James Collip.[50] Unbeknownst at the time, this would later lead to years of bitter disputes among the four scientists about whose roles were the most meaningful in the landmark discovery.[51] Notwithstanding their battles over scientific credit, the four scientists all agreed on the principle that insulin should be available to the world, rather than owned and monopolized.[52] Following this principled beginning, the University of Toronto partnered with pharmaceutical companies Eli Lilly and Novo Nordisk to scale production and enable worldwide distribution to the millions suffering from diabetes.[53] This partnership marked the beginning of commercial insulin production, though the landscape evolved as technology advanced.

The next most significant breakthrough occurred in 1978 when researchers at the City of Hope National Medical Center in Duarte, California, collaborating with Genentech, Inc., in South San Francisco, developed synthetic human insulin.[54] Synthetic insulin offers both economic and medical advantages over animal-derived insulin, as it is less

[46] 100 Years: From Gift to Greed, T1International, https://www.t1international.com/100years/ [https://perma.cc/5CTF-9TU2] (last visited Oct. 8, 2025).

[47] Gary F. Lewis & Patricia L. Brubaker, The Discovery of Insulin Revisited: Lessons for the Modern Era, J. Clinical Investigation, Jan. 4, 2021, at 1, 6–7.

[48] Id. at 6 (citation omitted).

[49] Lars Rydén & Jan Lindsten, The History of the Nobel Prize for the Discovery of Insulin, Diabetes Rsch. & Clinical Prac., Apr. 15, 2021, at 1, 1.

[50] Id. at 2.

[51] See Bliss, supra note 45, at 193–200 (describing the disputes over credit).

[52] T1International, supra note 46.

[53] Lewis & Brubaker, supra note 47, at 6.

[54] Arthur D. Riggs, Making, Cloning, and the Expression of Human Insulin Genes in Bacteria: The Path to Humulin, 42 Endocrine Revs. 374, 378–79 (2021).

expensive to mass-produce and triggers fewer allergic reactions in patients.

B. From Animal to Synthetic to Analog Insulin

The commercialization of synthetic human insulin began in 1982 when Eli Lilly brought Humulin, a form of human insulin, to market under license.[55] Novo Nordisk later followed with its competing product, Novolin.[56] The superior properties of synthetic human insulin ultimately led to the complete displacement of animal-based insulin products from the United States market.[57]

The next groundbreaking phase arrived in the 1990s and early 2000s, as scientific advances enabled researchers to modify the molecular structure of human insulin. These modifications led to the development of analog insulins, so named because they mirror the human body's natural patterns of insulin release.[58] Analog insulin offers patients more precise control over their blood glucose levels and greater flexibility in their treatment regimens.[59] Today, most of the insulin prescribed in the United States is analog insulin. In 2000, ninety-six percent of insulin users used human insulin, as compared to nineteen percent using analog insulin.[60] By 2010, the number of patients using human insulin was down to fifteen percent, with ninety-two percent using analog insulin.[61]

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[55] Id. at 375, 379.

[56] Biologic License Application: 019938, Drugs@FDA: FDA-Approved Drugs, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019938 [https://perma.cc/FVV2-Y9RM] (last visited Nov. 3, 2025) (illustrating that the original approval date of Novolin was June 25, 1991).

[57] Irl B. Hirsch, Rattan Juneja, John M. Beals, Caryl J. Antalis & Eugene E. Wright, Jr., The Evolution of Insulin and How It Informs Therapy and Treatment Choices, 41 Endocrine Revs. 733, 735–36 (2020).

[58] See Julia Flaherty, The Differences Between Biosimilar, Human and Analog Insulins, Beyond Type 1 (Apr. 14, 2022), https://beyondtype1.org/biosimilar-human-analog-insulin-differences/ [https://perma.cc/TS3W-SZ2C].

[59] Feroze, Advancements in Insulin Therapy: Current Status and Future Directions, 6 J. Diabetes Medication & Care 47, 48 (2023).

[60] Tara O'Neill Hayes & Margaret Barnhorst, Understanding the Insulin Market, Am. Action F. 4 (2020) (citing Kasia J. Lipska et al., Use and Out-of-Pocket Costs of Insulin for Type 2 Diabetes Mellitus From 2000 Through 2010, 311 JAMA 2331, 2332 (2014)), https://www.americanactionforum.org/research/understanding-the-insulin-market/ [https://perma.cc/2TUL-TV3C].

[61] Id. The World Health Organization recently deemed human insulin preferable to analog insulin, in part due to human insulin's much lower price, but also because of an active debate in the health field about whether analog insulin indeed offers significant comparative benefits.

Furthermore, while synthetic human insulins are sold over the counter, analog insulin is a prescription drug. These insulin analogs reflect a sophisticated understanding of the body's complex metabolic processes. Modern insulin therapy operates within a carefully constructed taxonomy based on three key characteristics: the fundamental nature of the insulin (whether it is analog or human), its onset time (how quickly it begins to work after administration), and its duration of action (how long its glucose-regulating effects persist in the body).[62] This classification system helps healthcare providers and patients develop optimal treatment strategies tailored to individual needs.[63]

Edwin A.M. Gale & John S. Yudkin, Commentary: Politics of Affordable Insulin, 343 Brit. Med. J. 566, 566 (2011); see also W. Nicholson Price II & Arti K. Rai, Are Trade Secrets Delaying Biosimilars?, Sci. Mag., Apr. 10, 2015, at 188, 188 (analyzing the barriers to competitive entry in biologics manufacturing); Jing Luo & Aaron S. Kesselheim, Evolution of Insulin Patents and Market Exclusivities in the USA, 3 Lancet Diabetes & Endocrinology 835, 836–37 (2015) (illustrating the ramifications patents have on insulin market competition); Lutz Heinemann, Biosimilar Insulin and Costs: What Can We Expect?, 10 J. Diabetes Sci. & Tech. 457, 461 (2016) (analyzing the challenges associated with biosimilar insulins).

[62] See Insulin Basics for Diabetes, Am. Diabetes Ass'n, https://diabetes.org/health-wellness/medication/insulin-basics [https://perma.cc/W6TP-32WF] (last visited Oct. 28, 2025) ("Insulin has three characteristics: . . . [which include] [p]eak time . . . [and] [d]uration . . . ."); see also Am. Diabetes Ass'n, Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2019, 42 Diabetes Care S90, S91 (2019) (describing the different medical outcomes associated with human insulin versus analog insulin).

[63] Within this framework, rapid-acting analog insulins, classified as prandial insulins, serve a specific and crucial function in diabetes management. These insulins are designed to address the challenge of post-meal glucose spikes, a significant concern in maintaining stable blood sugar levels. Patients typically administer these rapid-acting analogs shortly before meals—termed *bolus*—allowing them to better mirror the body's natural insulin response to food intake. This timing helps prevent the dangerous blood glucose elevations that commonly occur after eating. Complementing these short-term agents, long-acting analog insulins, categorized as *basal* insulins, fulfill a different but equally essential role in diabetes management. These formulations are typically administered once or twice daily and provide a steady background level of insulin that helps maintain stable glucose levels, particularly during overnight periods when glucose control is especially challenging. This basal-prandial approach, combining long-acting and rapid-acting insulins, allows for a more physiologic replacement of insulin that better approximates normal pancreatic function. See Steven Edelman, George Dailey, Thomas Flood, Louis Kuritzky & Susan Renda, A Practical Approach for Implementation of a Basal-Prandial Insulin Therapy Regimen in Patients with Type 2 Diabetes, Osteopathic Med. & Primary Care, Apr. 20, 2007, at 1, 4, 7–11 (describing best practices for diabetes management and glucose control); see also Ralph Oiknine, Marla Bernbaum & Arshag D. Mooradian, A Critical Appraisal of the Role of Insulin Analogues in the Management of Diabetes Mellitus, 65 Drugs 325, 327–28 (2005) (describing the need for fast-acting insulin in addition to basal insulin to prevent out-of-range sugar levels).

The development of these specialized insulin formulations represented a significant advancement in the treatment of diabetes, offering patients more precise control to manage their care. At the same time, this groundbreaking medical progress has also introduced complexities in the commercial insulin market, with grave implications for both healthcare delivery and economic accessibility. In other words, the increasing sophistication of insulin products raises both costs and acute questions about the relationship between pharmaceutical innovation and patient well-being.[64] The contrast between the original inventors' public-looking vision and the current state of insulin pricing provides a striking case study of how intellectual property, corporate interests, market concentration, and industry structures operate. This history helps illuminate the contemporary debates about the balance between pharmaceutical innovation and accessible health care.

C. Product Hopping and Patent Evergreening

Although age-old pharmaceutical drugs like insulin should typically experience generic competition over time, manufacturers have subverted that competition by continuing to introduce new versions of insulin products, both by developing slight incremental improvements to already-patented products and by altering the delivery device for the drug, limiting the ability of competitors to enter the market.[65] Despite a century having

[64] See infra Section I.C.

[65] See Reed F. Beall & Aaron S. Kesselheim, Tertiary Patenting on Drug-Device Combination Products in the United States, 36 Nature Biotechnology 142, 143 (2018) ("Our finding that tertiary patents are being listed in the Orange Book and that they typically expire later than other patent types implies that for these products, generic versions are prevented from entering the market for longer than would otherwise be the case." (footnote omitted)); see also Heinemann, supra note 61, at 458 (discussing cost implications and the market impact of biosimilar insulin products). For example, insulin pens, first introduced by the three major insulin manufacturers in the 1980s, have undergone continuous updates. They have evolved into next-generation devices such as smart pens and, more recently, connected pens. Many of these changes appear to emphasize technological differentiation rather than health-related improvements. See Sarah L. Sy, Medha M. Munshi & Elena Toschi, Can Smart Pens Help Improve Diabetes Management?, 16 J. Diabetes Sci. & Tech. 628, 628–29, 632 (2022) (discussing technological advancements in insulin pens and simultaneous difficulties with integrating those advancements into healthcare practice); Jean-Louis Selam, Evolution of Diabetes Insulin Delivery Devices, 4 J. Diabetes Sci. & Tech. 505, 509–10 (2010) (cataloging technological features of currently available insulin pumps); Jerome E. Thurman, Insulin Pen Injection Devices for Management of Patients with Type 2 Diabetes: Considerations Based on an Endocrinologist's Practical Experience in the United States, 13 Endocrine Prac. 672, 672

passed since the discovery of insulin, insulin products have rarely entered the market as generics or biosimilars.[66]

The strategy is a pervasive one: the adoption of generic drugs is slowed down to protect the brand-name drug. While conventional economic analysis suggests that pharmaceutical products should face robust generic competition following patent expiration, particularly for well-established therapeutic agents like insulin, manufacturers have successfully employed a sophisticated pattern of incremental innovations to maintain market dominance—*evergreening* their patent exclusivity.[67] These iterative improvements have created significant barriers to market entry. These shift strategies in the pharmaceutical marketplace typically manifest as two distinct variants: *hard switches*, where manufacturers wholly withdraw the original product from the market, compelling a transition to the new formulation; and *soft switches*, where manufacturers maintain the original product but deploy intensive marketing campaigns and preferential pricing strategies to incentivize migration to the modified version.[68] The timing of such switches—termed *product hopping*—frequently coincides with the imminent expiration of patent protection on

(2007) (articulating the non-technological considerations a clinician should consider when choosing a specific insulin pen for an individual patient).

[66] See Heinemann, supra note 61, at 458 (suggesting that the availability of generic insulin products in North America is precluded by incremental innovation).

[67] When manufacturers evergreen patents, they extend their lifetimes and prevent generics from entering the market. Generic competitors face a dangerous gamble in challenging these potentially invalid patents if litigation ends unfavorably for them. Manufacturers engage in other strategies to delay the entry of generics, such as paying generic manufacturers what they would otherwise earn (and often more) if the generic actually got to market. See Uri Y. Hacohen, Evergreening at Risk, 33 Harv. J.L. & Tech. 479, 481 (2020) (explaining how brand-name manufacturers leverage follow-on "improvement" patents to strengthen and prolong market exclusivity for existing drugs); S. Sean Tu & Mark A. Lemley, What Litigators Can Teach the Patent Office About Pharmaceutical Patents, 99 Wash. U. L. Rev. 1673, 1682 (2022) (offering ways to simplify and streamline patent prosecution and litigation to make it harder to exclude generic entry with a thicket of bad patents).

[68] This switching from one product to another also disincentivizes generic entry into the market, as sales shift to the new product after the switch. Courts are divided as to whether this behavior should be subject to antitrust scrutiny. See Bret Dickey, Kun Huang & Daniel L. Rubinfeld, Pharmaceutical Product Hopping: Is There a Role for Antitrust Scrutiny?, 82 Antitrust L.J. 679, 694 (2019) (discussing the paths for antitrust enforcement against practices that prevent generic entry).

the original formulation—a calculated effort to preserve market exclusivity.[69]

Importantly, product hopping in the pharmaceutical industry most often entails minor modifications—such as changing from twice-daily to once-daily dosing, from one hardware delivery system to another, or from tablet to capsule formulation.[70] Thus, both direct drug formulation hopping and device hopping enable manufacturers to maintain premium pricing and market exclusivity. These changes offer marginal benefits but rarely represent therapeutic breakthroughs commensurate with their economic impact. Nevertheless, these switches can effectively forestall generic competition.

D. Generics, Biosimilars, and Drug Substitution Circumvention

The regulatory framework that governs prescription drug manufacturing, which requires generic manufacturers to demonstrate both therapeutic and device equivalence, compounds market access challenges. In particular, product hopping circumvents generic substitution laws. Thirty-six states allow substitution of brand-name drugs with generics, while fourteen states mandate substitution.[71] Importantly, in pharmaceutical products regulated by the U.S. Food and Drug Administration, there is a distinction between drugs and biologics.[72]

[69] See Michael A. Carrier & Steve D. Shadowen, Product Hopping: A New Framework, 92 Notre Dame L. Rev. 167, 168, 176 (2016) (defining "product hopping" and describing product-hopping schemes).

[70] See id. at 168, 177, 206 (providing examples of minor modifications).

[71] Jordan Paradise, The Legal and Regulatory Status of Biosimilars: How Product Naming and State Substitution Laws May Impact the United States Healthcare System, 41 Am. J.L. & Med. 49, 75 (2015) [hereinafter Paradise, Biosimilars] (citing Off. of the Assistant Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Hum. Servs., Expanding the Use of Generic Drugs, at app. A (2010), https://aspe.hhs.gov/sites/default/files/private/pdf/76151/ib.pdf [https://perma.cc/4YN8-T6FW]) (summarizing trends in generic-drug use and potential cost savings from increasing substitution); Jeffrey J. Masters, Not Exactly the Same: An Examination of How Generic Substitution Laws Inadequately Protect Consumers' Needs if Taking Generic Drugs Results in Injuries, 8 Drexel L. Rev. 233, 241 (2015) (cataloging state approaches to regulating substitution). For a similar discussion on generic substitution laws in the naloxone context, see Evan D. Peet, David Powell & Rosalie Liccardo Pacula, Using Policy and Innovation to Improve Life-Saving Access to Naloxone 15 (Nat'l Bureau of Econ. Rsch., Working Paper No. 33105, 2024) (noting that thirty-six states enacted naloxone access laws through standing / protocol orders or prescriptive authority before Narcan entered the market).

[72] The top-selling therapeutic products are predominantly biologics, which generate hundreds of billions in sales. See Krishan Maggon, R&D Paradigm Shift and Billion-Dollar

Biologics do not achieve generic status. Instead, competing products can be "biosimilar," as defined by the FDA, when there is no clinical significance between products, and competing products for biologics must meet regulatory requirements of biosimilarity and interchangeability.[73]

Once again, the case of insulin provides insight into the complexities involved in supporting, rather than impeding, drug substitution through law and policy. Insulin is a biologic product, as opposed to a chemical drug. Still, following intra-agency agreements, the FDA, until 2020, regulated insulins as drugs. While this allowed for FDA oversight, the classification of insulin as a drug—though it is in fact biologic—meant that insulin competitors could not reach generic status.[74] Every new insulin had to go through a new process of approval because the naturally occurring nature of insulin and variability between each batch meant that products could not be generic.[75]

In 2020, insulin was transitioned to being regulated as a biological product, meaning that it can now be used as a reference product for biosimilars.[76] This shift in classification opens more of the market to

Biologics, *in* Handbook of Pharmaceutical Biotechnology 161, 162 (Shayne Cox ed., 2007) (describing the shift in pharmaceutical research and development toward biologics and the emergence of blockbuster biologic drugs as multibillion-dollar products); Michael A. Sanzo, The Promise and Problem of Biologics, 34 Santa Clara High Tech. L.J. 78, 80 (2017) (analyzing the risks and challenges in regulating biologics).

[73] David R. Owens, Wolfgang Landgraf, Andrea Schmidt, Reinhard G. Bretzel & Martin K. Kuhlmann, The Emergence of Biosimilar Insulin Preparations—A Cause for Concern?, 14 Diabetes Tech. & Therapeutics 989, 994 (2012).

[74] The FDA regulates insulin and other biologics. See Am. Hosp. Ass'n, FDA Finalizes Rule to Regulate Insulin as Biological Product (Feb. 20, 2020, 2:25 PM) (citing Definition of the Term "Biological Product," 85 Fed. Reg. 10057 (Feb. 21, 2020) [hereinafter FDA 2020 Final Rule] (to be codified at 21 C.F.R. pt. 600)), https://www.aha.org/news/headline/2020-02-20-fda-finalizes-rule-regulate-insulin-biological-product [https://perma.cc/K6PH-VRCR] (reporting that the FDA issued a final rule reclassifying insulins as biologics); see also, e.g., Michael S. Kinch, An Overview of FDA-Approved Biologics Medicines, 20 Drug Discovery Today 393, 393–94 (2015) (noting that the FDA has approved a total of ninety-one new molecular entities since the approval of Humulin, the first recombinant human insulin, in 1982).

[75] See Paradise, Biosimilars, supra note 71, at 59, 68; see also Anne Park Kim & Ross Jason Bindler, The Future of Biosimilar Insulins, 29 Diabetes Spectrum 161, 163 (2016); Jordan Paradise, Insulin Federalism, 27 B.U. J. Sci. & Tech. L. 118, 120, 122 (2021) (describing batch-to-batch variability and the nongeneric nature of insulin in particular).

[76] See Paradise, Biosimilars, supra note 71, at 64–65; Press Release, U.S. Food & Drug Admin., U.S. Dep't of Health & Hum. Servs., FDA Works to Ensure Smooth Regulatory Transition of Insulin and Other Biological Products (Feb. 20, 2020), https://www.fda.gov/news-events/press-announcements/fda-works-ensure-smooth-regulatory-transition-insulin-and-ot

competition. The regulatory process of receiving a biosimilar and establishing interchangeable status is rigorous. The interchangeable status—a step beyond biosimilarity—requires additional evidence showing that the biosimilar can be substituted for the reference biologic with no adverse effects on efficacy or safety.[77] This designation is particularly valuable, as it permits pharmacists to substitute the biosimilar for the original biologic without consulting the prescribing physician, similar to generic drug substitution.[78] Yet, mirroring the product hopping tactics to delay generic drugs described above, biologic manufacturers use patent strategies and exclusivity provisions to delay competition. For instance, although Lantus (insulin glargine) lost its primary patent in 2015, over seventy additional patents were filed to extend its market protection by up to thirty-seven years.[79] Consequently, while the core insulin molecule itself may be off-patent, the intricate web of patents, as well as regulatory approval of drugs surrounding modern drug composition and delivery systems, has created a de facto monopolistic environment that has proven remarkably resistant to traditional generic competition.

her-biological-products [https://perma.cc/C6XV-GQNG]; FDA 2020 Final Rule, supra note 74, at 10058 ("[FDA's revised definition] enables insulin to be brought into the regulatory pathway for biological products, including biosimilar and interchangeable products.").

[77] Paradise, Biosimilars, supra note 71, at 65–66.

[78] See generally U.S. Food & Drug Admin., Biological Product Definitions, https://www.fda.gov/media/108557/download [https://perma.cc/5VAP-XM4M] (last visited Oct. 8, 2025). See also Eur. Meds. Agency & Eur. Comm'n, Biosimilars in the EU: Information Guide for Healthcare Professionals 29 (2019) (similarly defining interchangeability and substitution for healthcare professionals within the European Union).

[79] Srividhya Ragavan, Make America Healthy: Reducing High Pharmaceutical Prices Without Reducing Innovation, 77 SMU L. Rev. 787, 807 (2024) (citing Initiative for Meds., Access & Knowledge, Sanofi's Lantus Is Overpatented and Overpriced, T1International (Nov. 1, 2018, 4:21 PM), https://www.t1international.com/blog/2018/11/01/sanofis-lantus-overpatented-and-overpriced [https://perma.cc/L5PJ-H2N9]); Deana Ferreri, Average Net Price for Insulin Glargine Declined After Basaglar Won FDA Approval, Am. J. of Managed Care, Ctr. for Biosimilars (Aug. 2, 2021), https://www.centerforbiosimilars.com/view/average-net-price-for-insulin-glargine-declined-after-basaglar-won-fda-approval [https://perma.cc/NBG6-W4XL].

II. THE SHAPE OF THE MARKET

A. The Manufacturers

"I'm demanding Sanofi to decrease the cost of insulin. It is a medication that all type 1 diabetics need to survive. And without it, they will die like my daughter did."

- T1 Diabetes Journey Founder, Antroinette Worsham[80]

On average, prescription drug prices in the United States are over double those in other high-income nations.[81] Over the last decade, drug prices have been dramatically increasing, even for medicines that were developed decades ago.[82] High drug prices harm all patients, but they disproportionately harm low-income communities, many of which are predominantly populated by individuals in racial minority groups who are more likely to be diagnosed with chronic diseases and more likely to be uninsured or underinsured.[83] In 2023, the U.S. healthcare system spent $772.5 billion on prescription drugs, $91 billion of which were patient out-of-pocket costs.[84] This annual spending was nearly twice that of other countries.[85] Brand-name drugs account for eighty percent of prescription

[80] Hyacinth Empinado, 'I Shouldn't Have to Go Beg': A Protest over Insulin Prices Is Seen as a Fight for Life, STAT News (Nov. 27, 2018), https://www.statnews.com/2018/11/27/insulin-prices-protest-sanofi/ [https://perma.cc/D3SM-NWXU].

[81] Andrew W. Mulcahy et al., RAND Corp., International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies, at vii (2021).

[82] Richard Payerchin, FTC to Examine Drug Makers, PBMs Due to Insulin Prices, Dermatology Times (June 28, 2022), https://www.dermatologytimes.com/view/ftc-to-examine-drug-makers-pbms-due-to-insulin-prices [https://perma.cc/2H36-STLN].

[83] Nicolle A. Mode, Michele K. Evans & Alan B. Zonderman, Race, Neighborhood Economic Status, Income Inequality and Mortality, PLOS One, May 12, 2016, at 1, 2 ("The influence of economic status on overall health and mortality extends beyond the individual to the neighborhood. Place of residence in the US follows patterns of race and economic position, often due to residential segregation. . . . Low neighborhood economic status has been associated with an increased risk of overall mortality, and mortality from cancer and cardiovascular disease." (footnotes omitted)).

[84] Eric M. Tichy et al., National Trends in Prescription Drug Expenditures and Projections for 2024, 81 Am. J. Health-Sys. Pharmacy 583, 585 (2024); IQVIA Inst. for Hum. Data Sci., The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028, at 27 (2024).

[85] Staff of H. Comm. on Oversight & Accountability, 118th Cong., The Role of Pharmacy Benefit Managers in Prescription Drug Markets 3 (Comm. Print 2024) ("Americans spend more today on prescription drugs than any other country, and prescription drug prices in the

drug spending but account for less than twenty percent of prescribed drugs.[86] The entry of generics into the drug market is the most robust path to lower prices.[87] Yet spending on prescription drugs has only increased over time.[88]

Perversely, while spending on brand-name drugs has increased over time, the industry is more concentrated than ever. The insulin industry is the poster child for such market concentration. Despite the sharp increase in insulin demand, the market grows more concentrated, making the global insulin market one of the most concentrated sectors in the pharmaceutical industry. In the past two decades, the list price of various leading insulins increased by more than six hundred percent.[89] A 2021 congressional report found that insulin manufacturers "raised the [list price] of their insulin products absent significant advances in the efficacy

U.S. are more than double the cost of identical drugs in other high-income nations."); see also Sonal Parasrampuria & Stephen Murphy, Off. of the Assistant Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Hum. Servs., Comparing U.S. and International Market Size and Average Pricing for Prescription Drugs, 2017–2022, at 1 (2024), https://www.ncbi.nlm.nih.gov/books/NBK611829/pdf/Bookshelf_NBK611829.pdf [https://perma.cc/S8M8-FJW9] ("The U.S. made up about 50 percent of worldwide sales revenues but only 13 percent of total volume for prescription drugs in 2022 among countries covered in IQVIA MIDAS.").

[86] Sonal Parasrampuria & Stephen Murphy, Off. of the Assistant Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Hum. Servs., Trends in Prescription Drug Spending, 2016–2021, at 1 (2022), https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf [https://perma.cc/88VC-R5JF].

[87] See Nguyen Xuan Nguyen, Steven H. Sheingold, Wafa Tarazi & Arielle Bosworth, Effect of Competition on Generic Drug Prices, 20 Applied Health Econ. & Health Pol'y 243, 243 (2022) (finding that drug prices decrease as more competitors enter the market and that generics are a "critical part" of the U.S. strategy to lower prescription drug costs); see also Daniel J. Hemel & Lisa Larrimore Ouellette, The Generic Drug Trilemma, 2 Entrepreneurship & Innovation Pol'y & Econ. 41, 56 (2023) (citing Chana A. Sacks et al., Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions, 181 JAMA Internal Med. 16 (2021)) (reporting that it is possible for physicians to provide patients with cheaper generic drugs rather than prescribe them expensive brand-name drugs).

[88] Katherine Drabiak, Manipulating the Prescription Drug Market: Spiking Prices, Inducing Demand, and Costs to the Public, 23 DePaul J. Health Care L. 20, 24, 27–28 (2022).

[89] Abdul Hamid Zargar et al., Rising Cost of Insulin: A Deterrent to Compliance in Patients with Diabetes Mellitus, Diabetes & Metabolic Syndrome: Clinical Rsch. & Revs., May 25, 2022, at 1, 3; see also Steve Inskeep & Allison Aubrey, Insulin Costs Increased 600% over the Last 20 Years. States Aim to Curb the Price, NPR (Sept. 12, 2022, 5:07 AM), https://www.npr.org/2022/09/12/1122311443/insulin-costs-increased-600-over-the-last-20-years-states-aim-to-curb-the-price [https://perma.cc/N9UR-FDQQ] (discussing the impacts of the high price of insulin on Americans, as well as federal and state actions to reduce it).

of the drugs."[90] The dramatic increase has made insulin unaffordable for many patients, incentivizing those patients to engage in dangerous rationing practices that end in emergency room visits, amputations, and even deaths.[91]

As the patient population continues to grow, the value of the insulin market is skyrocketing.[92] Spending in the past decade on insulin nearly tripled, from eight billion dollars in 2012 to over twenty-two billion dollars today.[93] Three multinational pharmaceutical companies—Eli Lilly, Novo Nordisk, and Sanofi—dominate this lucrative market, collectively controlling over ninety percent of global insulin sales in volume and value.[94] In the United States, "these companies control[] 99% of the market by value and 96% of the market by volume."[95] Rising sales have led to a diversification of production sites and insulin products. However, the sector has not seen the entry of any significant new companies, even as global demand continues to grow steadily. Novo Nordisk now operates production facilities in the United States, Brazil, China, Japan, Bangladesh, and Russia.[96] Similarly, Eli Lilly produces

[90] Staff of S. Comm. on Fin., 116th Cong., Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug 2 (Comm. Print. 2021).

[91] See Samantha Willner, Robin Whittemore & Danya Keene, "Life or Death": Experiences of Insulin Insecurity Among Adults with Type 1 Diabetes in the United States, SSM-Population Health, June 27, 2020, at 1, 3–6 (analyzing the "life or death" implications of insulin availability for those with diabetes); Souers, supra note 23 (noting that rationing insulin can lead to emergency room visits, amputations, and death); see also Scott Hulver, Equitable State Policies for Increasing Insulin Access, 30 Annals Health L. Advance Directive 123, 123 (2021) (indicating that high costs create a barrier to obtaining insulin).

[92] See Grand View Rsch., Insulin Delivery Devices Market Summary, https://www.grandviewresearch.com/industry-analysis/insulin-delivery-devices-market [https://perma.cc/28RM-BJWW] (last visited Oct. 8, 2025) (stating that, like the market for insulin production, the insulin pump and glucose monitoring device markets are highly concentrated).

[93] Press Release, Am. Diabetes Ass'n, supra note 40.

[94] Ryan Knox, Insulin Insulated: Barriers to Competition and Affordability in the United States Insulin Market, J.L. & Biosciences, Oct. 9, 2020, at 1, 9; see also William H. Herman & Shihchen Kuo, 100 Years of Insulin: Why Is Insulin So Expensive and What Can Be Done to Control Its Cost?, 50 Endocrinology & Metabolism Clinics N. Am. e21, e22 (2021) (reviewing the regulatory and market factors that drive the high prices of insulin).

[95] Herman & Kuo, supra note 94, at e22 (citing David Beran, Margaret Ewen & Richard Laing, Constraints and Challenges in Access to Insulin: A Global Perspective, 4 Lancet Diabetes & Endocrinology 275 (2016)).

[96] D. Beran et al., A Perspective on Global Access to Insulin: A Descriptive Study of the Market, Trade Flows and Prices, 36 Diabetic Med. 726, 728 (2019).

insulin in the United States, France, Italy, China, and Russia, while Sanofi manufactures its insulin in Germany, Ireland, and Russia.[97]

The leading brand-name insulin drugs cost manufacturers between two dollars and four dollars per vial to produce.[98] Upon entering the market in the late 1990s, the vials were priced at about twenty dollars.[99] Today, their prices have skyrocketed to over three hundred dollars per vial.[100] To wit, over the past decade, manufacturers have raised insulin prices by as much as 1,200%.[101]

Decades of research show that competition is important to technological progress, innovation, and consumer welfare.[102]

[97] Id. ("Denmark, France, USA, Brazil, China, Japan and Russia were identified as production sites for Novo Nordisk. Eli Lilly has production sites in the USA, France, Italy, China and Russia. Germany, Russia and Ireland are where Sanofi produces its insulin. There is overlap between companies and countries where insulin is produced; for example, Eli Lilly and Novo Nordisk both produce insulin in the USA and France as well as between these two companies and manufacturers of biosimilar insulin in Russia and China." (footnotes omitted)).

[98] Serena Crawford, The Price of Insulin: A Q&A with Kasia Lipska, Yale Sch. of Med. (Apr. 27, 2023), https://medicine.yale.edu/news-article/the-price-of-insulin-a-qanda-with-kasia-lipska/ [https://perma.cc/DA56-FWQR].

[99] Id. ("The same vial of insulin that cost $21 in the U.S. in 1996 now costs upward of $250.").

[100] See Kathryn E. Nagel, Reshma Ramachandran & Kasia J. Lipska, Lessons from Insulin: Policy Prescriptions for Affordable Diabetes and Obesity Medications, 47 Diabetes Care 1246, 1247 (2024) ("For example, the list price for a single 10-mL U100 vial of Humalog rose from $26 in the 1990s to more than $300 by the mid-2010s, despite no difference in the actual product. . . . Similarly, by the mid-2010s the list prices for long-acting insulins had reached anywhere from $160 to $350 for a 10-mL vial." (footnotes omitted)).

[101] See Josh Sisco & Lauren Gardner, Feds Sue Pharmacy Gatekeepers Over High Insulin Costs, Politico (Sept. 20, 2024, 3:21 PM), https://www.politico.com/news/2024/09/20/feds-sue-pharmacy-insulin-costs-00180240 (reporting that Eli Lilly's insulin saw a staggering 1,200% price increase, with the average list price rising from $21 in 1999 to more than $274 by 2017); Elisabeth Rosenthal, When High Prices Mean Needless Death, 179 JAMA Internal Med. 114, 115 (2019) (discussing statistics concerning the growth of insulin product prices).

[102] See Orly Lobel, The Equality Machine: Harnessing Digital Technology for a Brighter, More Inclusive Future 92, 161 (2022) (detailing the benefits of competition in technology); see also Orly Lobel, Boilerplate Collusion: Clause Aggregation, Antitrust Law & Contract Governance, 106 Minn. L. Rev. 877, 908 (2021) [hereinafter Lobel, Boilerplate Collusion] (indicating that barriers to competition suppress innovation); Orly Lobel, Talent Wants to Be Free: Why We Should Learn to Love Leaks, Raids, and Free-Riding 74 (2013) (warning that enforcement of noncompete agreements will reduce innovation and creation); Orly Lobel, Knowledge Pays: Reversing Information Flows and the Future of Pay Equality, 120 Colum. L. Rev. 547, 557–58 (2020) [hereinafter Lobel, Knowledge Pays] (discussing gender disparity in job mobility and the impact of noncompete agreements in the labor force); Orly Lobel, Gentlemen Prefer Bonds: How Employers Fix the Talent Market, 59 Santa Clara L. Rev. 663, 665 (2020) [hereinafter Lobel, Gentlemen Prefer Bonds] (arguing that competition among employers for workers results in higher wages, better work conditions, and higher quality

Contemporary research demonstrates that markets thrive and innovate—and products improve in quality—when competition exists.[103] Concentrated or collusive markets, where competitors do not actively and vigorously compete over consumers, hinder innovation, suppress economic growth, and give rise to customer lock-ins and price raises.[104] In the insulin market, pricing practices also exhibit signs of "shadow pricing," where competitors increase prices in tandem.[105] Between 2009 and 2015, the prices of Lantus and Levemir (long-acting insulins) rose simultaneously thirteen times, while the prices of Humalog and Novolog (fast-acting insulins) did so seventeen times over a decade.[106]

A key ingredient of competition and innovation is the entry of new companies into concentrated markets. In health care, concentrated markets reduce innovation incentives and patient welfare. Dominant actors holding significant market shares are less likely to innovate, which effectively equates to "self-cannibalizing" their own successful

human capital); Jean Tirole, Competition and the Industrial Challenge for the Digital Age, 15 Ann. Rev. Econ. 573, 583 (2023) (detailing real-world instances of innovation as a result of competition); Ilya Segal & Michael D. Whinston, Antitrust in Innovative Industries, 97 Am. Econ. Rev. 1703, 1715–78 (2007) (discussing how antitrust policies affect innovation and how improved innovation leads to higher quality goods).

[103] See Steven Klepper & Sally Sleeper, Entry by Spinoffs, 51 Mgmt. Sci. 1291, 1305 (2005) (detailing the impact of competition and market concentration in the laser industry); Benjamin Bental & Menahem Spiegel, Network Competition, Product Quality, and Market Coverage in the Presence of Network Externalities, 43 J. Indus. Econ. 197, 198 (1995) (modeling comparisons between noncooperative (competitive) markets versus cartel (noncompetitive) markets); see also Marshall Steinbaum, Eric Harris Bernstein & John Sturm, Roosevelt Inst., Powerless: How Lax Antitrust and Concentrated Market Power Rig the Economy Against American Workers, Consumers, and Communities 42 (2018), https://rooseveltinstitute.org/wp-content/uploads/2020/07/RI-Powerless-201802.pdf [https://perma.cc/6QPM-R5QW] (highlighting how weakened competition due to market power harms disadvantaged communities); Donald J. Brown & G.A. Wood, Competition, Consumer Welfare and Monopoly Power 9–12 (Cowles Found., Discussion Paper No. 1466R, 2004), https://ssrn.com/abstract=586141 [https://perma.cc/LA9H-4RKR] (discussing the economic loss attributed to monopolization and anticompetitive markets); Gregory J. Werden, Essays on Consumer Welfare and Competition Policy 21–22 (May 15, 2009) (unpublished manuscript), https://ssrn.com/abstract=1352032 [https://perma.cc/V6XV-4G3D] (discussing how noncooperative activity is categorically condemned under competition laws).

[104] See, e.g., Kenneth A. Bamberger & Orly Lobel, Platform Market Power, 32 Berkeley Tech. L.J. 1051, 1065–67 (2017) (discussing how first-mover advantages and switching costs lock in consumers).

[105] Anurag S. Rathore & Faheem Shereef, Shadow Pricing and the Art of Profiteering from Outdated Therapies, 37 Nature Biotechnology 217, 218–19 (2019).

[106] Herman & Kuo, supra note 94, at e25–26.

products.[107] As Nobel laureate Kenneth Arrow put it, "The preinvention monopoly power acts as a strong disincentive to further innovation."[108] Nobel laureate Jean Tirole terms this phenomenon the "replacement effect": a new entrant, unlike the incumbent dominant actor, has greater incentives to improve and innovate upon the products and services offered.[109] While competition and innovation are important in every market, competition in health care and patient-related markets is critical to ensuring a healthy and thriving society. A recent research report by the Open Markets Institute, titled *America's Concentration Crisis*, documents the implications of market concentration in health care.[110] According to the research, market concentration is a central driver of artificial inflation of healthcare costs.[111] The report demonstrates that "exorbitant prices in healthcare are largely a symptom of increasingly concentrated healthcare markets."[112] In short, the growing monopoly power of dominant actors in health care contributes significantly to the high prices of drugs, poor quality of care, and lack of access to care that millions of American patients experience.[113] When a small number of sellers control a large share of the supply, the result is more expensive and yields lower-quality products for consumers. A study led by Congresswoman Diana DeGette, co-chair of the Congressional Diabetes Caucus, to determine what Congress could do to help lower the cost of

[107] See Kenneth J. Arrow, Economic Welfare and the Allocation of Resources for Invention, *in* The Rate and Direction of Inventive Activity: Economic and Social Factors 609, 620 (Nat'l Bureau of Econ. Rsch. ed., 1962) (explaining how market failures and information asymmetries limit private incentives to invest in innovation).

[108] Id.

[109] Jean Tirole, The Theory of Industrial Organization 392 (1988).

[110] Open Mkts. Inst., America's Concentration Crisis (2025), https://concentrationcrisis.openmarketsinstitute.org/ [https://perma.cc/HCM4-4QXP].

[111] Id.

[112] Id.; Press Release, Open Mkts. Inst., Open Markets Publishes Exclusive Concentration Data Exposing the Monopoly Problem in Health Care (June 10, 2019), https://www.openmarketsinstitute.org/publications/open-markets-publishes-exclusive-concentration-data-exposing-monopoly-problem-health-care [https://perma.cc/5P2Q-LNH2].

[113] Open Mkts Inst., supra note 110; see also Phillip Longman, Opinion, How Big Medicine Can Ruin Medicare for All, The Guardian (Nov. 1, 2017, 7:11 AM), https://www.theguardian.com/commentisfree/2017/oct/28/big-medicine-monopoly-medicare-for-all [https://perma.cc/4AVT-9ZYR] (suggesting that the negative effects of a monopolized health system will cripple even a socialist model of health care); see also Robert Pearl, U.S. Healthcare: A Conglomerate of Monopolies, Forbes (Feb. 9, 2023, 11:49 AM), https://www.forbes.com/sites/robertpearl/2023/01/16/us-healthcare-a-conglomerate-of-monopolies/ (exploring a hospital-centered solution to the problem posed by raised prices and diminished quality, which was caused by the existing monopolies of health care).

insulin concluded that "Congress needs to find ways to increase the number of drug manufacturers who are making insulin available to consumers."[114]

More competition on the manufacturing side is unquestionably an important factor in tackling high drug costs. Important interventions on the patent and drug approval fronts are necessary. Nevertheless, the problem of the high cost of insulin and other drugs does not stem solely from the market concentration in the manufacturing industry. A closer study reveals a more complex source of the illness: the inscrutable structures of the market, along with opaque and ever-shifting tactics among different dominant actors along the pharmaceutical supply chain.[115] The following Sections examine the pharmaceutical industry and the deals struck between manufacturers and PBMs.

B. The Distributors: PBMs and the Formulary Blackbox

"[PBMs and other d]rug middlemen function at the center of the pharmaceutical supply chain and have virtually unparalleled power to affect drug costs, acting as intermediaries between insurers, manufacturers, and pharmacies."

- American Diabetes Association 2023 Letter to Congress[116]

The structure of the drug distribution market is complex and opaque. The distribution chain moves from manufacturers and wholesalers, through PBMs, insurance companies, doctors, hospitals, and pharmacies,

[114] Price of Insulin, Congresswoman Diana DeGette, https://degette.house.gov/issues/price-insulin [https://perma.cc/KNE2-5ZMJ] (last visited Oct. 8, 2025); see also Understanding Insulin Market Dynamics in Low- and Middle-Income Countries: Producers, Supply and Costs, IQVIA Inst. for Hum. Data Sci. 3 (2021), www.iqvia.com/insights/the-iqvia-institute/reports/understanding-insulin-market-dynamics-in-low-and-middle-income-countries [https://perma.cc/C2CM-8EA2] (stating that nineteen low- and middle-income countries in the sample depend on the three largest companies for more than ninety-five percent of their insulin supplies).

[115] See Herman & Kuo, supra note 94, at e26 ("Structural factors that contribute to higher insulin costs include limited flexibility for the federal government to negotiate drug prices and lack of transparency in negotiations with pharmacy benefit managers."); see also infra Section II.B.

[116] Press Release, Am. Diabetes Ass'n, American Diabetes Association Presses Congress to Act on Rebate Reform (Sept. 8, 2023), https://diabetes.org/sites/default/files/2023-10/ada_statement_-_rebate_reform.pdf [https://perma.cc/D7ED-96QY].

until it reaches the end consumers—the patients.[117] PBMs—the powerful middlemen—act as administrators of prescription drug benefits for insurers, employers, and government programs. PBMs primarily serve three functions: (1) negotiating drug prices with manufacturers; (2) creating formularies, which are tiered lists that determine which drugs are covered by health plans; and (3) contracting with pharmacies on the selling of the drugs.[118] These three functions are interrelated—in price

[117] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 6–7.

[118] Id. For further discussion on the breadth of the problem created by this middleman role, see José R. Guardado, Am. Med. Ass'n, Competition in PBM Markets and Vertical Integration of Insurers with PBMs: 2024 Update 1 (2024), https://www.ama-assn.org/system/files/prp-pbm-shares-hhi-2024.pdf [https://perma.cc/P8S8-RQGC] (providing data about PBMs' consolidation and market dominance); Kate Ho & Robin S. Lee, Contracting Over Pharmaceutical Formularies and Rebates 2 (Nat'l Bureau of Econ. Rsch., Working Paper No. 32790, 2024) (describing the negotiation and contracting of deals between PBMs and manufacturers); Luke Froeb & Mikhael Shor, Formularies, Rebates, and the Economics of PBM Bargaining 2–5, 58–59 (May 8, 2023) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4442064 [https://perma.cc/VM75-2DB4] (analyzing how the bargaining dynamics between pharmaceuticals and PBMs affect placements on formularies); Casey B. Mulligan, Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences 18, 51 (Nat'l Bureau of Econ. Rsch., Working Paper No. 30998, 2023) (using quantitative models to predict the effects of regulatory interventions to limit PBM dealings); Kevin A. Schulman & Matan Dabora, The Relationship Between Pharmacy Benefit Managers (PBMs) and the Cost of Therapies in the US Pharmaceutical Market: A Policy Primer for Clinicians, 206 Am. Heart J. 113, 113–15 (2018) (explaining PBM business practices and their influence on therapeutic costs from a clinical policy perspective); James C. Robinson, Pharmacy Benefit Management: The Cost of Drug Price Rebates, 51 J.L. Med. & Ethics 52, 52–54 (2023) [hereinafter Robinson, Pharmacy Benefit Management] (arguing that PBM practices inflate the costs of drugs); Robin Feldman, Drugs, Money, and Secret Handshakes: The Unstoppable Growth of Prescription Drug Prices 2–3, 16–17, 19 (2019) (detailing the opacity of PBM rebate arrangements and the effect they have on pharmaceutical pricing); Karen Van Nuys, Rocio Ribero, Martha Ryan & Neeraj Sood, Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans from 2014 to 2018, JAMA Health F., Nov. 5, 2021, at 1, 3 (finding that in the distribution of insulin expenditures between 2014 and 2018, the list price of insulin increased, and the net price received by manufacturers decreased); Sheila R. Shulman, Pharmacy Benefit Management Companies (PBMs): Why Should We Be Interested?, 14 Pharmacoeconomics 49, 50 (Supp. 1 1998) (describing the role of PBMs in managing formularies and containing costs); Richard Dolinar, Christine G. Kohn, Frank Lavernia & Elaine Nguyen, The Non-Medical Switching of Prescription Medications, 131 Postgraduate Med. 335, 338–39 (2019) (discussing nonmedical switching—aimed to reduce costs—in the United States, taking into account the different parties involved, such as patients, healthcare providers, pharmacists, payers, and pharmacy benefit managers); Mark Meador, Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation, 20 Annals Health L. 77, 109–11 (2011) (calling for legislation to eliminate underhanded dealing in the PBM industry and lower the cost of prescription drugs); Elizabeth Seeley & Aaron S. Kesselheim, Commonwealth Fund,

negotiations, PBMs leverage their large customer bases to secure rebates and discounts from manufacturers.[119] Such rebates are often tied to a drug's placement on a formulary.[120] PBMs then select preferred pharmacies to which they steer patients, charge additional brokerage fees, and maximize their profits on affiliated pharmacies.[121] In effect, as described in detail below, PBMs generate billions of dollars in revenue through these deals and practices by squeezing other parties in the supply chain.

While the intermediary role of PBMs flew under the radar for a long time, it is increasingly becoming the subject of public scrutiny.[122] Ironically, the original idea behind and justification for PBMs was that they would negotiate with both drug manufacturers and pharmacies to help control spending and reduce the overall cost of drug purchases.[123] When PBMs first began to operate in the 1960s, they exercised a rather

Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead 3–4 (2019), https://www.commonwealthfund.org/sites/default/files/2019-03/Seeley_pharmacy_benefit_managers_ib_v2.pdf [https://perma.cc/4CNW-Y298] (finding that PBMs' use of rebates has contributed to high pharmaceutical prices, but arguing that passing the rebate through to payers or patients will not on its own reduce overall pharmaceutical spending without other policies that drive toward value); Neeraj Sood, Rocio Ribero, Martha Ryan & Karen Van Nuys, USC Schaeffer Ctr. for Health Pol'y & Econ., The Association Between Drug Rebates and List Prices 3 (2020), https://schaeffer.usc.edu/wp-content/uploads/2024/10/SchaefferCenter_RebatesListPrices_WhitePaper-1.pdf [https://perma.cc/9EXE-GZ3C] (finding that rebates play a role in increasing list prices and that reducing or eliminating rebates could lower list prices); Kevin A. Schulman & Barak D. Richman, The Evolving Pharmaceutical Benefits Market, 319 JAMA 2269, 2269 (2018) (describing the striking rise in the wealth and profit of PBMs); Barak D. Richman & Eli Y. Adashi, Pharmacy Benefit Managers and the Federal Trade Commission: A Relationship Gone Sour, 329 JAMA 367, 367 (2023) (providing a brief history of PBMs and their influence on the prescription drug distribution system).

[119] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 25 ("The largest PBMs have significantly more leverage when negotiating rebates compared to smaller PBMs and should be able to command higher rebates.").

[120] Dolinar et al., supra note 118, at 339.

[121] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 4, 11, 15–16.

[122] Dolinar et al., supra note 118, at 339.

[123] See PBM Policies and Their Impact on Drug and Device Costs, Am. Diabetes Ass'n, https://diabetes.org/tools-resources/managing-diabetes-costs/pbm-policies-and-their-impact-drug-and-device-costs [https://perma.cc/86AX-X39B] (last visited Oct. 8, 2025) (explaining how PBMs now often contribute to higher prices through opaque rebate structures); see also Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan & Nathan Wilson, PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied Against Pharmacy Benefit Managers 1–6, 141 (2025) (on file with author) (arguing that PBMs actually do contain the cost of prescription drugs); Robin J. Strongin, Issue Brief No. 749: The ABCs of PBMs, Nat'l Health Pol'y F., Oct. 27, 1999, at 1, 2.

passive role of processing prescription drug claims.[124] Today, proponents of PBMs continue to claim that they reduce overall drug costs and enhance consumer welfare.[125] Empirical evidence, however, reveals their perverse incentives to increase costs.[126] A 2024 congressional report on PBMs concluded that rather than improving patient care and access, PBMs result in "patients . . . seeing significantly higher costs with fewer choices and worse care."[127]

Like the pharmaceutical industry itself, the PBM market is highly concentrated. The three largest PBMs are CVS Caremark, Express Scripts, and Optum Rx—owned by CVS, UnitedHealth Group, and Cigna, respectively—and they dominate approximately eighty percent of the prescription drug market.[128] The largest six PBMs collectively control

[124] See Strongin, supra note 123, at 2, 4–7 (providing an overview of the functions of PBMs).

[125] See, e.g., Tony Lo Sasso, The Case of PBMs, Regul., Winter 2024–2025, at 31, 31 ("PBMs demonstrate the indispensable role of intermediaries in healthcare, balancing cost containment with access to essential medications.").

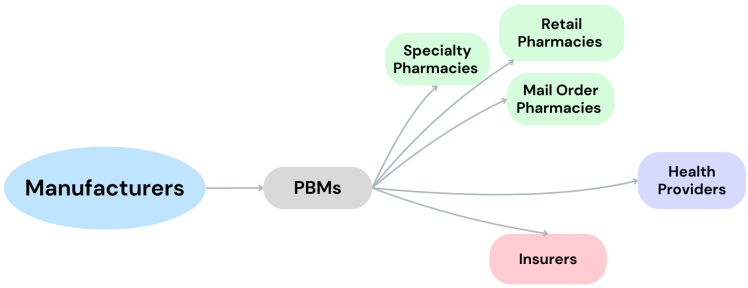
[126] See, e.g., Leemore Dafny, Christopher Ody & Matt Schmitt, When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization, 9 Am. Econ. J. 91, 92–93 (2017) (exploring how the use of copay coupons by drug manufacturers incentivizes PBMs to drive up premiums); David Dranove & Lawton R. Burns, Big Med: Megaproviders and the High Cost of Health Care in America 212 (2021) ("When drug coverage is divorced from medical coverage, . . . pharmacy benefit managers (PBMs) may have less incentive to promote substitution toward expensive drugs . . . . The result is a formulary that reduces drug costs but raises overall treatment costs.").

[127] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 3 (emphasis omitted); see also U.S. Gov't Accountability Off., GAO-23-105270, Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending 1, 18 (2023) (finding that the use of medical rebates by plan sponsors or PBMs may lead them to promote more costly drugs over lower cost alternatives); U.S. Gov't Accountability Off., GAO-19-498, Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization 7, 27 (2019) [hereinafter GAO-19-498] (finding that utilization services provided by a PBM or other entity resulted in financial savings but may have had effects on medication adherence and access to drugs).

[128] Guardado, supra note 118, at 8, 16 (reporting that CVS Health is the largest PBM (21.3% national market share), followed by Optum Rx (20.8% national market share), and Express Scripts (17.1% national market share)); Press Release, U.S. Senate Comm. on Com., Sci. & Transp., FTC Sues Pharmacy Benefit Managers for Inflating Insulin Prices (Sept. 20, 2024), https://www.commerce.senate.gov/2024/9/ftc-sues-pharmacy-benefit-managers-for-inflating-insulin-prices [https://perma.cc/J557-AJH9] (noting that "just three PBMs control nearly 80 percent of the entire prescription drug market"); The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II: Not What the Doctor Ordered: Hearing Before the H. Comm. on Oversight & Accountability, 118th Cong. 1 (2023) [hereinafter The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II Hearing] (statement of Rep. James Comer, Chairman, H. Comm. on Oversight & Accountability) ("Instead of fierce competition, now just three PBMs control 80 percent of the market, and each of the three

ninety-six percent of the market.[129] In 2021, Congress issued a report warning against the consolidation of PBMs.[130] In law and economics, this consolidation of major players in a single industry is termed *horizontal integration*. Consolidation across the different industries along the consumer supply chain is termed *vertical integration*. Vertical integration exacerbates conflicts of interest and barriers to market entry for competitors. In the case of PBMs, we witness both. In effect, each PBM is owned by a major health insurer and owns or is owned by a retail pharmacy chain, specialty pharmacy, healthcare provider, or medical clinic.

Figure I. Chains of Drug Delivery



As the House Committee on Oversight and Accountability puts it, "CVS Health Corporation, a healthcare company, owns . . . CVS Caremark, a PBM, CVS Pharmacy, a retail pharmacy chain, and CVS Specialty, a specialty pharmacy."[131] In 2018, CVS acquired Aetna, a

major PBMs—CVS Caremark, Express Scripts, and Optum Rx[—]is owned by a major health insurer and is owned by a pharmacy.").

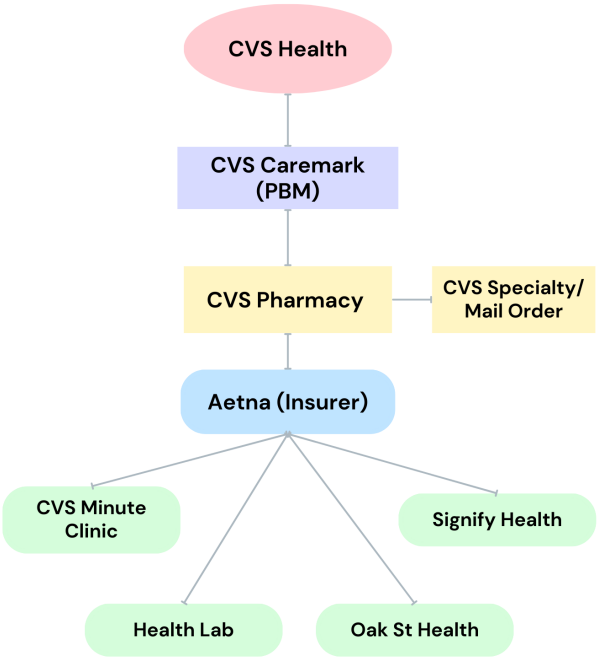
[129] Paige Twenter, Top PBMs by 2022 Market Share, Becker's Hosp. Rev. (May 23, 2023), https://www.beckershospitalreview.com/pharmacy/top-pbms-by-2022-market-share/ [https://perma.cc/4W2Q-SYHP].

[130] Minority Staff of H. Comm. on Oversight & Reform, 117th Cong., A View from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets 4, 6–7, 10–11 (Comm. Print 2021).

[131] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 9; see also CVS Health, 2024 Annual Report 1–2 (2025), https://s206.q4cdn.com/752775519/files/doc_financials/2024/ar/CVS-Health-2024-Annual-Report.pdf [https://perma.cc/7PXS-LHWH] (noting CVS ownership of CVS Caremark, CVS Pharmacy, and CVS Specialty).

health insurer.[132] As the largest PBM, a retail pharmacy chain, and a healthcare insurer, CVS thus occupies multiple levels of the distribution system, creating opportunities for leveraging market power in ways that, as Part IV describes, traditional antitrust frameworks struggle to address.

Figure II. Vertical Integration of the PBM Market-CVS Conglomerate



Similarly, Cigna, a healthcare company, owns Express Scripts, a PBM, and Express Scripts Pharmacy, a mail-order pharmacy.[133] UnitedHealth Group, a healthcare company, owns Optum Rx, a PBM, and an Optum

[132] CVS Health Completes Acquisition of Aetna, Marking Start of Transforming Consumer Health Experience, CVS Health (Nov. 28, 2018), https://www.cvshealth.com/news/company-news/cvs-health-completes-acquisition-of-aetna-marking-start-of.html [https://perma.cc/75MQ-LT5G].

[133] Cigna Group, 2024 Annual Report: Purpose & Performance 99 (2025), https://s202.q4cdn.com/757723766/files/doc_financials/2024/ar/2024-Annual-Report.pdf [https://perma.cc/9ZST-FB49].

Specialty Pharmacy.[134] In the supply chain of pharmaceutical drugs, the three dominant PBMs are most often "either negotiating with themselves or one of their direct competitors."[135]

Like the shape of the market, characterized by horizontal and vertical integrations, anticompetitive deals or strategies between entities are generally classified as either *horizontal restraints* or *vertical restraints*, depending on the nature of the relationship between the parties. PBMs actively create both horizontal and vertical restraints in the pharmaceutical supply chain. Horizontal restraints occur between two or more independent entities that are actual or potential competitors within the same market level. These restraints often involve practices designed to limit competition directly, such as price-fixing, agreements to restrict production or output, and the allocation of specific geographic territories to reduce competitive overlap.[136] As aforementioned, this includes the practice of shadow pricing among insulin manufacturers, which involves raising prices in tandem. Such practices aim to control market dynamics and undermine the benefits of competition for consumers, often in direct violation of antitrust law. Vertical restraints operate within the framework of a supply chain and involve parties at different levels of production, distribution, or sales—from the manufacturer to intermediaries and, ultimately, the end-user. As explained in the following two Sections, these practices may be designed to exert control over downstream or upstream markets with the aim of ensuring dominance and profit maximization. Such practices risk reducing consumer choice and inflating prices.

[134] UnitedHealth Group, Annual Report (Form 10-K), at 1 (Feb. 27, 2025).

[135] The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II Hearing, supra note 128, at 1 (statement of Rep. James Comer, Chairman, H. Comm. on Oversight & Accountability).

[136] See Louis Kaplow, An Economic Approach to Price Fixing, 77 Antitrust L.J. 343, 343–62, 388–94 (2011) (discussing price-fixing and output restrictions); Market Division or Customer Allocation, Fed. Trade Comm'n, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/dealings-competitors/market-division-or-customer-allocation [https://perma.cc/D3WA-DNRH] (last visited Oct. 8, 2025) (describing the anticompetitive nature of territorial allocation practices).

C. Pushing the Limits: Closed Formularies and Rebate Walls

"The drug formulary is a giant black box."

- Robert Galvin and Roger Longman, *Harvard Business Review*[137]

For years, PBMs included nearly all available drugs in the formularies.[138] However, a decade ago, PBMs began excluding a large and growing number of drugs.[139] In the early 2010s, PBMs became bolder, devising formularies that excluded clinically effective drugs from coverage. Termed restrictive, "closed," or "exclusionary" formularies, this system created a very real threat for manufacturers: their drug might be marked off the list of approved drugs for coverage if they did not cooperate with greedy demands by the PBMs.[140] CVS's Caremark became the first PBM to integrate these formulary exclusions.[141] In 2012, it suddenly excluded Eli Lilly's Humalog, keeping only the identical

[137] Robert Galvin & Roger Longman, We Need More Transparency on the Cost of Specialty Drugs, Harv. Bus. Rev. (Nov. 4, 2014), https://hbr.org/2014/11/we-need-more-transparency-on-the-cost-of-specialty-drugs.

[138] See Adam J. Fein, The Big Three PBMs' 2025 Formulary Exclusions: Humira, Stelara, Private Labels, and the Shaky Future for Pharmacy Biosimilars, Drug Channels Inst. (Jan. 22, 2025), https://www.drugchannels.net/2025/01/the-big-three-pbms-2025-formulary.html [https://perma.cc/983Y-Y2TX] ("Since 2012, the number of unique products excluded from the formularies of the three largest PBMs—Caremark (CVS Health), Express Scripts (Cigna), and Optum Rx (UnitedHealth Group)—has grown dramatically.").

[139] See Majority Staff of H. Comm. on Oversight & Reform, 117th Cong., Drug Pricing Investigation 119, 121, 123 (Comm. Print 2021) (reporting on the Committee on Oversight and Reform's three-year investigation of drug pricing, which included a review of more than 1.5 million pages of documents, such as internal strategy documents, communications among top executives, board materials, and nonpublic pricing data).

[140] Id. at 59 n.228, 108, 119; see also Staff of H. Comm. on Oversight & Accountability, supra note 85, at 31–32 ("Drug manufacturers are increasing drug list prices to satisfy PBMs' demands for higher rebates. New generic drugs are experiencing historically slow adoption by patients directly resulting from PBM coverage decisions to prefer higher priced drugs with high rebates over lower list price drugs." (footnote omitted)).

[141] See Larry Blandford & Andrew Cournoyer, Formulary Exclusion Lists Create Challenges for Pharma and Payers Alike, J. Clinical Pathways (Oct. 2016), https://www.hmpgloballearningnetwork.com/site/jcp/article/formulary-exclusion-lists-create-challenges-pharma-and-payers-alike [https://perma.cc/FQ47-EFVY] ("[W]hen CVS first published its exclusion list in 2012, it contained 38 drugs across 18 therapeutic classes."); Adam J. Fein, Here Come the 2016 PBM Formulary Exclusion Lists!, Drug Channels Inst. (Aug. 4, 2015), https://www.drugchannels.net/2015/08/here-come-2016-pbm-formulary-exclusion.html [https://perma.cc/KXF4-4V9U].

competitor—Novo's Novolog.[142] The PBMs each selected favorites among the clinically interchangeable insulin competitors and excluded the others.[143] Not coincidentally, the price of insulin began to dramatically rise with the introduction of closed formularies.[144]

PBMs negotiate rebates with drug manufacturers by giving a manufacturer's drug a preferred or exclusive status on the formulary. Since the introduction of closed formularies, the pharmaceutical companies have had to accept demands for fast-growing rebates in exchange for spots on the formulary lists. The rebates paid to PBMs are normally a percentage of a drug's list price, which drives the drugmakers to increase the list prices, such that the PBM will receive a higher rebate. For over eight decades, insulin was sold at affordable prices. In 1996, Humalog cost payers twenty-one dollars.[145] The advent of formulary exclusivity as a practice drove exponential growth in drug prices.[146] Moreover, the practice of bestowing preferred formulary status on

[142] FTC Complaint, supra note 20, ¶¶ 139–42 (describing clinically identical products of Lilly, Novo, and Sanofi that were not included because of their lower prices); see also Adam J. Fein, Five Takeaways from the Big Three PBMs' 2022 Formulary Exclusions, Drug Channels Inst. (Jan. 19, 2022), https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html [https://perma.cc/F742-MU5B] ("Express Scripts and OptumRx are aligned with Eli Lilly's Humalog and Humulin, but exclude Novo Nordisk's NovoLog and Novolin. By contrast, CVS Health's formulary excludes Lilly's insulins in favor of Novo Nordisk's products.").

[143] See Christine Simmon, Ass'n for Accessible Meds., Biosimilars Council, Comment Letter on Proposed Rule Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products 2, 5 (May 31, 2019), https://www.regulations.gov/comment/FDA-2019-N-1132-0326 [https://perma.cc/HPL8-45EQ] (stating that the insulin products of Novo and Eli Lilly—Novolog and Fiasp—for example, are functionally interchangeable). As the Association for Accessible Medicines ("AAM") explains, brand-to-brand alternations of insulin are common, with the risk of diminished safety or efficacy from a transition being "minimal or not present." Id. at 5; see also FTC Complaint, supra note 20, ¶¶ 110–11 (noting that "[i]nsulin products within the rapid-acting class are generally considered clinically substitutable" and "insulin products within the long-acting class are generally considered clinically interchangeable").

[144] Sisco & Gardner, supra note 101; see also FTC Complaint, supra note 20, ¶¶ 119–31.

[145] Mary Caffrey, Lilly to Launch Half-Price Version of Humalog, Am. J. of Managed Care (Mar. 4, 2019), https://www.ajmc.com/view/lilly-to-launch-halfprice-version-of-humalog [https://perma.cc/42QA-3DQS].

[146] Id.; see also Cencora, Persistent Growth in PBM Formulary Exclusions Continues to Raise Concerns About Patient Access 8 (2025), https://cdn.aglty.io/phrma/global/resources/import/pdfs/Report%20-%20Persistent%20Growth%20in%20PBM%20Formulary%20-%20August%202025.pdf [https://perma.cc/48QE-ACE4] (noting that PBMs' exclusion of generics and biosimilars has "increasingly shifted healthcare costs onto patients"); Staff of H. Comm. on Oversight & Accountability, supra note 85, at 31 (linking exclusionary formularies to higher patient costs).

expensive brand-name drugs, rather than on affordable generics or biosimilars, has expanded beyond just the insulin drug market.[147] From 2019 to 2020, Caremark and Express Scripts excluded 109 and 54 more drugs, respectively.[148] A 2024 FTC investigation found direct evidence that the level of rebates agreed upon hinged on whether the PBMs promised to exclude a competitor's drug from the formulary.[149]

PBMs negotiate these confidential deals for post-sale discounts—or rebates—with the drug manufacturers, and the PBM receives the rebate.[150] Importantly, the rebate contracts do not require the PBMs to pass the rebate to the consumers, and indeed, most of the time, they do not.[151] Rather, patients pay the deductibles and coinsurance based on the medicine's undiscounted list price.[152] In both May and September of 2023, the House Committee on Oversight and Accountability held hearings to discuss how PBMs have created a monopoly in the pharmaceutical marketplace, driving up the cost of prescriptions.[153] The Committee found that insulin was one of the lead drugs that PBMs chose to skyrocket in price.[154] The congressional report found that insulin has a

[147] See AAM and the Biosimilars Council Statement on UnitedHealthcare Announcement to Reverse Course on Biosimilars, Biosimilars Council (May 30, 2019), https://biosimilarscouncil.org/news/statement-reverse-course-biosimilars/ [https://perma.cc/RZ2Z-M238] (explaining that preferred formulary status for brand-name drugs "jeopardize[s] patient access and savings"); Caleb J. Scheckel & S. Vincent Rajkumar, Generics and Biosimilars: Barriers and Opportunities, 96 Mayo Clinic Procs. 2947, 2949–50 (2021).

[148] FTC Complaint, supra note 20, ¶ 114.

[149] Id. ¶ 118.

[150] Christopher Cai & Benjamin N. Rome, Reforming Pharmacy Benefit Managers—A Review of Bipartisan Legislation, 389 NEJM 1640, 1640 (2023) ("Rather than negotiating prices directly, PBMs typically arrange confidential rebates that are provided by manufacturers after patients fill prescriptions.").

[151] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 7, 42 (noting that "PBMs may keep portions of manufacturer rebates as a form of compensation" and that "patient out-of-pocket costs typically do not reflect rebates that are paid directly from drug manufacturers to PBMs").

[152] FTC Complaint, supra note 20, ¶ 6.

[153] Press Release, H. Comm. on Oversight & Accountability, Hearing Wrap Up: Pharmacy Benefit Managers Push Anticompetitive Drug Pricing Tactics to Line Their Own Pockets (Sept. 19, 2023), https://oversight.house.gov/release/hearing-wrap-up-pharmacy-benefit-managers-push-anticompetitive-drug-pricing-tactics-to-line-their-own-pockets [https://perma.cc/4JWG-L67E].

[154] See Staff of H. Comm. on Oversight & Accountability, supra note 85, at 26.

rebate of eighty-four percent, and that none of it is reimbursed to the patients.[155] Patients are charged the full list price.[156]

State-focused inquiry has yielded similar results. For instance, Texas is unique in that it has a mandatory requirement of annual reports on rebates, fees, and other payments.[157] A 2023 Texas investigation found that PBMs operating in the state did not pass the rebates on to patients. Of the $2.12 billion in manufacturer rebates, $91 million was kept as revenue, and $2.07 billion was passed on to health insurers, frequently owned by the PBMs, while only $15 million was received by patients.[158] A 2021 Senate report on insulin describes how PBM-manufacturer rebate

[155] Id. (quoting The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II Hearing, supra note 128, at 36–37 (statement of Lori Reilly, Chief Operating Officer, Pharm. Rsch. & Mfrs. of Am.)).

[156] The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II Hearing, supra note 128, at 36 (statement of Lori Reilly, Chief Operating Officer, Pharm. Rsch. & Mfrs. of Am.). In May 2023, Congress held an additional hearing about PBMs. The three largest PBMs testified that they pass on ninety-five to ninety-eight percent of the rebates they receive from drug companies to the payers. See, e.g., The Need to Make Insulin Affordable for All Americans: Hearing Before the S. Comm. on Health, Educ., Lab. & Pensions, 118th Cong. 29, 32, 60 (2023) (statements of David Joyner, CVS Health, Adam Kautzner, Express Scripts & Heather Cianfrocco, Optum Rx). These percentages are called into question, however, by other evidence suggesting that PBMs keep a much larger percentage to themselves. See T. Joseph Mattingly II, David A. Hyman & Ge Bai, Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy, JAMA Health F., Nov. 3, 2023, at 1, 5 (first citing GAO-19-498, supra note 127; and then citing Pew Charitable Trs., The Prescription Drug Landscape, Explored: A Look at Retail Pharmaceutical Spending from 2012 to 2016 (2019), https://www.pew.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored [https://perma.cc/Y9NU-E47P]).

[157] Texas has been able to provide unique insight into the role of PBMs in drug pricing because of the required annual reports on rebates, fees, and other financial arrangements. See Adam J. Fein, Texas Shows Us Where PBMs' Rebates Go, Drug Channels Inst. (Aug. 9, 2022), https://www.drugchannels.net/2022/08/texas-shows-us-where-pbms-rebates-go.html [https://perma.cc/VF5S-Y3RD]. One analysis of Texas data concluded that between 2016 and 2021, PBMs retained between 9% and 21% of pharmaceutical companies' total payments. Id. In the Texas analysis, only 0.2% of the rebates were shared directly with patients. Id. The Texas Department of Insurance found that the PBMs kept $409 million to themselves. Tex. Dep't of Ins., 2022 Prescription Drug Cost Transparency Review: Pharmacy Benefit Managers, https://www.tdi.texas.gov/reports/life/2022-pharmacy-benefit-managers.html [https://perma.cc/P7P6-JAUD] (last updated May 31, 2024).

[158] Tex. Dep't of Ins., 2023 Prescription Drug Cost Transparency Review: Pharmacy Benefit Managers, https://www.tdi.texas.gov/reports/life/2023-pharmacy-benefit-managers.html [https://perma.cc/2E5Q-FMV8] (last updated May 31, 2024); see also Press Release, Am. Med. Ass'n, PBM Markets Are at Risk of Harming Patients (July 31, 2025), https://www.ama-assn.org/press-center/ama-press-releases/pbm-markets-are-risk-harming-patients [https://perma.cc/9M73-4TRA] ("At the national level, 77% of commercial and [Medicare] Part D enrollees were in a [prescription drug plan] where the insurer and PBM were vertically integrated.").

"contracts and subsequent amendments can stretch over hundreds of pages and cover multiple therapies offered by a manufacturer. The base contracts and subsequent amendments are updated frequently—sometimes multiple times a year . . . ."[159] As former Department of Justice ("DOJ") and FTC attorney David Balto testified before the Senate in 2022, "PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information. PBMs prevent payors from being able to audit rebate information."[160] As the Council of Economic Advisors observed, the PBM market lacks transparency, as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret."[161]

In 2024, the Congressional Oversight Committee on PBMs found that rather than prioritizing the formulary medications that impose lower costs on plans and patients, the PBMs prioritize their own financial benefit by placing a drug on a lower tier.[162] The Oversight Committee identified over three hundred examples of the three largest PBMs preferring medications that cost at least five hundred dollars per claim more than an identical competing drug excluded on their formulary.[163] The Oversight Committee

[159] Staff of S. Comm. on Fin., supra note 90, at 40.

[160] Ensuring Fairness and Transparency in the Market for Prescription Drugs: Hearing Before the Subcomm. on Consumer Prot., Prod. Safety & Data Sec. of the S. Comm. on Com., Sci. & Transp., 117th Cong. 5 (2022) (statement of David A. Balto).

[161] Council of Econ. Advisers, Exec. Off. of the President, Reforming Biopharmaceutical Pricing at Home and Abroad 10 (2018).

[162] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 27. Each PBM does have a process of evaluating existing and new drugs based on clinical efficacy, but after receiving independent evaluations from doctors and scientists, PBMs make economic decisions on the tier placement and employ other tools such as utilization management programs—including prior authorization, quantity limits, and step therapies—to ensure that the most lucrative drugs will be prioritized in the sales. Id. at 27–28. Typically, the clinical scientific evaluations are made public while the financial decisions remain secret. Id. For example, Optum Rx has the following process: First, its National Pharmacy and Therapeutics Committee, composed of professionals not employed by the conglomerate, independently evaluates drugs. Id. Their discussions and findings are open to the public. Id. After that first step, the Formulary Management Committee, an internal group, makes its decisions based on the financial effects of the formulary tiering. Id. at 28. This Committee's meetings are secret. Id. For further discussion on the economic decision-making of PBMs, see 46brooklyn, How PBMs Distort and Undermine Specialty Drug Pricing Guarantees (May 10, 2023), https://www.46brooklyn.com/research/2023/5/10/how-pbms-distort-and-undermine-specialty-drug-pricing-guarantees-blac [https://perma.cc/9D3H-7YYR].

[163] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 31 ("[T]he Committee found 300 examples . . . of the three largest PBMs preferring medications that cost at least $500 per claim more than the medication they excluded on their formulary.").

found that "PBMs often choose higher cost medications for their formularies costing patients more at the counter, employers more to subsidize their prescription drug plans, and taxpayers more for federal health care programs."[164] The Committee continued,

> While some of these decisions likely have valid clinical reasons, the sheer quantity and dramatic increase in costs highlight the priority of PBMs. In total, the Committee identified more than 1000 examples of medications that . . . would have been less expensive had the excluded medication been given preference or simply able to compete on a level playing field.[165]

The Committee estimated these practices to cost taxpayers billions per year in Medicare costs.[166] Similarly, a 2023 report from the Association for Accessible Medicines ("AAM") found that PBMs restrict patient access to lower-cost generic drugs, instead favoring higher-priced brand-name drugs that offer substantial rebates.[167] In sum, through the formulary / rebate deals, PBMs perversely favor the costliest drugs and exclude lower-cost drugs, generics, and biosimilars.

On top of the formulary tiers and exclusions linked to rebate deals, PBMs employ strategies like *prior authorization* and *step therapy*—or "*fail first*."[168] Step therapy forces patients to use drugs selected for the formulary first and fail on them before the prescribed treatment is

[164] Id.

[165] Id. Medical devices such as insulin pumps and syringes, as well as drugs, are similarly placed on tiered formularies. See Memorandum from Jennifer R. Shapiro, Acting Dir., Medicare Drug Benefit & C&D Data Grp., Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Hum. Servs., to All Part D Plan Sponsors (Jan. 5, 2018), www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Medical-Supplies-Associated-with-the-Injection-of-Insulin.pdf [https://perma.cc/6DQY-K9MK]; see also Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Hum. Servs., Medicare & You 2025, at 88 (2024) ("Covered insulin products are included on your plan's formulary.").

[166] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 40.

[167] Ass'n for Accessible Meds., Middlemen Increasingly Block Patient Access to New Generics 2 (2023), https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-Middlemen-Block-Patient-Access-New-Generics-2023-1.pdf [https://perma.cc/BUT3-QKZH]; see also Joanna Shepherd, Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs, 38 Yale L. & Pol'y Rev. 360, 377 (2020) (articulating PBMs' incentives to favor higher-priced drugs for formulary status).

[168] See Sheva J. Sanders & Jessica C. Wheeler, Trading Pain for Gain: Addressing Misaligned Interests in Prescription Drug Benefit Administration, 55 U. Mich. J.L. Reform 423, 431–44, 439 n.48 (2022) (explaining how requirements like prior authorization and step therapy increase costs to beneficiaries).

approved.[169] Prior authorization requires doctors to get PBM approval before a prescription is covered, which the American Medical Association ("AMA") warns can harm clinical outcomes.[170] Both strategies are designed to further entrench preferences for a select group of expensive drugs.

The opaque nature of pricing has also meant that different patients pay vastly different prices. *Spread pricing* is a tactic by which the PBM charges the payer—the insurers, employers, or government programs—more for a drug than they reimburse the pharmacy for dispensing it, keeping the difference as profit.[171] A simple example is a PBM that charges a health plan fifty dollars for a prescription, but reimburses the pharmacy thirty dollars for that same drug. The PBM retains the twenty-dollar "spread" as profit. This means that the payers' costs are artificially inflated above and beyond what the PBMs already have orchestrated with the formulary schemes; in turn, patients are charged higher insurance premiums or out-of-pocket costs, or their benefits eligibility is reduced to save costs.

[169] See Step Therapy, healthinsurance.org, https://www.healthinsurance.org/glossary/step-therapy/ [https://perma.cc/Y5WY-Z6N9] (last visited Oct. 9, 2025) ("If a health plan uses step therapy for certain drugs, it means that a patient can be required to try a lower cost prescription drug that treats a given condition before 'stepping up' to a similar-acting, but more expensive drug.").

[170] Aaron Tallent, Oncologists Say Prior Authorization Is Causing Delays in Care, Oncology News Cent. (Mar. 25, 2022), https://www.oncologynewscentral.com/conference-news/oncologists-say-prior-authorization-is-causing-delays-in-care [https://perma.cc/XU4T-94FX]; What Is Prior Authorization?, Cigna Healthcare, https://www.cigna.com/knowledge-center/what-is-prior-authorization [https://perma.cc/PWZ5-VWFF] (last visited Oct. 28, 2025); see also Kevin B. O'Reilly, 1 in 3 Doctors Has Seen Prior Auth Lead to Serious Adverse Event, Am. Med. Ass'n (Mar. 29, 2023), https://www.ama-assn.org/practice-management/prior-authorization/1-3-doctors-has-seen-prior-auth-lead-serious-adverse-event [https://perma.cc/HQA6-LFQA] (reporting on an AMA survey that found that prior authorization requirements lead to adverse events for patients).

[171] See Catherine Candisky, State Report: Pharmacy Middlemen Reap Millions from Tax-Funded Medicaid, Columbus Dispatch (June 21, 2018), https://stories.usatodaynetwork.com/sideeffects/state-report-pharmacy-middlemen-reap-millions-from-tax-funded-medicaid/ [https://perma.cc/P9B2-FELX] (reporting how PBMs bill taxpayers significantly more than what is actually paid to pharmacies); see also Robert I. Garis, Bartholomew E. Clark, Mark V. Siracuse & Michael C. Makoid, Examining the Value of Pharmacy Benefit Management Companies, 61 Am. J. Health-Sys. Pharmacy 81, 83 (2004) ("Spread pricing is a revenue source PBMs have used in recent years."); Dillon J. Patel, Neal Bhatia & Mark D. Kaufmann, The Impact of Pharmacy Benefit Managers on Drug Pricing, 19 J. Drugs Dermatology 900, 900–01 (2020) (describing how the lack of transparency in pricing and the practice of spread pricing contribute to the high costs of drugs).

Spread pricing has been difficult to detect because of the opacity in pricing by PBMs. In 2018, the Ohio Attorney General investigated Centene—a healthcare conglomerate managing the state's Medicaid prescription drug program.[172] The Ohio Attorney General found that Centene engaged in spread pricing while managing the state's Medicaid prescription drug program, resulting in nearly $225 million in losses.[173] Ohio subsequently sued Centene, which agreed to a settlement of $88.3 million.[174] In the wake of the Ohio lawsuit, Centene has paid close to $1 billion across eighteen states for issues related to spread pricing practices.[175] Centene is not alone in its practices: an audit in Washington, D.C., found that PBMs retained $23.3 million in improper spread pricing from 2016 to 2019.[176] In 2022, Express Scripts agreed to pay $3.2 million to settle allegations that it overcharged Massachusetts's workers' compensation system for prescription drugs.[177] More recently, the 2024 congressional report of the Committee on Oversight and Accountability describes "numerous instances" of government and private contractors discovering that PBMs are overcharging the plans and payers, amounting to hundreds of millions of dollars.[178]

[172] Press Release, Dave Yost, Ohio Att'y Gen., Centene Agrees to Pay a Record $88.3 Million to Settle Ohio PBM Case Brought by AG Yost (June 14, 2021), https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-$88-3-Million-to-Se# [https://perma.cc/H92L-K7VK].

[173] Cara Young, The PBM Fire That Started in Ohio Is Spreading Across the States—and APhA Is Fanning the Flames, Am. Pharmacists Ass'n: CEO Blog (June 10, 2021), https://web.archive.org/web/20210616171614/https://www.pharmacist.com/CEO-Blog/the-pbm-fire-that-started-in-ohio-is-spreading-across-the-statesand-apha-is-fanning-the-flames-updated [https://perma.cc/S3RJ-B2LJ].

[174] Dave Yost, Ohio Att'y Gen., supra note 172.

[175] Andy Miller, Years Later, Centene Settlements with States Still Unfinished, KFF Health News (Mar. 5, 2025), https://kffhealthnews.org/news/article/centene-settlements-pbms-medicaid-silence-holdouts-georgia-florida/ [https://perma.cc/E5AG-EM2N].

[176] Off. of Inspector Gen., U.S. Dep't of Health & Hum. Servs., The District of Columbia Has Taken Significant Steps to Ensure Accountability over Amounts Managed Care Organizations Paid to Pharmacy Benefit Managers 3 (2023).

[177] Press Release, Maura Healey, Mass. Att'y Gen., Pharmacy Benefits Manager to Pay $3.2 Million for Alleged Failure to Follow Pricing Procedures for Workers' Compensation Prescriptions (Nov. 7, 2022), https://www.mass.gov/news/pharmacy-benefits-manager-to-pay-32-million-for-alleged-failure-to-follow-pricing-procedures-for-workers-compensation-prescriptions [https://perma.cc/56T5-JRMU].

[178] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 4.

Finally, PBMs make additional profits by charging fees from the various other actors. The fees are often labeled as administrative fees.[179] As one report describes,

> One way in which PBMs have driven up drug costs are with murky "direct and indirect remuneration" fees (DIR Fees) charged to providers who dispense drugs, such as retail and specialty pharmacies and physician-run medical practices that operate retail pharmacies or dispensing facilities . . . . DIR Fees charged by PBMs to Pharmacy Providers lack any reasonable transparency, threaten the viability of Pharmacy Providers, and, most importantly, increase the cost of drugs to Medicare and beneficiaries.[180]

For example, the PBM charges pharmacies "[p]erformance metric fees," which

> entail a PBM's review of a Pharmacy Provider's performance in a number of "quality metric" categories. . . . Based on the Pharmacy Provider's performance in these "quality metric categories," they are typically assessed a corresponding DIR Fee by the PBM, with lower performing Pharmacy Providers being assessed higher DIR Fees and better performing Pharmacy Providers being assessed lower DIR Fees . . . .[181]

PBMs also collect data fees from manufacturers, granting them information about the use of their drugs by patients.[182] Like with spread pricing, these fees are not uniform, and, as described in the following Section, PBMs impose higher fees on pharmacies that are not affiliated with them.

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[179] Regina Sharlow Johnson, PBMs: Ripe for Regulation, 57 Food & Drug L.J. 323, 333 (2002).

[180] Frier Levitt, LLC, PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues 2 (2017), https://www.frierlevitt.com/articles/service/pharmacylaw/white-paper-pbm-dir-fees-costing-medicare-beneficiaries-investigative-white-paper-background-cost-impact-legal-issues/.

[181] Id. at 13.

[182] See FTC Complaint, supra note 20, ¶¶ 47–48 (detailing the extraction of data fees from drug manufacturers by PBMs); see also PhRMA, Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines 3–4, 15 (2017); Purchaser Bus. Grp. on Health, Pharmacy Benefit Tactics Drive Up Drug Prices, Limit Access, Contribute to Health Risks 7 (2022).

D. Vertical Integration and Pharmacy Steering

"You know what PBM really stands for? It stands for Pretty Big Markups. We've got to stop this."

- Rep. Raja Krishnamoorthi (D-Ill.)[183]

The oligopolistic structure of PBM markets is compounded by their vertical integration; they each own pharmacies. PBMs profit from steering patients toward their affiliated pharmacies, including both retail and mail-order pharmacies, and away from nonaffiliated pharmacies. PBMs negotiate with pharmacies on reimbursement of drug costs according to how much they sell, and in turn, they offer pharmacies preferred status, promising to steer patients to that pharmacy. The structure and power of PBMs make it incredibly difficult for unaffiliated chains and independent community pharmacies to survive.[184] PBMs do not offer independent and unaffiliated chain pharmacies the same reimbursement rates, charging these smaller competitors higher fees.[185] Furthermore, spread pricing—the secrecy and clout exercised by PBMs over drug prices and the details of each contract they broker—makes it difficult for unaffiliated pharmacies to understand the terms of the deals and to determine how to plan for higher volumes in order to receive better negotiated pricing.

A 2024 analysis commissioned by the Washington State Pharmacy Association revealed that contrary to the PBMs' claims of cost savings, when PBMs steer patients to their affiliated mail-order pharmacies,

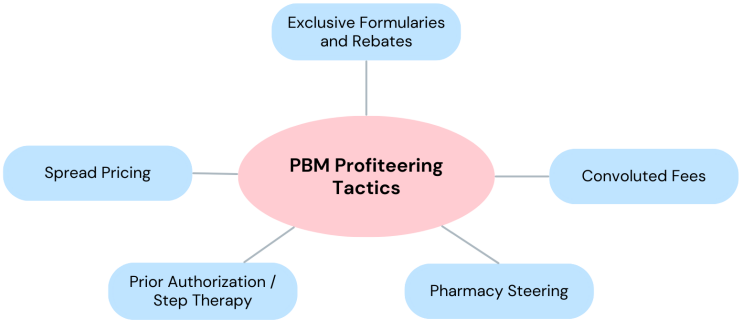
[183] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 14.

[184] See Stacy Mitchell & Zach Freed, How the FTC Protected the Market Power of Pharmacy Benefit Managers, ProMarket (Feb. 19, 2021), https://www.promarket.org/2021/02/19/ftc-market-power-pharmacy-benefit-managers/ [https://perma.cc/YBP2-DR3K] (describing PBMs as "highly concentrated" and "driving independent pharmacies out of the market").

[185] DIR Fees, Nat'l Ass'n of Chain Drug Stores, https://www.nacds.org/dir-fees [https://perma.cc/5STC-2KFR] (last visited Oct. 9, 2025); Andy Miller, PBM Math: Big Chains Are Paid $23.55 to Fill a Blood Pressure Rx. Small Drugstores? $1.51., KFF Health News (Oct. 24, 2024), https://kffhealthnews.org/news/article/pbm-pharmacy-benefit-managers-independent-drugstores-versus-big-chain-prices/ [https://perma.cc/7JDQ-GCXV]; Nat'l Cmty. Pharmacists Ass'n, The Truth About Pharmacy Benefit Managers: They Increase Costs and Restrict Patient Choice and Access, https://ncpa.org/sites/default/files/2020-09/ncpa-response-to-pcma-ads.pdf [https://perma.cc/G97P-RY5A] (last visited Oct. 9, 2025).

patients and providers end up with higher costs.[186] The review found that generic prescriptions filled via mail order were over three times more expensive, and branded drugs were three to six times costlier, than those filled at traditional pharmacies.[187] Branded drugs obtained through mail order were approximately thirty-five times more expensive than those filled at independent pharmacies.[188] Similarly, an audit of Florida's Medicaid managed care program uncovered that PBM-owned pharmacies charged significantly higher prices for specialty drugs than competing pharmacies did, highlighting the anticompetitive nature of PBM practices.[189] In sum, the shape of the market has led to a series of problematic tactics and perverse incentives along the pharmaceutical supply chain to inflate prices to the detriment of patients.

Figure III. PBM Profiteering Tactics



III. LEGISLATIVE REFORMS

Over the past few years, there has been an increasing amount of proposed legislation seeking to regulate insulin and PBMs. As of

[186] 3 Axis Advisors, Understanding Drug Pricing from Divergent Perspectives: State of Washington Prescription Drug Pricing Analysis 5 (2024), https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/667a03dc16a9fb18a1b13614/1719272422304/3AA_Washington_Report_20240620.pdf [https://perma.cc/2HVD-NWKT].

[187] Id. at 59.

[188] Id.

[189] 3 Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida. Medicaid Pharmacy Claims Analysis 124–30 (2020), https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf [https://perma.cc/2JJ3-YLYW].

September 9, 2025, there were fifteen bills introduced in the 119th U.S. Congress that mention PBMs.[190] A draft version of the now-enacted One Big Beautiful Bill contained reforms about PBMs, but that draft did not get passed by the Senate.[191] While none of them have advanced past the chamber where they started, six bills have been introduced in the Senate, and nine have been introduced in the House of Representatives.[192]

[190] As of September 2025, there are fifteen bills in the current session of the U.S. Congress that mention "pharmacy benefit manager." Six were introduced in the Senate and nine in the House of Representatives, and none have been engrossed in the chamber where they started to be able to get to the other chamber. See Congress.gov, "pharmacy benefit manager", 15 results (Sept. 9, 2025) (on file with the *Virginia Law Review*) (filtered by "Legislation", "119 (2025-2026)", "Bills (H.R. or S.)"), https://www.congress.gov/search?q=%7B%22congress%22%3A%5B%22119%22%5D%2C%22search%22%3A%22%5C%22pharmacy+benefit+manager%5C%22%22%2C%22source%22%3A%22legislation%22%2C%22type%22%3A%22bills%22%7D.

There were four proposed amendments from the Senate that would affect House and Senate concurrent resolutions. See Congress.gov, +"insulin" +"point of order", 4 results (Sept. 9, 2025) (on file with the *Virginia Law Review*) (filtered by "Legislation", "119 (2025-2026)"), https://www.congress.gov/search?q=%7B%22congress%22%3A%5B%22119%22%5D%2C%22search%22%3A%22%2B%5C%22insulin%5C%22+%2B%5C%22point+of+order%5C%22%22%2C%22source%22%3A%22legislation%22%7D. Two of the amendments would stop the Senate from considering any bill that increases the price of insulin by making it "not be in order in the Senate" to discuss such a bill. 171 Cong. Rec. S1249–50 (daily ed. Feb. 20, 2025) (statement of Sen. Jacky Rosen) (introducing S. Amdt. 850, 119th Cong. (2025)); id. at S1301 (statement of Sen. Jacky Rosen) (introducing S. Amdt. 1216, 119th Cong. (2025)).

There are ten bills (seven in the House and three in the Senate) that deal with limiting the price of insulin. See Congress.gov, "insulin", 10 results (Sept. 9, 2025) (on file with the *Virginia Law Review*) (filtered by "Legislation", "119 (2025-2026)", "Bills (H.R. or S.)"), https://www.congress.gov/search?q=%7B%22congress%22%3A%5B%22119%22%5D%2C%22search%22%3A%22%5C%22insulin%5C%22%22%2C%22source%22%3A%22legislation%22%2C%22type%22%3A%22bills%22%7D.

[191] Compare One Big Beautiful Bill Act, Pub. L. No. 119-21, 139 Stat. 72 (2025) (enacted with no use of "pharmacy benefit manager"), with One Big Beautiful Bill Act, H.R. 1, 119th Cong. (2025) (as placed on the Senate calendar, June 28, 2025) (containing "pharmacy benefit manager" forty-one times).

[192] Health Care PRICE Transparency Act, H.R. 267, 119th Cong. (2025); Medicaid Third Party Liability Act, H.R. 497, 119th Cong. (2025); Saving Seniors Money on Prescriptions Act, H.R. 950, 119th Cong. (2025); Pharmacy Benefit Manager Transparency Act of 2025, S. 526, 119th Cong. (2025); Prescription Pricing for the People Act of 2025, S. 527, 119th Cong. (2025); Lower Costs for Everyday Americans Act, H.R. 1768, 119th Cong. (2025); Patients Before Middlemen Act, S. 882, 119th Cong. (2025); Bipartisan Health Care Act, S. 891, 119th Cong. (2025); Protecting Pharmacies in Medicaid Act, S. 927, 119th Cong. (2025); DRUG Act, H.R. 2214, 119th Cong. (2025); Seniors' Access to Critical Medications Act of 2025, H.R. 2484, 119th Cong. (2025); One Big Beautiful Bill Act, H.R. 1 (enacted); PBM Reform Act of 2025, H.R. 4317, 119th Cong. (2025); Fair Pharmacies for Federal Employees Act of 2025, H.R. 4409, 119th Cong. (2025); Patients Deserve Price Tags Act, S. 2355, 119th Cong. (2025).

Additionally, there are two proposed amendments that would stop the Senate from considering any bill that increases the price of insulin.[193] Further, there are six bills—five in the House and one in the Senate—that seek to limit the price of insulin. Clearly, the accessibility of insulin is a large focus at the federal congressional level, and it is a priority for other parts of the government as well.

A. Patents and Generic Drug Entry Law Reforms

In 2021, President Biden's executive order on "Promoting Competition in the American Economy" called upon the FDA and the U.S. Patent and Trademark Office ("USPTO") to collaborate to increase competition and lower prices in the pharmaceutical marketplace.[194] The order directed the FDA and the USPTO to expedite the approval and availability of both generic and biosimilar drugs.[195] The order highlighted the phenomenon of product hopping, described in Section I.C, in which pharmaceutical companies use patents to strategically block competition in the marketplace.[196]

From a legal perspective, product hopping highlights the tension between encouraging pharmaceutical innovation and promoting market competition. While patent law aims to reward genuine innovation, the incremental nature of many product hops in the prescription drug industry raises questions about whether such modifications merit extended market exclusivity. According to one study, seventy-eight percent of drugs that were issued new patents in recent years were already on the market.[197] Essentially, product hopping often enables manufacturers to "evergreen" their patent exclusivity and market dominance, contravening the fundamental balance that patent law seeks to strike between incentivizing innovation and ensuring public access to affordable medicines.[198] In a

[193] 171 Cong. Rec. S1249–50 (statement of Sen. Jacky Rosen) (introducing S. Amdt. 850, 119th Cong. (2025)); id. at S1301 (statement of Sen. Jacky Rosen) (introducing S. Amdt. 1216, 119th Cong. (2025)).

[194] Exec. Order No. 14,036, 3 C.F.R. 609, 621–22 (2022). On August 13, 2025, President Trump revoked the executive order. See Exec. Order No. 14,337, 90 Fed. Reg. 40227 (Aug. 19, 2025).

[195] Exec. Order No. 14,036, 3 C.F.R. at 621.

[196] Id. at 610, 617.

[197] Robin Feldman, May Your Drug Price Be Evergreen, 5 J.L. & Biosciences 590, 597 (2018).

[198] See Michael S. Sinha, Unpatenting Product Hops, 15 U.C. Irvine L. Rev. (forthcoming 2025) (manuscript at 101, 136–39), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=475

2006 case, *Abbott Laboratories v. Teva Pharmaceuticals USA Inc.*, the defendant introduced a slightly reformulated product—a move from capsules to tablets—stopping the sale of the capsules product, which included buying back all supplies of capsules to prevent pharmacies from assigning generics to fill prescriptions for the drug.[199] The U.S. District Court for the District of Delaware ruled that when there is "anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by [the d]efendant[]."[200] Since then, courts have been increasingly willing to address the anticompetitive use of patent law through the practice of product hopping.

In a 2013 case, *Federal Trade Commission v. Actavis, Inc.*, the Supreme Court further explained that to achieve a proper balance between promoting public policy and preserving market competition, patent law must be examined through the lens of antitrust law.[201] Thereafter, the U.S. Court of Appeals for the Second Circuit, in *New York ex rel. Schneiderman v. Actavis PLC*, addressed the legality of product hopping in the pharmaceutical industry from an antitrust perspective.[202] The case established that certain forms of product hopping may constitute anticompetitive conduct under Section Two of the Sherman Act, particularly when accompanied by coercive switching strategies that effectively eliminate consumer choice.[203] Specifically, the discontinuation of a twice-daily drug formulation shortly before generic entry to the market, combined with the introduction of a new once-daily version of the drug, forced patients to switch to the new version of the drug with no evidence of material benefit.[204] The court found that the hard switch, depriving consumers of choice, was an act of consumer coercion

2093 [https://perma.cc/2842-RWJF] (arguing that by elevating patentability standards, the USPTO could mitigate product hopping through the rejection of weaker patents); M. Sean Royall, Ashley E. Johnson & Jason C. McKenney, Antitrust Scrutiny of Pharmaceutical "Product Hopping," 28 Antitrust 71, 72 (2013) (calling for caution in the application of antitrust law principles in relation to pharmaceutical innovation).

[199] Abbott Lab'ys v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006).

[200] Id. at 422.

[201] 570 U.S. 136, 153–59 (2013); see also DeForest McDuff, Mickey Ferri & Noah Brennan, Patents and Antitrust in the Pharmaceuticals Industry, 31 Competition J. 127, 134–44 (2021) (discussing antitrust lawsuits as an enforcement mechanism used to combat patent-based strategies and market-based strategies for extending patent life).

[202] 787 F.3d 638, 643 (2d Cir. 2015).

[203] Id. at 655; see also *Abbott Lab'ys*, 432 F. Supp. 2d at 431 (analyzing claims of anticompetitive product hopping in pharmaceuticals); In re Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 682–83 (E.D. Pa. 2014) (analyzing pharmaceutical generic delay tactics).

[204] *Actavis PLC*, 787 F.3d at 659.

used to improperly impede biosimilar competition, conferring no benefit to consumers.[205] Thus, such product hopping was deemed anticompetitive and unlawful.[206]

The timing of market entry of a new drug, specifically timing that coincides with patent expiration, can indicate an intent to stifle competition, thereby preventing consumer choice. A federal district court in *In re Asacol Antitrust Litigation* further refined this analysis by requiring material consumer benefits in the new formulation of a drug when product hopping is a concern, as well as looking deeper into the effect on market price and consumer access.[207] Still, *In re Asacol* clarifies that simply adding new products or variations of drug formulations to the market does not, on its own, amount to product hopping.[208] Other recent litigation has clarified that "hard switches"—ceasing production of the previous drug—are not the only unlawful means of product hopping.[209] In 2017, a federal district court found in *In re Suboxone Antitrust Litigation* that even a pharmaceutical company's disparagement of and threats to remove an old formulation may be unlawful.[210] The court emphasized that when a new drug, without substantial benefits over the old product, is introduced in an attempt to avoid the expiration of exclusivity—whether via patent protection or FDA regulation—and the company engages in coercion of healthcare professionals' prescription decisions or in a hard switch, it can constitute a violation of the Sherman Act.[211]

In 2024, the Senate unanimously passed the Affordable Prescriptions for Patients Act, which aids in lowering the costs of prescription drugs by limiting the number of patents that pharmaceutical companies may assert during litigation of individual products.[212] Federal actors have also taken

[205] Id. at 654–55.
[206] Id. at 655.
[207] 233 F. Supp. 3d 247, 267–70 (D. Mass. 2017).
[208] Id. at 270.
[209] See *Actavis PLC*, 787 F.3d at 654–55 (finding that product hopping impeded generic drugs); see also Mylan Pharms. Inc. v. Warner Chilcott Pub. Co., 838 F.3d 421, 429 (3d Cir. 2016) (distinguishing *Actavis PLC* and finding no antitrust violation where a new drug formulation was introduced to improve patient adherence and no monopolization occurred).
[210] 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014).
[211] Id.
[212] Affordable Prescriptions for Patients Act of 2023, S. 150, 118th Cong. (2024); see also New City Ins., Senate Unanimously Passes Bipartisan Pharma Patent Reform Bill (Sept. 9, 2024), https://newcityinsurance.com/senate-unanimously-passes-bipartisan-pharma-patent-reform-bill/ [https://perma.cc/K2ZN-NJSP].

action on the informational front. An important element of the product-hopping mess is the educational effort pharmaceutical companies have undertaken to market their products as superior to generics and bioequivalents.[213] In 2020, the FDA and FTC issued a joint statement to encourage competition and deter anticompetitive behaviors in the biologics market.[214] The agencies announced that they will police false and misleading statements that compare innovator biologics to biosimilars, as well as engage in educational and collaborative outreach to guide promotional materials, such that patients and healthcare professionals will not be misled.[215] In addition, the FDA was tasked with exploring ways in which prescription drugs can be safely imported from Canada to lower prescription drug prices, further promoting efforts to make drug pricing more transparent to consumers.[216]

Following President Biden's 2021 executive order,[217] the FDA also introduced the Drug Competition Action Plan and Biosimilars Action Plan, both of which provide efforts to improve the approval process for generic and biosimilar drugs, expand guidance for drug manufacturers to increase competition, and facilitate the development of state programs for drug importation.[218] These programs aim to encourage the efficiency and transparency of the drug approval process, aiding in timely market competition for generic drugs.[219]

[213] See Cynthia M. Ho, Biosimilar Bias: A Barrier to Addressing American Drug Costs, 99 Denv. L. Rev. 517, 521 (2022) (discussing how U.S. laws, industry actions, and cognitive biases work together to impede U.S. biosimilar use).

[214] Stephen M. Hahn & Joseph J. Simons, Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace (Feb. 3, 2020), https://www.ftc.gov/system/files/documents/public_statements/1565273/v190003fdaftcbiologicsstatement.pdf [https://perma.cc/AF7Q-GE5X].

[215] Id. at 4–5.

[216] Press Release, U.S. Food & Drug Admin., FDA Takes Steps to Enhance State Importation Programs to Help Lower Prescription Drug Prices (May 21, 2025), https://www.fda.gov/news-events/press-announcements/fda-takes-steps-enhance-state-importation-programs-help-lower-prescription-drug-prices [https://perma.cc/BFW9-A4J9].

[217] Exec. Order No. 14,036, 3 C.F.R. 609 (2022).

[218] See Biosimilars Action Plan, U.S. Food & Drug Admin., https://www.fda.gov/drugs/biosimilars/biosimilars-action-plan [https://perma.cc/NK7V-DVB7] (last visited Nov. 3, 2025); see also FDA Drug Competition Action Plan, U.S. Food & Drug Admin., https://www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan [https://perma.cc/QB2X-CCRM] (last visited Nov. 3, 2025).

[219] See Biosimilars Action Plan, supra note 218; FDA Drug Competition Action Plan, supra note 218.

In conjunction, the USPTO introduced initiatives to scrutinize patent applications more rigorously.[220] These initiatives focus on preventing excessive patent filings and engaging in discussions about policy changes aimed at reducing abuse in the pharmaceutical sector while simultaneously protecting innovation.[221] The USPTO has emphasized the need to preserve incentives for those who create original lifesaving drugs, as well as incentives for those who later enter the market with more affordable biosimilar drugs.[222] By lowering regulatory barriers to entry, encouraging generic and biosimilar development, and recalibrating existing patent protections, these reforms together can reduce the drug manufacturer market concentration and help lower prices.

B. Price Controls, Copayment Caps, and Cost Transparency

When drug prices are out of control, one direct and immediate legal solution is to mandate lower prices. Indeed, in recent years, numerous federal and state reforms establishing price controls and copayment caps have been enacted or proposed. As part of the Inflation Reduction Act of 2022, Congress implemented a monthly cap of thirty-five dollars on out-of-pocket costs for insulin for Medicare beneficiaries, effective on January 1, 2023.[223] For the broader population of patients not on Medicare, the Affordable Insulin Now Act, passed by the House in 2022, would cap insulin copays at thirty-five dollars per thirty-day supply for all insured patients.[224]

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[220] See FDA-USPTO Collaboration Initiatives, U.S. Food & Drug Admin., https://www.fda.gov/about-fda/reports/fda-uspto-collaboration-initiatives [https://perma.cc/52XA-9DVT] (last visited Nov. 18, 2025) (detailing USPTO initiatives established to enhance collaboration with the FDA).

[221] Id.

[222] Kathi Vidal & Robert M. Califf, The Biden Administration Is Acting to Promote Competition and Lower Drug Prices for All Americans, U.S. Pat. & Trademark Off. (July 6, 2022), https://www.uspto.gov/subscription-center/2022/biden-administration-acting-promote-competition-and-lower-drug-prices-all [https://perma.cc/6Z8C-7ZTK].

[223] See Sisco & Gardner, supra note 101; see also Sayed et al., supra note 15, at 1; Luhby, supra note 15; Ved, supra note 15, at 131 (reporting findings on cost savings since the Affordable Insulin Now Act was enacted).

[224] Affordable Insulin Now Act, S. 3700, 117th Cong. (2022); see also The Insulin Cap Bill Offers Hope for Americans with Diabetes, Phia Grp. (June 28, 2022), https://www.phiagroup.com/media/posts/the-insulin-cap-bill-offers-hope-for-americans-with-diabetes/ [https://perma.cc/7EZU-GQ4Z] (elaborating on the need for insulin legislation and detailing the potential benefits of the Affordable Insulin Now Act).

In May 2019, Colorado became the first state to pass a law limiting copayments for insulin to one hundred dollars for residents.[225] Since then, twenty-eight other states, plus the District of Columbia, have followed suit, with each implementing its own price-capping initiative to curb the high costs of insulin for taxpayers.[226] In 2023, Montana's governor signed and enacted into law legislation capping insulin prices at thirty-five dollars per thirty-day supply.[227] Illinois's insulin law caps the amount a patient would have to pay at one hundred dollars for a thirty-day insulin supply, provided the patient is covered by insurance.[228] In 2024, Ohio introduced a bipartisan bill that seeks to lower insulin costs by capping out-of-pocket costs for insulin and devices used in treating diabetes.[229] The legislation would cap costs for insulin at thirty-five dollars per month, with related devices such as test strips, syringes, and insulin pumps capped at one hundred dollars per month.[230] Unlike Ohio's proposed bill, many caps do not cover diabetes-related equipment.[231] As of 2025, twenty-nine states and the District of Columbia have enacted legislation to cap insulin copayments.[232]

The state law caps typically range from twenty-five dollars to one hundred dollars for a thirty-day supply, with variations in scope and applicability across states. Several states have also implemented emergency insulin programs to provide those facing financial hardships with short-term access to insulin. For example, Minnesota's Alec Smith

[225] See H.R. 19-1216, 72d Gen. Assemb., Reg. Sess. (Colo. 2019); Sarah Min, Colorado Becomes First State to Put Cap on Rising Insulin Prices, CBS News, https://www.cbsnews.com/news/colorado-caps-insulin-prices-colorado-becomes-first-state-to-cap-insulin-prices/ [https://perma.cc/J487-DE5T] (last updated May 28, 2019, 3:58 PM).

[226] See State Insulin Copay Caps, Am. Diabetes Ass'n, https://diabetes.org/tools-resources/affordable-insulin/state-insulin-copay-caps [https://perma.cc/J29L-E3SR] (last visited Nov. 21, 2025) ("[Twenty-nine] states plus the District of Columbia . . . have capped insulin copayments in state-regulated commercial health insurance plans.").

[227] Souers, supra note 23; Charlie Klepps, 'Not Every Day You Get to Save Lives:' Montanans Rejoice over Insulin Cap, KTVQ (Jan. 5, 2024, 11:37 AM), https://www.ktvq.com/news/local-news/not-every-day-you-get-to-save-lives-montanans-rejoice-over-insulin-cap [https://perma.cc/3QGP-XFLF]; see also Mont. Code Ann. § 33-22-312 (2023).

[228] Hulver, supra note 91, at 130.

[229] Marty Schladen, Bipartisan Ohio House Bill Seeks to Lower Insulin Costs, Ohio Cap. J. (Feb. 15, 2024, 4:55 AM), https://ohiocapitaljournal.com/2024/02/15/bipartisan-ohio-house-bill-seeks-to-lower-insulin-costs/ [https://perma.cc/4GWV-X3R3].

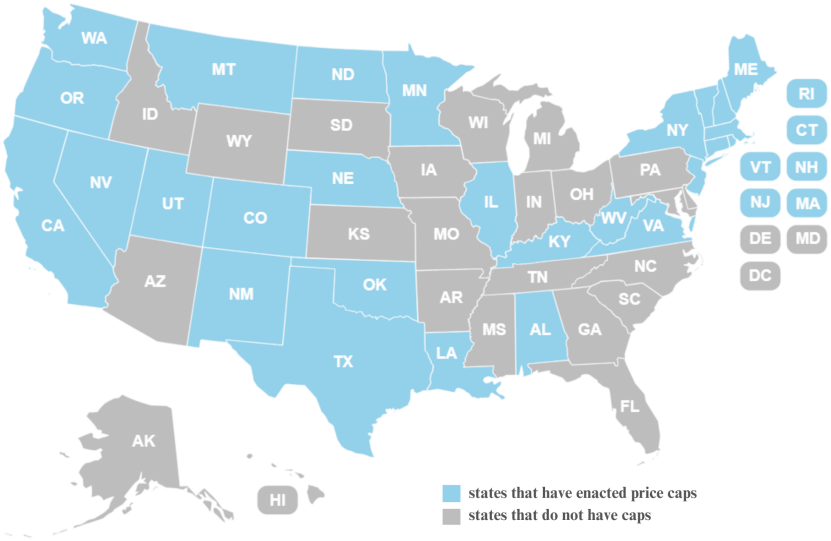
[230] Id.; H.B. 384, 135th Gen. Assemb., Reg. Sess. (Ohio 2024) (proposing caps on cost sharing for prescription insulin drugs and diabetes devices).

[231] Souers, supra note 23.

[232] See infra Table I; see also Hulver, supra note 91, at 125.

Insulin Affordability Act, named after a young man who died rationing his insulin due to cost, allows eligible Minnesotans to receive a thirty-day supply of insulin for a copay of thirty-five dollars in emergency situations.[233] Another prevalent reform, enacted in twenty-one states, the District of Columbia, and Puerto Rico, limits the out-of-pocket costs patients must pay for medications, by accounting for manufacturer rebates or coupons and passing those savings to consumers.[234]

Figure IV. Map of States (and D.C.) with Insulin Price Caps



[233] Press Release, Minn. House of Reps., Alec's Law Helps 465 Minnesotans Access Affordable Insulin (Mar. 11, 2021), https://www.house.mn.gov/Caucus/View/DFL/31433 [https://perma.cc/C6AB-48L3].

[234] Copayment Adjustment Programs, Nat'l Conf. of State Legislatures, https://www.ncsl.org/health/copayment-adjustment-programs/maptype/tile [https://perma.cc/BFJ4-TKR2] (last updated Dec. 10, 2024).

Table I. State Laws of Price Caps[235]

State	Title	Number of Days Supply	Price of Copay Cap	Status
Alabama	House Bill 249[236]	30	$100 cap	Effective (10/1/2021)
California	Senate Bill 40[237]	30	$35 cap	Enacted (10/13/2025)
Colorado	House Bill 19-1216[238]	30	$100 collective cap	Effective (1/1/2020)
Connecticut	House Bill 6003[239]	30	$25 cap, $100 cap for devices	Effective (1/1/2022)
Delaware	House Bill 263[240]	30	$100 collective cap	Enacted (7/16/2020)[241]
District of Columbia	D.C. Law 23-252[242]	30	$30 cap, $100 cap for devices	Enacted (1/11/2022)

[235] The bills listed in Table I are taken from several sources, including those listed in notes infra 236–68. Many of them are found in State Insulin Copay Caps, supra note 226.

[236] Press Release, Am. Diabetes Ass'n, American Diabetes Association Applauds Alabama Governor and State Legislature for Passing Bill to Cap Monthly Insulin Co-Pays (Apr. 21, 2021), https://diabetes.org/newsroom/ada-applauds-AL-gov-insulin-copays?utm_source= [https://perma.cc/D4JF-WWBG].

[237] S.B. 40, 2025–2026 Leg., Reg. Sess. (Cal. 2025).

[238] H.B. 19-1216, 72d Gen. Assemb., 2019 Reg. Sess. (Colo. 2020).

[239] H.B. 6003, 2020 Gen. Assemb., Spec. Sess. (Conn. 2020).

[240] Press Release, Am. Diabetes Ass'n, Delaware Governor Signs Law Capping Insulin Co-Pays at $100 for People with Diabetes (July 22, 2020), https://diabetes.org/newsrooms/delaware-governor-signs-law-capping-insulin-co-pays-at-100-for-people-with-diabetes?utm= [https://perma.cc/XZZ8-CDDK].

[241] H.B. 263, 150th Gen. Assemb., Reg. Sess. (Del. 2020).

[242] D.C. L. 23-252, Council Sess. (D.C. 2021).

Illinois	Senate Bill 667[243]	30	$35 collective cap	Effective (1/1/2021)
Kentucky	House Bill 95[244]	30	$30 cap	Effective (1/1/2022)
Louisiana	House Bill 677[245]	30	$75 cap	Effective (8/1/2022)
Maine	Legislative Document 2096[246]	30	$35 cap	Effective (1/1/2021)
Maryland	House Bill 1397[247]	30	$30 cap	Effective (1/1/2023)
Massachusetts	House Bill 4653[248]	30	$25 cap	Effective (7/1/2025)
Minnesota	The Alec Smith Insulin Affordability Act[249]	30	$25 cap	Enacted (4/15/2020)

[243] S.B. 667, 101st Gen. Assemb., Reg. Sess. (Ill. 2020); Peter Hancock, Pritzker Signs Bill Capping Insulin Costs, Capitol News Ill. (Jan. 25, 2020), https://capitolnewsillinois.com/news/pritzker-signs-bill-capping-insulin-costs/?utm [https://perma.cc/729K-FAXF].

[244] Press Release, Am. Diabetes Ass'n, American Diabetes Association Applauds Kentucky Governor and State Legislature for Passing Bill to Cap Monthly Insulin Co-Pays (Mar. 22, 2021), https://diabetes.org/newsroom/ada-applauds-KY-gov-insulin-copays [https://perma.cc/PCC3-BSS4].

[245] H.B. 677, 2022 Leg., Reg. Sess. (La. 2022).

[246] H.P. 1493, 129th Leg., 2d Reg. Sess. (Me. 2020).

[247] H.B. 1397, 2022 Leg., Reg. Sess. (Md. 2022).

[248] Anne M. Murphy, Stephanie Trunk & Aida Al-Akhdar, Massachusetts Enacts Drug Pricing Legislation: Introducing PBM Licensure, Mandatory Cost Reporting, and Consumer Cost-Sharing Limits, ArentFox Schiff (Feb. 27, 2025), https://www.afslaw.com/perspectives/health-care-counsel-blog/massachusetts-enacts-drug-pricing-legislation-introducing-pbm?utm_source [https://perma.cc/A7XZ-2TFY].

[249] Minnesota Insulin Safety Net Program, Minn. Bd. of Pharmacy, https://mn.gov/boards/pharmacy/public/lowercostmedications/insulinsafetynetprogram.jsp [https://perma.cc/N82E-PF9W] (last visited Oct. 9, 2025). Minnesota also has a state-required manufacturer assistance program, which is composed of two parts: urgent need and continuing need. The urgent need program is available to eligible individuals with less than a seven-day supply of insulin who will likely have serious health consequences if they run out. This program is only applicable for one thirty-day supply. The continuing need program is available to eligible individuals for one year, with the option to renew annually. This program is applicable for each ninety-day supply within the covered year. Id.

Montana	Senate Bill 340[250]	30	$35 cap	Effective (1/1/2024)
Nebraska	Legislative Bill 92[251]	30	$35 cap	Effective (1/1/2024)
Nevada	Assembly Bill 555[252]	30	$35 cap	Effective (10/1/2025)
New Hampshire	House Bill 1280[253]	30	$30 cap	Enacted (9/14/2020)
New Jersey	Senate Bill 1614[254]	30	$35 cap	Effective (1/1/2025)[255]
New Mexico	House Bill 292[256]	30	$25 cap	Effective (1/1/2021)
New York	Senate Bill S504-A[257]	30	$0 cost sharing	Effective (1/1/2025)[258]
North Dakota	Senate Bill 2140[259]	30	$25 cap	Effective (7/1/2023)
Oklahoma	House Bill 1019[260]	30; 90	$30 cap; $90 cap	Effective (1/1/2021)

[250] S.B. 340, 68th Leg., Reg. Sess. (Mont. 2023).

[251] Veronica Barreto, Gov. Jim Pillen Approves Insulin Price Cap in Nebraska, KLKN-TV (June 7, 2023, 1:29 PM), https://www.klkntv.com/gov-jim-pillen-approves-insulin-price-cap-in-nebraska/ [https://perma.cc/FG2J-79Y3].

[252] Assemb. B. 555, 83d Leg., Reg. Sess. (Nev. 2025).

[253] Press Release, Am. Diabetes Ass'n, Insulin Co-Pays Capped at $30 for Those in the Granite State with Diabetes (July 16, 2020), https://diabetes.org/newsroom/insulin-co-pays-capped-at-30-for-those-in-the-granite-state-with-diabetes [https://perma.cc/RPX4-TMZ3].

[254] Press Release, Off. of Governor Phil Murphy, Governor Murphy Signs Legislative Package to Make Prescription Drugs More Affordable for New Jerseyans (July 10, 2023), https://www.nj.gov/governor/news/news/562023/20230710a.shtml [https://perma.cc/2MXY-6RLT].

[255] Nikita Biryukov, Price Caps on Insulin, Inhalers, EpiPens Take Effect, N.J. Monitor (Jan. 1, 2025, 8:00 AM), https://newjerseymonitor.com/briefs/price-caps-on-insulin-inhalers-epipens-take-effect/ [https://perma.cc/C3M4-N2NJ].

[256] H.B. 292, 2020 Leg., Reg. Sess. (N.M. 2020).

[257] S.B. 504A, 2023–2024 Leg., Reg. Sess. (N.Y. 2023).

[258] John Camera, New York State Eliminates Insulin Copayments Starting Jan. 1, Spectrum News 1 (Dec. 31, 2024, 4:16 PM), https://spectrumlocalnews.com/nys/central-ny/news/2024/12/31/insulin-copay-eliminated [https://perma.cc/3WHV-EGRR].

[259] S.B. 2140, 68th Leg. Assemb., Reg. Sess. (N.D. 2023).

[260] KOCO Staff, Gov. Kevin Stitt Signs Bill Capping Copay Cost for Insulin for Oklahomans with Diabetes, KOCO News, https://www.koco.com/article/gov-kevin-stitt-signs-bill-capping-copay-cost-for-insulin-for-oklahomans-with-diabetes/36189684 [https://perma.cc/XPT7-PPHF] (last updated Apr. 21, 2021, 6:36 PM).

Oregon	Senate Bill 1508[261]	30; 90	$35 cap; $105 cap	Effective (1/1/2025)
Rhode Island	House Bill 5196A[262]	30	$40 cap	Effective (1/1/2022)
Texas	Senate Bill 827[263]	30	$25 cap	Effective (9/1/2021)
Utah	House Bill 207[264]	30	$30 cap	Effective (1/1/2021)
Vermont	House Bill 969[265]	30	$100 collective cap	Effective (1/1/2022)
Virginia	House Bill 66[266]	30	$50 cap	Effective (1/1/2021)
Washington	Senate Bill 5729[267]	30	$35 cap	Effective (7/23/2023)
West Virginia	Senate Bill 577[268]	30	$35 collective cap; $100 collective cap for equipment	Effective (1/1/2024)

Beyond insulin price caps, a more systematic way to adopt price controls is through international reference pricing, where drug prices in one country are based on the prices of the same drugs in other countries—

[261] S.B. 1508, 82d Leg., Reg. Sess. (Or. 2024).

[262] Press Release, Off. of Governor Dan McKee, Governor McKee Signs Prescription Drug Affordability Bills (Sept. 1, 2021), https://governor.ri.gov/press-releases/governor-mckee-signs-prescription-drug-affordability-bills [https://perma.cc/VZ7F-HWD5].

[263] Press Release, Am. Diabetes Ass'n, American Diabetes Association Applauds Texas as It's Added to Growing List of States Working to Reduce Cost-Sharing on Insulin (June 15, 2021), https://diabetes.org/newsroom/ada-applauds-TX-added-to-growing-list-states-working-reduce-cost-sharing-insulin [https://perma.cc/5KFN-W9BB].

[264] H.B. 207, 63d Leg., Gen. Sess. (Utah 2020).

[265] H.B. 969, 2019–2020 Gen. Assemb., Reg. Sess. (Vt. 2020).

[266] H.B. 66, 161st Gen. Assemb., Reg. Sess. (Va. 2020).

[267] Wash. State Health Care Auth., Total Cost of Insulin Work Group: Final Report 4 (2023), https://www.hca.wa.gov/assets/program/leg-report-insulin-work-group20230629.pdf [https://perma.cc/U5G6-AU9B].

[268] S.B. 577, 86th Leg., Reg. Sess. (W. Va. 2023).

typically those with similar economic conditions.[269] Countries can create a basket of reference nations and set prices based on the average or lowest price among them. Canada uses the median price among eleven reference countries for patented drugs, while Japan considers prices in four reference countries when setting its drug prices.[270] Unlike many other countries, the United States does not have direct government price controls on pharmaceuticals.[271]

On May 12, 2025, Trump issued a new executive order entitled "Delivering Most-Favored-Nation [("MFN")] Prescription Drug Pricing to American Patients," which directs the Department of Health and Human Services ("HHS") and other agencies to communicate price targets to manufacturers and, if "significant progress" is not made, to pursue rulemaking and consider other actions, including importation from foreign countries.[272] The order states that "Americans should not be forced to subsidize low-cost prescription drugs and biologics in other developed countries, and face overcharges for the same products in the United States. Americans must therefore have access to the most-favored-nation price for these products."[273] On May 20, 2025, HHS set MFN pricing targets for brand-name drugs that lack generic or biosimilar competition, specifically expecting manufacturers to align U.S. prices for such drugs with the lowest respective price across countries that are

[269] See Leah Z. Rand & Aaron S. Kesselheim, International Reference Pricing for Prescription Drugs: A Landscape Analysis, 27 J. Managed Care & Specialty Pharmacy 1309, 1309 (2021) (examining countries that use reference pricing in setting drug prices).

[270] Wei Zhang, Daphne P. Guh, Paul Grootendorst, Aidan Hollis & Aslam H. Anis, The Impact of Changing the Reference Countries on the List Prices for Patented Medicines in Canada: A Policy Analysis, Health Pol'y, Apr. 7, 2024, at 1, 1; see also C. Lin & M. Izmirlieva, Impact of Huge-Seller Repricing on Price Trend for Reimbursable Cancer Drugs in Japan, GlobalData, https://www.ispor.org/docs/default-source/euro2024/isporeurope24linpt20poster142639-pdf.pdf?sfvrsn=98bdcfaf_0 [https://perma.cc/95YM-FEU9] (last visited Nov. 17, 2025).

[271] See Erin M. Barker, When Market Forces Fail: The Case for Federal Regulation of Insulin Prices, 42 Campbell L. Rev. 311, 318, 333 (2020) (finding that the United States' emphasis on patent law is a poor substitute for direct price controls on pharmaceuticals); see also Juliette Cubanski, Meredith Freed & Tricia Neuman, A Status Report on Prescription Drug Policies and Proposals at the Start of the Biden Administration, KFF (Feb. 11, 2021), https://www.kff.org/medicare/issue-brief/a-status-report-on-prescription-drug-policies-and-proposals-at-the-start-of-the-biden-administration/ [https://perma.cc/Y5H6-HCDU] (explaining that the first Trump Administration proposed a "Most Favored Nation" model for Medicare Part B drugs, which would tie prices to the lowest price among a group of economically similar countries, but that the rule was repealed by the Biden Administration).

[272] Exec. Order No. 14,297, 90 Fed. Reg. 20749, 20749–50 (May 15, 2025).

[273] Id. at 20749.

members of the Organization for Economic Co-operation and Development and have a GDP per capita of at least sixty percent of U.S. per capita GDP.[274]

Price control reforms may intuitively appear to be the most direct and effective solutions to high prices. Yet they are controversial solutions, heatedly debated in economics and policy.[275] When prices are set by law, research and development incentives may be distorted, steering pharmaceutical companies to invest in the development of drugs that are not regulated. For example, the AAM and the Biosimilars Council have stated that by setting price caps, the federal Inflation Reduction Act "replace[s] competition—the only proven way to provide patients relief from high brand drug prices—with a flawed framework for government price setting that will chill the development of, and reduce patient access to, lower-cost generic and biosimilar medicines."[276] A review of empirical research that evaluates the impact of pharmaceutical price controls on innovation estimates that research and development activity decreases by approximately 1.5% for every 1% reduction in projected revenue.[277] Still, price controls can have immediate positive effects and lead to pricing shifts on a broader scale. The public pressure and legislative reforms have recently led the three dominant insulin manufacturers to announce national price reductions. Eli Lilly, Novo Nordisk, and Sanofi announced that they are committed to keeping at least some of their insulin products at thirty-five dollars per month or less.[278] Sanofi stated it would introduce an out-of-pocket cap of thirty-five dollars per month for Lantus for those

[274] Press Release, U.S. Dep't of Health & Hum. Servs., HHS, CMS Set Most-Favored-Nation Pricing Targets to End Global Freeloading on American Patients (May 20, 2025), https://www.hhs.gov/press-room/cms-mfn-lower-us-drug-prices.html [https://perma.cc/D3RL-RZ8Q].

[275] See, e.g., Tomas J. Philipson & Troy Durie, The Evidence Base on the Impact of Price Controls on Medical Innovation 1–4 (Becker Friedman Inst. for Econ., Univ. of Chi., Working Paper No. 2021-108, 2021) (canvassing arguments for and against price control reforms in the United States).

[276] Press Release, Dan Leonard, Ass'n for Accessible Meds., AAM Statement on Senate Passage of Inflation Reduction Act (Aug. 7, 2022), https://accessiblemeds.org/resources/press-releases/aam-statement-senate-passage-inflation-reduction-act/ [https://perma.cc/3LYX-S68T].

[277] Philipson & Durie, supra note 275, at 1, 6.

[278] Ahmed Aboulenein, Insulin Makers Testify on Capitol Hill over Prices, Reuters (May 10, 2023, 5:54 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/pharma-ceos-testify-us-senate-hearing-insulin-prices-2023-05-10/ [https://perma.cc/6N7P-GS8C].

with commercial insurance.[279] Novo Nordisk announced the MyInsulinRx program; it provides a thirty-day supply of insulin for thirty-five dollars to eligible patients, which can include the uninsured.[280] Eli Lilly also announced a monthly cap of thirty-five dollars on out-of-pocket costs for those with commercial insurance if patients buy its insulin at participating retail pharmacies.[281]

Like many other states, California has also legislated a cap on insulin prices. Initially, though, a bill passed to that effect was vetoed in October 2023 by Governor Gavin Newsom, who instead announced a plan for California to publicly produce insulin.[282] In vetoing the California insulin price cap bill, Governor Newsom explained in 2023 that the bill, as a copay cap, would prompt insurance companies to increase insurance premiums, which would only benefit those with insurance.[283] Patients without insurance would still have to pay the full price of insulin out of pocket.[284] Moreover, Newsom described such copay caps as unsustainable solutions that result in passing down long-term costs to patients through higher premiums on patients' health insurance plans.[285] Newsom concluded that CalRx, the public drug production program analyzed in Section V.B, would get at the underlying issue and present a

[279] Luhby, supra note 15; Aboulenein, supra note 278; Press Release, Sanofi, Sanofi Cuts U.S. List Price of Lantus, Its Most-Prescribed Insulin, by 78% and Caps Out-of-Pocket Lantus Costs at $35 for All Patients with Commercial Insurance (Mar. 16, 2023), https://www.sanofi.com/assets/dotcom/pressreleases/2023/2023-03-16-20-06-43-2629188-en.pdf [https://perma.cc/QSS7-7M6M].

[280] Luhby, supra note 15; Aboulenein, supra note 278.

[281] Luhby, supra note 15; see also Press Release, Eli Lilly & Co., Lilly Cuts Insulin Prices by 70% and Caps Patient Insulin Out-of-Pocket Costs at $35 Per Month (Mar. 1, 2023), https://investor.lilly.com/news-releases/news-release-details/lilly-cuts-insulin-prices-70-and-caps-patient-insulin-out-pocket [https://perma.cc/JD5C-QY6T].

[282] Souers, supra note 23; Berthold, supra note 23.

[283] ABC10 Staff & Associated Press, List: The California Bills Gov. Newsom Signed and the Ones Still Waiting for a Decision, ABC10 (Oct. 8, 2023, 7:34 PM), https://www.abc10.com/article/news/politics/california-newsom-bills/103-d70e9739-66b5-4c35-ae56-a89956a83477 [https://perma.cc/PML9-8C64]; Ana B. Ibarra, Gavin Newsom Rejected Plan to Lower Insulin Copays, Saying a Better Deal Is the Works, CalMatters (Oct. 12, 2023), https://calmatters.org/health/2023/10/gavin-newsom-vetoes-insulin-copay-cap/ [https://perma.cc/6CCB-ZTKY].

[284] Ibarra, supra note 283.

[285] Letter Vetoing S.B. 90 from Off. of Governor Gavin Newsom to Members of the Cal. St. Senate (Oct. 7, 2023) [hereinafter Letter Vetoing S.B. 90], https://www.gov.ca.gov/wp-content/uploads/2023/10/SB-90-Veto.pdf [https://perma.cc/M8X2-XC8B]; Associated Press, California Gov. Gavin Newsom Vetoes Bill Aimed at Limiting the Price of Insulin, AP News, https://apnews.com/article/california-insulin-veto-newsom-854bce0003db862f8bc5f916ed909196 (last updated Oct. 8, 2023, 4:54 PM).

truly sustainable solution to the ongoing cost issues.[286] Over the last two years, however, the CalRx program has hit multiple roadblocks—namely, a series of production delays and budget cuts that have forced the state to adjust the program's timeline for implementation.[287] As a response to these delays, in October 2025, California became the twenty-ninth state to cap insulin prices.[288] Effective January 1, 2026, large group insurers are required to cap insulin copayments at thirty-five dollars for a thirty-day supply.[289] Individual or small group healthcare insurers will need to cap copayments starting on January 1, 2027.[290]

Still, without the right complementary levers, price controls risk unintended consequences, such as reduced incentives for innovation or drug supply shortages. Manufacturers may intensify their efforts to switch production to drugs not included in the price control basket, deprioritize the U.S. market, or shift costs to other areas of the healthcare system. In sum, while price controls have immediate benefits, they are limited in their reach and are rather blunt reactive solutions. More systemic reforms, analyzed in the following Sections, must support longer-term shifts and solutions.

One important complementary reform that involves direct pricing is worth mentioning here. Pharmaceutical companies have been engaged in a long battle litigating against disclosure of actual prices and true costs, and they have invoked trade secrecy related to their company's financial information, which includes information about research and development costs, manufacturing costs, and strategic financial planning.[291] In addition

[286] See Letter Vetoing S.B. 90, supra note 285 (vetoing the bill and focusing on public production).

[287] See infra notes 493–95 and accompanying text (detailing obstacles to CalRx's implementation).

[288] Press Release, Am. Diabetes Ass'n, The American Diabetes Association Applauds California's Action to Cap Copayments for Insulin on State-Regulated Health Plans (Oct. 14, 2025) [hereinafter Am. Diabetes Ass'n, California Press Release], https://diabetes.org/newsroom/press-releases/american-diabetes-association-applauds-californias-action-cap-copayments [https://perma.cc/FL9R-RY9T]; S.B. 40, 2025–2026 Leg., Reg. Sess. (Cal. 2025).

[289] Am. Diabetes Ass'n, California Press Release, supra note 288; Cal. S.B. 40.

[290] Am. Diabetes Ass'n, California Press Release, supra note 288; Cal. S.B. 40.

[291] See Richard A. Epstein, The Constitutional Protection of Trade Secrets and Patents Under the Biologics Price Competition and Innovation Act of 2009, 66 Food & Drug L.J. 285, 289–90 (2011) (describing how trade secrecy may impede the pathway for FDA approval of biosimilars). See generally Joseph S. Ross, Cary P. Gross & Harlan M. Krumholz, Promoting Transparency in Pharmaceutical Industry-Sponsored Research, 102 Am. J. Pub. Health 72 (2012) (calling for transparency and evidence-based objective research to inform clinical trials and decisions).

to direct price caps, several states have enacted laws requiring increased transparency in insulin pricing. Nevada's Diabetes Drug Transparency Law, for example, requires manufacturers of diabetes drugs, including insulin, to report detailed information on costs, profits, and planned price increases.[292] Minnesota passed the Prescription Drug Price Transparency Act to increase transparency in the pricing of prescription drugs by requiring manufacturers to report on prices for new drugs and on any price increases.[293] Maine enacted the Act to Further Expand Drug Price Transparency, establishing reporting requirements for high-cost medications like insulin.[294] Transparency requirements can also extend to reporting the deals and negotiations between drug manufacturers, PBMs, insurers, and pharmacies. As discussed in the next Section, a rising number of states have begun to legislate such demands.

C. PBM Regulation and Federalism

In the past few years, all fifty states have enacted PBM reforms.[295] The most widespread PBM reform, adopted by forty-four states, prohibits PBMs from enforcing contracts that restrict pharmacies or pharmacists from sharing accurate pricing information with patients.[296] Other reforms

[292] Mary Caffrey, Nevada's Sandoval Signs Insulin Transparency Law, Am. J. of Managed Care (June 19, 2017), https://www.ajmc.com/view/nevadas-sandoval-signs-insulin-transparency-law [https://perma.cc/3M26-JAGX] (stating that PBMs must submit annual reports detailing the total rebates negotiated with drug manufacturers and the amounts retained).

[293] Minn. Dep't of Health, Minnesota Prescription Drug Price Transparency: Report to the Minnesota Legislature 23 (2025), https://www.health.state.mn.us/data/rxtransparency/docs/rxlegrpt2024.pdf [https://perma.cc/CG5F-9R8B] (stating that the law applies to drugs that cost one hundred dollars or more for a thirty-day supply; that for brand-name drugs, reporting is triggered by a price increase of ten percent or more within one year, or sixteen percent over two years; and that for generic drugs, a price increase of fifty percent or more requires disclosure).

[294] See generally Me. Health Data Org., 2020 Annual Prescription Drug Pricing Transparency Report (2021), https://mhdo.maine.gov/_pdf/MHDO%20Rx%20Transparency%20Report%20210209%20FINAL.pdf [https://perma.cc/6KFE-CBDL] (noting that manufacturers must disclose detailed information about the costs associated with producing and marketing the drug, including research and development expenses, manufacturing costs, and marketing expenditures, and stating that PBMs are also required to report the total amount of rebates negotiated with drug manufacturers and specify the portion of these rebates retained by the PBMs).

[295] See Mattingly et al., supra note 156, at 8 (citing Mattingly et al., supra note 19) (calling for policies that would increase competition in the PBM market).

[296] See Staff of H. Comm. on Oversight & Accountability, supra note 85, at 48–49 (describing reforms to limit PBM pharmacy restrictions); see also Deborah Yetter, Reprieve for Kentucky's Independent Pharmacies Is Saving Medicaid Millions, Ky. Lantern (Oct. 5,

include prohibitions on PBMs limiting patients from seeking care at pharmacies unaffiliated with the PBMs or charging unaffiliated pharmacies more than the pharmacies owned by the PBMs.[297] A 2024 Government Accountability Office ("GAO") report examined five leading states—Arkansas, California, Louisiana, Maine, and New York—that have enacted PBM reforms.[298] The report found that states are more successful when the state agencies overseeing the reforms have "[b]road [s]tate [r]egulatory [a]uthority" and "[r]obust [e]nforcement [p]owers" to carry out the legislative reforms.[299] The leading reforms include a duty for PBMs to act in good faith toward the best interest of the health plan, as well as prohibitions on spread pricing, the term used to denote when PBMs pay pharmacies less than they charge health plans.[300] Other state law reforms include licensing and transparency requirements for PBMs, which include reporting requirements for drug pricing, fees, and rebates, as well as prohibitions on discrimination against smaller and independent pharmacies.[301]

However, these reforms are under fire. The PBMs' trade group, the Pharmaceutical Care Management Association ("PCMA"), spent millions lobbying Congress in 2024 alone[302] and is actively challenging state authority to regulate PBMs. The state of Oklahoma is currently in litigation with PCMA in an effort to uphold the state's authority to restrict PBMs from practices such as steering patients to PBM-affiliated pharmacies at the expense of competitors.[303] In 2019, PCMA sued Oklahoma over its Patient's Right to Pharmacy Choice Act.[304] PCMA claimed that the state law is void because it is preempted by the federal

2023, 5:50 AM), https://kentuckylantern.com/2023/10/05/reprieve-for-kentuckys-independent-pharmacies-is-saving-medicaid-millions/ [https://perma.cc/E5RD-4959] (stating that in 2020, Kentucky passed a law requiring a single PBM to manage Kentucky's Medicaid prescription drug business).

[297] See Staff of H. Comm. on Oversight & Accountability, supra note 85, at 49 (describing reforms to limit PBM pharmacy restrictions).

[298] U.S. Gov't Accountability Off., GAO-24-106898, Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers 3 (2024).

[299] Id. at 22.

[300] Id. at 10–12.

[301] Id. at 11–14.

[302] Noah Tong, Lobbying Groups Pushing Priorities in Year-End Package and in 2025, Fierce Healthcare (Oct. 31, 2024, 3:00 AM), https://www.fiercehealthcare.com/special-reports/lobbying-groups-pushing-priorities-year-end-package-and-2025.

[303] Pharm. Care Mgmt. Ass'n v. Mulready, 78 F.4th 1183, 1187 (10th Cir. 2023).

[304] Id. at 1201–02.

Employee Retirement Income Security Act ("ERISA").[305] PCMA also challenged the Act as preempted under the federal Medicare Part D program.[306]

The current case marks a watershed moment in determining the scope of federal preemption of such state regulations. Four provisions of the Oklahoma Act were challenged: (1) the *Access Standards Provision*, which requires that a certain percentage of covered individuals, ranging from seventy percent to ninety percent depending on the geographic location, are within a certain mile radius of a retail pharmacy; (2) the *Discount Prohibition Provision*, which prohibits PBMs from limiting a patient's right to seek care from retail or mail-order pharmacies participating in the PBMs' network, or, in other words, prohibits price discrimination deals which appear to promote the PBM-affiliated pharmacy over independent pharmacies, such that patients will be dissuaded from using independent pharmacies; (3) the *Any Willing Provider Clause*, which prohibits PBMs from denying pharmacies the opportunity to participate in PBMs' networks when they meet the terms and conditions of participation; and (4) the *Probation Provision*, which prohibits PBMs from denying, limiting, or terminating a pharmacy's contract based on the employment status of any employee who has an active license to dispense, even if that employee was placed on probation by the State Board of Pharmacy.[307]

In 2022, a federal district court upheld the Oklahoma Act, but the Tenth Circuit Court of Appeals overturned the decision in 2023, holding that ERISA preempts state regulation of PBMs.[308] The Tenth Circuit found that the provisions of the Oklahoma Act were connected with ERISA plans because they limited the PBM-network-design options available to

[305] Id. at 1191–92. For background on ERISA preemption, see generally Edward A. Zelinsky, The Ninth Circuit's *Jarvis* Opinion: A Correct Application of Retrenched ERISA Preemption (Benjamin N. Cardozo Sch. of L., Faculty Research Paper No. 649, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3874227 [https://perma.cc/JJX6-MGJW]; Rebecca E. Wolitz, States, Preemption, and Patented Drug Prices, 52 Seton Hall L. Rev. 385 (2021).

[306] *Mulready*, 78 F.4th at 1191–92. For background on Medicare Part D preemption, see generally George Horvath, Recovery and Preemption: The Collision of the Medicare Secondary Payer Act and the Medical Device Amendments, 103 Calif. L. Rev. 1353 (2015) (calling on Congress and the Supreme Court to narrow the reach of preemption under Medicare).

[307] *Mulready*, 78 F.4th at 1190–91.

[308] Pharm. Care Mgmt. Ass'n v. Mulready, 598 F. Supp. 3d 1200 (W.D. Okla. 2022), *rev'd and remanded*, 78 F.4th 1183.

plans.[309] The Tenth Circuit held that all four challenged provisions were preempted by ERISA because they interfered with core aspects of plan administration.[310] The court stated that the provisions imposed specific structures and operational requirements on benefit plans, undermining the uniform regulatory framework ERISA was designed to create.[311] Furthermore, the court found that the Any Willing Provider provision was also preempted by Medicare Part D, as it conflicted with federal standards governing the operation of Medicare prescription drug plans.[312] The court relied on the preemption language of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which prohibits state laws that regulate matters within Medicare Part D's scope.[313] The court analyzed Medicare Part D preemption as akin to a field preemption, a scope of preemption that the Supreme Court has described as applying when "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."[314] Applying this broad standard of preemption, the Tenth Circuit in *Pharmaceutical Care Management Ass'n v. Mulready* concluded that Oklahoma's law "detract[s] from the integrated scheme of [Medicare] regulation[s] created by Congress" by regulating healthcare plans above what Medicare laws and regulations require.[315]

The Supreme Court denied certiorari in *Mulready*.[316] For the petition in support of Oklahoma, a bipartisan coalition of thirty-two state attorneys general submitted an amicus brief urging the Supreme Court to review the case and overturn the Tenth Circuit's decision.[317] The Tenth Circuit decision creates a textbook circuit split, and is in tension with the 2020 Supreme Court case *Rutledge v. Pharmaceutical Care Management*

[309] *Mulready*, 78 F.4th at 1209.
[310] Id. at 1200, 1205.
[311] Id.
[312] Id. at 1209.
[313] See Thomas R. Oliver, Philip R. Lee & Helene L. Lipton, A Political History of Medicare and Prescription Drug Coverage, 82 Milbank Q. 283, 316–18 (2004) (discussing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003's prohibition on state governments' negotiating prices with Medicare Part D drug manufacturers, as well as other regulations pertaining to beneficiaries of Medicare Part D).
[314] Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).
[315] *Mulready*, 78 F.4th at 1205 (first alteration in original) (quoting Arizona v. United States, 567 U.S. 387, 402 (2012)).
[316] 145 S. Ct. 2843 (2025) (mem.).
[317] Brief of Amici Curiae States of Minnesota et al. in Support of Petitioners, *Mulready*, 145 S. Ct. 2843 (No. 23-1213).

Ass'n.[318] In *Rutledge*, the Supreme Court unanimously upheld Arkansas's law regulating PBM reimbursement rates for pharmacies.[319] Arkansas was one of the first states to pass a law to rein in PBM practices, requiring that PBMs "reimburse pharmacies for prescription drugs at a rate equal to or higher than the pharmacy's acquisition cost," or the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice.[320] As in *Mulready*, the PCMA challenged the Arkansas Act, arguing that it was preempted under federal law.[321] In *Rutledge*, the Court upheld Arkansas's PBM law, finding it was not preempted by ERISA because it regulated reimbursement rates without dictating plan choices or directly targeting ERISA plans.[322] The Court held that ERISA did not preempt the state law because it only had an indirect economic influence on plan administration.[323] The law did not "require providers to structure benefit plans in particular ways" or "requir[e] payment of specific benefits."[324] In *Mulready*, the Tenth Circuit stated, "*Rutledge* was a win for States and a loss for PBMs, but it does not shield the Act from preemption."[325] The Tenth Circuit described the state act as "attempting to 'govern[] a central matter of plan administration' and 'interfer[ing] with nationally uniform plan administration.'"[326] The Tenth Circuit held that ERISA preempts state laws even if they have merely de minimis impact on "benefit design."[327]

Congress enacted ERISA's state-rule preemption to create uniform federal benefits rules and encourage large, multistate employers to offer benefit plans without navigating fifty separate sets of regulations.[328]The rationale behind ERISA preemption was the concern that too many regulatory state-by-state requirements regarding the administration of healthcare plans would burden employers.[329] As the Court explained in *Rutledge*, ERISA's objectives serve "as a guide to the scope of the state

[318] 141 S. Ct. 474 (2020); see infra notes 350–52 and accompanying text.
[319] *Rutledge*, 141 S. Ct. at 483.
[320] Id. at 481.
[321] Id. at 481–83.
[322] Id. at 481.
[323] Id.
[324] Id. at 480 (citing Shaw v. Delta Air Lines, Inc., 463 U.S. 85 (1983)).
[325] Pharm. Care Mgmt. Ass'n v. Mulready, 78 F.4th 1183, 1200 (10th Cir. 2023).
[326] Id. (first alteration in original) (quoting *Rutledge*, 141 S. Ct. at 480).
[327] Id. at 1201.
[328] *Rutledge*, 141 S. Ct. at 480 (first citing Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312, 320–21 (2016); and then citing Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 142 (1990)).
[329] Id.

law that Congress understood would survive."[330] The Court explained that two kinds of state laws would be preempted: (1) state laws that directly interfere with "a central matter of plan administration,"[331] such as laws "requiring payment of specific benefits"[332] and imposing "specific rules for determining beneficiary status";[333] and (2) state laws that indirectly affect plan administration if they have "acute, albeit indirect, economic effects . . . [that] force an ERISA plan to adopt a certain scheme of substantive coverage."[334] Beyond this narrower set of laws, the Court emphasized that state regulations may affect ERISA plans, especially costs, without being preempted.[335] A state law should not be preempted merely because it might "affect a plan's shopping decisions."[336] As the Court warned in an earlier case, *California Division of Labor Standards Enforcement v. Dillingham Construction, N.A., Inc.*,

> [I]f ERISA were concerned with any state action—such as medical-care quality standards or hospital workplace regulations—that increased costs of providing certain benefits, and thereby potentially affected the choices made by ERISA plans, we could scarcely see the end of ERISA's pre-emptive reach, and the words "relate to" would limit nothing.[337]

Similarly, the Court explained in *Rutledge* that an overly broad interpretation of ERISA preemption "would pre-empt any suits under state law that could affect the price or provision of benefits."[338]

Importantly, federalism embeds "the historic police powers of the State," which "include the regulation of matters of health and safety."[339] PBMs have a history of attempting to use ERISA to limit states' abilities to protect their citizen employees, with litigation "primarily effectuated through managed care organizations' use of ERISA's preemption clause

[330] Id. (quoting Cal. Div. of Lab. Standards Enf't v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 325 (1997)).
[331] Id. at 480 (quoting *Gobeille*, 577 U.S. at 320).
[332] Id. (citing Shaw v. Delta Air Lines, Inc., 463 U.S. 85 (1983)).
[333] Id. (citing Egelhoff v. Egelhoff ex rel. Breiner, 532 U.S. 141 (2001)).
[334] Id. (quoting *Gobeille*, 577 U.S. at 320).
[335] N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 659–60 (1995).
[336] Id. at 660.
[337] Cal. Div. of Lab. Standards Enf't v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 329 (1997) (citing *Travelers Ins.*, 514 U.S. at 660–61).
[338] *Rutledge*, 141 S. Ct. at 482.
[339] De Buono v. NYSA-ILA Med. & Clinical Servs. Fund, 520 U.S. 806, 814 (1997).

to preempt state laws that attempt regulation of managed care organizations."[340] Broad preemption is harmful, as it imposes a legal vacuum that leaves patients without oversight over the complex system of healthcare delivery.[341] As discussed in Part II, without state law intervention, PBMs, insurance providers, and pharmacy conglomerates will continue to engage in profit-building strategies to the detriment of citizens.[342] And, as referenced above, the Supreme Court declined an opportunity to clarify that ERISA preemption does not infringe on the states' authority to regulate patient welfare. The issues in *Mulready* extend beyond regulating PBMs to the broader scope of states' authority to govern health care and insurance. For example, overly broad preemption could endanger state laws requiring third-party payors to honor benefits, preventing patients from facing upfront costs, mandating that payors honor prior authorizations, protecting patients from surprise bills, or prohibiting patient restrictions to designated laboratories. In a series of cases, the Supreme Court held that ERISA preemption is limited to "the areas with which ERISA is expressly concerned—'reporting, disclosure, fiduciary responsibility, and the like.'"[343] The *Rutledge* Court drew the right balance between respecting ERISA's preemption provision as applied to the statute's explicit substantive scope, while also allowing the states to exercise their long-standing authority of overseeing the fair delivery of health care.

In *Mulready*, the Tenth Circuit expanded the scope of preemption beyond this Supreme Court delineation.[344] In its decision, it did not distinguish between state laws that regulate how plans are paid for and those that regulate how care is provided.[345] Calibrating preemption's scope is thus a fundamental issue of federalism. As the Court admonished in an earlier case, *Fort Halifax Packing Co. v. Coyne*, "If a State creates

[340] Larry J. Pittman, ERISA's Preemption Clause: Progress Towards A More Equitable Preemption of State Laws, 34 Ind. L. Rev. 207, 209 (2001); see also Jordan May, A Case for Brandeisian Federalism: The ERISA Preemption Clause and State Health Care Reform, DePaul J. Health Care L., Jan. 2023, at 1, 1–2 (noting that ERISA's preemption clause acts as an impediment to states in implementing significant changes to their healthcare systems because of how intertwined those systems are with private employee benefit plans).

[341] May, supra note 340, at 18–19.

[342] See supra Part II.

[343] Cal. Div. of Lab. Standards Enf't v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 330 (1997) (quoting N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 661 (1995)).

[344] Pharm. Care Mgmt. Ass'n v. Mulready, 78 F.4th 1183, 1200, 1209 (10th Cir. 2023).

[345] Id. at 1194, 1196.

no prospect of conflict with a federal statute, there is no warrant for disabling it from attempting to address uniquely local social and economic problems."[346] In a subsequent case, *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*, the Court warned against interpreting ERISA as though "Congress chose to displace general health care regulation,"[347] an interpretation that would be "unsettling."[348] Thus, the trajectory of recent Supreme Court cases, including *Rutledge*, *Fort Halifax Packing*, *Travelers*, and *Dillingham*, demonstrates that ERISA preemption only extends to what ERISA substantively regulates: "determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements."[349] The Tenth Circuit decision also conflicts with the recent Eighth Circuit holding in *Pharmaceutical Care Management Ass'n v. Wehbi*, which ruled that a nearly identical North Dakota law limiting a PBM's ability to impose network-participation conditions merely regulates a noncentral "matter of plan administration."[350] The Eighth Circuit held in *Wehbi* that such provisions are not preempted by ERISA or Medicare Part D.[351] The tension between these two recent circuit cases creates what Oklahoma has called a "textbook" circuit split.[352]

In October 2024, the U.S. Supreme Court invited the Solicitor General to submit a brief expressing the federal government's views on the *Mulready* case, indicating the potential for further review.[353] The missed opportunity for the Supreme Court to clarify and narrow the scope of ERISA preemption in the regulation of PBMs has broad implications for

[346] 482 U.S. 1, 19 (1987).

[347] *Travelers Ins.*, 514 U.S. at 661.

[348] *Dillingham*, 519 U.S. at 330–31 (quoting *Travelers Ins.*, 514 U.S. at 665).

[349] *Fort Halifax Packing*, 482 U.S. at 9.

[350] 18 F.4th 956, 968 (8th Cir. 2021) (citing Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312, 320 (2016)).

[351] Id. (citing Rutledge v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474, 480 (2020)).

[352] See Michele Munk, Medicare Part D Preemption: Supreme Court Review Uncertain, Squire Patton Boggs (Aug. 5, 2024) (citation omitted), https://www.triagehealthlawblog.com/u-s-supreme-court/medicare-part-d-preemption-supreme-court-review-uncertain/ [https://perma.cc/M3W2-74KY].

[353] Press Release, Nat'l Cmty. Pharmacists Ass'n, Supreme Court Asks for Federal Government Input on Whether to Take Up PBM Case (Oct. 10, 2024), https://ncpa.org/newsroom/qam/2024/10/10/supreme-court-asks-federal-government-input-whether-take-pbm-case [https://perma.cc/LV58-GWPQ].

state efforts to address rising drug costs and healthcare access and, even more broadly, for the possibility of striking a productive balance between state uniformity and the spirit of experimentalism and innovation embedded in federalism. The ongoing circuit split continues to create uncertainty about state oversight of PBMs and, more generally, the healthcare market at large.

While PBM regulation is under attack in the courts, over the past two years, Congress has seen a surge in legislative efforts aimed at reforming the practices of PBMs. Multiple bills were introduced to increase transparency, reduce costs, and curb practices considered exploitative within the pharmaceutical supply chain.[354] As one commentator described at the end of 2024, "The debris field of dead legislation in Congress is littered with attempts at PBM reform from the past few years[,] as nothing has stuck so far."[355] Yet, reform efforts have been reinvigorated by new federal investigations and reports. The Pharmacy Benefit Manager Transparency Act of 2023 aims to eliminate some of these opaque PBM practices by banning PBMs from charging health plans more than they reimburse pharmacies.[356] It also prohibits unfair practices such as arbitrarily clawing back reimbursement payments or manipulating fees and reimbursements to offset changes in federally funded health plans.[357]

[354] Jeff Lagasse, Senate Finance Committee Targets PBM Reform in New Legislation, Healthcare Fin. News (Nov. 9, 2023, 4:19 PM), https://www.healthcarefinancenews.com/news/senate-finance-committee-targets-pbm-reform-new-legislation [https://perma.cc/89TC-TQW8]; Cissy Jackson & Daniel Sjostedt, Pending PBM-Reform Legislation on Capitol Hill, ArentFox Schiff (July 10, 2023), https://www.afslaw.com/perspectives/alerts/pending-pbm-reform-legislation-capitol-hill [https://perma.cc/7ERJ-4FGQ]; Dorthula H. Powell-Woodson & Brooke M. DeLoatch, Proposed State and Federal PBM Legislation: Is There Reason for Action Now?, Wiley (May 1, 2024), https://www.wiley.law/alert-Proposed-State-and-Federal-PBM-Legislation-Is-There-Reason-for-Action-Now [https://perma.cc/FG57-KBRA].

[355] Amy Baxter, PBMs Have Evaded Lawmakers' Reform Attempts So Far. Could 2025 Turn the Tide?, PharmaVoice (Jan. 6, 2025), https://www.pharmavoice.com/news/pbm-reform-attempts-2025-congress-pharma/736473/ [https://perma.cc/CAV4-WPBY].

[356] S. 127, 118th Cong. § 2 (2023).

[357] Id. The Lower Costs, More Transparency Act (H.R. 5378) obligates PBM contracts to allow health plan fiduciaries to audit claims and cost information, thus enhancing accountability. H.R. 5378, 118th Cong. § 401 (2023). Furthermore, for Medicaid-related PBM arrangements, the bill enforces pass-through pricing models and prohibits spread pricing. Id. § 202. The Congressional Budget Office projects that H.R. 5378 would generate $715 million in net savings and approximately $4.3 billion in revenue by 2033. Cong. Budget Off., Estimated Direct Spending and Revenue Effects of H.R. 5378, the Lower Costs, More Transparency Act 4–5 (2023), https://www.cbo.gov/system/files/2023-12/hr5378-DS-and-Revs_12-2023.pdf [https://perma.cc/CQ97-2LLZ]. Other bills have also proposed increasing PBM transparency. The Medicare PBM Accountability Act (H.R. 5385) proposes

The Delinking Revenue from Unfair Gouging Act targets PBMs that contract with carriers offering plans under the Federal Employees Health Benefits program by prohibiting spread pricing and patient steering.[358] The Pharmacy Benefits Manager Accountability Act introduces annual reporting obligations for PBMs, compelling them to provide plan sponsors with data on prescription drug copayment assistance, covered drugs, and total gross and net spending on prescription drugs.[359] Critical elements of these reports would also be submitted to the GAO, which would analyze pharmacy networks for potential vertical integration and assess whether such structures encourage plan enrollees to use certain pharmacies over others.[360] Multiple federal bills have also been proposed to prohibit spread pricing.[361] The Congressional Budget Office estimates

amendments to Title XVIII of the Social Security Act to impose comprehensive reporting requirements on PBMs concerning prescription drug plans and Medicare Advantage Prescription Drug plans under Medicare Part D. H.R. 5385, 118th Cong. (2023). The Protecting Patients Against PBM Abuses Act (H.R. 2880) introduces strict regulations on Medicare PBMs regarding remuneration, payments, and fees. H.R. 2880, 118th Cong. § 2 (2023). It prohibits PBMs from earning income beyond flat service fees, bans fee structures tied to drug prices or associated discounts, and prevents PBMs from charging plan sponsors amounts that differ from what is reimbursed to pharmacies. Id. Additionally, it requires that PBMs disclose disparities between formulary and non-formulary drug costs and report rebate and fee information from drug manufacturers, which the Centers for Medicare and Medicaid Services must publish online. Id. §§ 2, 4. The Pharmacy Benefit Manager Sunshine and Accountability Act (H.R. 2816) expands existing reporting requirements for PBMs. H.R. 2816, 118th Cong. § 2 (2023). While current law mandates that PBMs contracting with Medicare and state exchange plans report rebates and fees, this bill extends those obligations to PBMs serving private insurers. Id. It further requires disclosure of specific rebate information, including unshared manufacturer rebates and rebate percentage ranges across contracts. Id. The Department of Health and Human Services ("HHS") would be required to publicly post this information annually. Id.

[358] H.R. 6283, 118th Cong. §§ 2, 8915 (2023).

[359] H.R. 2679, 118th Cong. § 2 (2023).

[360] Id.

[361] See, e.g., H.R. 5378 § 202 ("[A]ny form of spread pricing . . . is not allowable . . . ."). Other proposals seek to eliminate the PBM safe harbor in the federal Anti-Kickback Statute, which prohibits the exchange of remuneration to induce or reward referrals for services or items reimbursable under federal healthcare programs. Thomas R. Barker & Ross Margulies, Foley Hoag LLP, The History of Rebates in the Drug Supply Chain and HHS' Proposed Rule to Change Safe Harbor Protection for Manufacturer Rebates 2–3 (2019). Recognizing that some financial arrangements could inadvertently fall within the statute's broad reach, Congress and HHS established regulatory safe harbors to protect certain practices deemed beneficial or neutral to federal healthcare programs. Id. at 5. PBMs have historically benefited from a safe harbor that permits drug manufacturer rebates paid to PBMs. Id. Prescription medication rebates were granted safe harbor in 1987 when Congress amended the Anti-Kickback Statute to add provisions directing the Secretary of HHS to protect certain practices from prosecution while establishing safeguards to prevent abuse. Id. (citing Medicare and

that increasing oversight on rebate deals and eliminating spread pricing in Medicaid managed care organizations, as proposed in the 2023 Lower Costs, More Transparency Act, could save the federal government $1.1 billion over the next decade.[362] In April 2025, the Trump Administration issued a similar executive order calling on HHS to lower the price of insulin and other drugs.[363] The executive order seeks to provide massive discounts to low-income patients for lifesaving medications, which would result in prices as low as three cents plus a nominal administrative fee.[364]

IV. ANTITRUST AND CONSUMER PROTECTION LITIGATION

"Normally, companies compete by lowering prices. And normally, insurance systems function by the healthy subsidizing the sick. Respondents' conduct has turned these basic principles on their head."

- FTC 2024 Complaint[365]

Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680). The Secretary delegated this duty to HHS Inspector General ("IG"), who issued regulations defining the safe harbors and their associated guardrails. Id. at 6 (citing 53 Fed. Reg. 12993, 12993 (Apr. 20, 1988)). Following extensive litigation and confusion during the 1990s, HHS IG revised the rules to their current form. Id. at 7. This provision was intended to encourage cost containment by allowing PBMs to negotiate discounts and rebates, ostensibly to lower drug costs for payers and patients. Id. at 8. As part of the outcry against PBM practices, reform efforts have also sought to revisit the rebate safe harbor to align PBM incentives with the broader goal of reducing prescription drug costs. In 2020, the Trump Administration finalized a rule aimed at reducing Medicare Part D drug costs. 42 C.F.R. § 1001.952(dd) (2024). The rule sought to enhance PBM transparency by allowing safe harbor protections for PBM service fees only if PBMs disclosed their compensation in written agreements with manufacturers, ensured compliance with state and federal laws, received fair market value for their services, and submitted annual written reports accessible to HHS. Id. However, the Inflation Reduction Act of 2022 delayed the rule's implementation to January 1, 2032. Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11301, 136 Stat. 1818, 1896.

[362] Cong. Budget Off., supra note 357, at 5; see also Staff of H. Comm. on Oversight & Accountability, supra note 85, at 22–23 (citing Cong. Budget Off., Answers to Questions for the Record Following a Hearing on Health Care Spending (2024), https://www.cbo.gov/system/files/2024-03/60073-Health-Care-Spending.pdf [https://perma.cc/T2HY-LK8Q]).

[363] Exec. Order No. 14,273, 90 Fed. Reg. 16441 (Apr. 18, 2025).

[364] Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices, White House (Apr. 15, 2025), https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-announces-actions-to-lower-prescription-drug-prices/ [https://perma.cc/ZFH4-XKHY].

[365] FTC Complaint, supra note 20, ¶ 2.

A. State and Federal Unfair Competition Complaints

In the past three years, multiple state attorneys general have filed lawsuits against the three dominant insulin manufacturers and the three largest PBMs: CVS Caremark, Express Scripts, and Optum Rx,[366] the latter of which were also sued by the FTC.[367] These cases are landmark test cases, applying consumer protection and antitrust laws to address pricing practices and complex business models.[368] In 2023, complaints of dozens of states and municipalities were consolidated in multidistrict litigation in New Jersey.[369] The lawsuits allege that the insulin manufacturers and PBMs use their market power to manipulate the market and overcharge patients.[370] They also allege that PBMs do not use their leverage to negotiate lower prices for customers, but instead try to increase their own profits by raising insulin prices.[371] Indeed, according to some findings of state investigations, PBM rebates can be as high as 79.75% for insulin; that money goes directly to PBMs.[372] The lawsuits describe how PBMs negotiate secret rebates that guarantee listing the high-price insulin products rather than lower-price insulins in return for kickback rebates—or, in other words, the lawsuits detail how PBMs elevate the prices and receive secret rebates, as described in Section III.B—from the manufacturers.[373] The lawsuits are expected to draw public scrutiny and magnitude of monetary settlements, as the opioid litigation did.[374] Indeed, litigators in these cases have said that the lawsuits

[366] Celine Castronuovo, Insulin, PBM Lawsuits Seen as Alternative to Pricing Legislation, Bloomberg L. News (Dec. 19, 2023, 5:05 AM), https://www.bloomberglaw.com/bloombergla wnews/health-law-and-business/X6CVP8MG000000.

[367] Annika Kim Constantino, FTC Sues Drug Middlemen for Allegedly Inflating Insulin Prices, CNBC (Sept. 21, 2024, 9:58 AM), https://www.cnbc.com/2024/09/20/ftc-sues-drug-middlemen-for-allegedly-inflating-insulin-prices.html [https://perma.cc/W3S8-TJVC].

[368] Castronuovo, supra note 366.

[369] Id.

[370] Id.

[371] Id.

[372] Staff of S. Comm. on Fin., supra note 90, at 60 ("For example, in 2019, Sanofi offered OptumRx rebates up to 79.75% for Lantus for preferred formulary placement on their client's commercial formulary, compared to just 42% in 2015." (footnotes omitted)).

[373] See In re Insulin Pricing Litig., No. 17-cv-00699, 2024 WL 5252471 (D.N.J. Dec. 31, 2024) (ongoing lawsuit between analog insulin consumers and Novo Nordisk, Sanofi-Aventus, and Eli Lilly for allegedly working with PBMs to use rebates and improperly raise prices for consumers); see also infra Section III.B.

[374] Castronuovo, supra note 366.

against the PBMs and insulin manufacturers follow the same path of the recent opioid lawsuits against manufacturers and distributors.[375]

The primary causes of action in the state lawsuits rest on violations of state consumer protection and unfair competition laws. For example, California's lawsuit uses California's Unfair Competition Law ("UCL") in its Business and Professions Code.[376] The UCL claim is particularly potent, as it encompasses three distinct prongs: (1) unlawful, (2) unfair, and (3) fraudulent business practices.[377] Under the *unlawful* prong, the state alleges that the PBMs' conduct violates the California Consumer Legal Remedies Act, effectively bootstrapping these violations into the UCL framework.[378] The complaint describes the rebate arrangements between PBMs and insulin manufacturers as falling within the prohibition on exclusive dealings.[379] While courts have traditionally analyzed exclusive dealing through the lens of explicit contractual requirements, in effect, the rebate system achieves similar exclusionary outcomes through economic incentives rather than direct mandates.[380] The *unfair* prong of the UCL claim presents perhaps the most novel legal theory, arguing that the practices violate the policy and spirit of California's unfair competition laws, even where they might not constitute explicit violations of specific statutes. In both the unlawful and unfair allegations, the complaint describes the rebate system as creating a system of perverse incentives to elevate prices, which directly harms patients.[381] The *fraudulent* aspect of the complaint focuses on the opacity of the deals and pricing practices.[382] The rebate and spread pricing mechanics disguise the true costs of health care to the detriment of consumers and health plans. As we have seen above, and as the lawsuits underscore, the PBM market in general, and rebates structures specifically, are cloaked in secrecy. The negotiations are confidential, as are the payments made by the drug

[375] Id.

[376] Complaint for Permanent Injunction, Civil Penalties & Other Equitable Relief ¶ 13, California v. Eli Lilly & Co., No. 23STCV00719 (Cal. Super. Ct. Jan. 12, 2023) [hereinafter California Complaint].

[377] Id. ¶ 226.

[378] Id. ¶ 229; see also, e.g., People v. McKale, 602 P.2d 731, 733 (Cal. 1979) (noting that an "unlawful business" practice includes "anything that can properly be called a business practice and that at the same time is forbidden by law" (quoting Barquis v. Merchs. Collection Ass'n, 496 P.2d 817, 830 (Cal. 1972))).

[379] California Complaint, supra note 376, ¶¶ 5, 9, 173.

[380] See Robinson, Pharmacy Benefit Management, supra note 118, at 53–54.

[381] California Complaint, supra note 376, ¶¶ 7–9.

[382] Id. ¶ 231.

companies thereafter to the PBMs. Importantly, under many unfair competition and consumer protection laws, fraudulent business practices include a likelihood of deception, which is broader than actual deception.[383] The California complaint also asserts violations of the Cartwright Act, the state's primary antitrust statute, which generally mirrors federal antitrust law under the Sherman Antitrust Act.[384] This cause of action centers on alleged horizontal coordination by the manufacturers and vertical coordination by the PBMs to maintain their rebate practices and exclude competition. As analyzed in Part II, the structure of oligopolies across the supply chain enables tacit coordination. According to the lawsuit, the three manufacturers have aggressively raised the list price of insulin

> in lockstep with each other to artificial levels. The inflated and artificial insulin price increases have significantly exceeded inflation and are not justified by advances in the efficacy of the drugs or the cost of manufacturing. Insulin costs less than $10 a month to manufacture and its development costs have long been recouped.[385]

Moreover, PBMs can use information they have from their subsidiaries to adjust their pricing demands, placing them in an even stronger position to negotiate ever-higher rebates, engage in spread pricing, and promise manufacturers exclusivity on the formularies. For example, because CVS is vertically integrated across the supply chain, it has unique access to competitive intelligence through its integrated operations.[386] The complaint alleges that CVS's position allows it to monitor competitor behavior, implement price-signaling mechanisms, and adjust its strategies

[383] See, e.g., Thomas A. Papageorge, The Unfair Competition Statute: California's Sleeping Giant Awakens, 4 Whittier L. Rev. 561, 568 (1982) (discussing the "sweeping language" of California's unfair competition statute (citation omitted)).

[384] Cal. Bus. & Prof. Code § 16720 (West 2025). Indeed, Ninth Circuit opinions often analyze Sherman Act and Cartwright Act claims together on the grounds that the analyses "mirror" each other. See, e.g., Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC, 31 F.4th 651, 665 n.8 (9th Cir. 2022) (citing County of Tuolumne v. Sonora Cmty. Hosp., 236 F.3d 1148, 1160 (9th Cir. 2001)).

[385] California Complaint, supra note 376, ¶ 6.

[386] See SmithRx, Unraveling PBM Complexity: The Consequences of Vertical Integration (Mar. 28, 2024), https://smithrx.com/blog/unraveling-pbm-complexity-the-consequences-of-vertical-integration [https://perma.cc/R75G-MHUP] ("Conglomerates are nothing new; CVS is just one example of insatiable corporate appetites. But when this structure is applied to the healthcare system, it does have repercussions that need careful consideration. The consolidation of services under a single corporate umbrella fundamentally alters market dynamics, leading to shifts in competitive balance, pricing, and accessibility of services.").

in ways that would be impossible for a standalone PBM or pharmacy to replicate.[387] This information advantage allegedly facilitates tacit coordination among PBMs and manufacturers in maintaining the rebate wall system.[388]

Similarly, the Texas complaint, filed in October 2024, asserts violations of the Texas Deceptive Trade Practices-Consumer Protection Act, alleging that the PBMs' and insulin manufacturers' practices constitute an unlawful conspiracy.[389] The Texas complaint details how PBMs falsely claim to act on behalf of pharmacies, healthcare providers, and diabetics to lower costs, improve access, and promote diabetic health, while actually colluding with manufacturers to manipulate the market and inflate drug prices.[390] According to the complaint, the manufacturers "artificially and willingly raise[d the prices of insulin] . . . then pa[id] a significant, yet undisclosed, portion of that price back to the PBMs . . . [as a] *quid pro quo* for . . . inclusion on the PBMs' standard offerings."[391] As I analyzed above, the PBMs grant the preferred status to the manufacturer whose drug has the highest list price, excluding lower-priced drugs. The claims about misrepresentation and falsely misleading consumers represent a novel take on consumer fraud. The complaints against the PBMs' role in creating and maintaining artificially inflated list prices describe an indirect form of misrepresentation: the inflated prices represent a starting point to shape market pricing, even if consumers are not the ones that directly negotiate or even witness the pricing schemes.

At the federal level, in 2024 the FTC filed a parallel complaint, which alleges that PBM defendants engaged in anticompetitive and unfair practices and deals with drug manufacturers that inflated the price of insulin, blocked access to more affordable products, and burdened vulnerable patients with the high insulin costs.[392] The FTC's lawsuit's claims also focus on the rebate deals. The FTC's complaint describes the practice of closed formularies, introduced a decade ago, as a *game changer*: "Manufacturers now face[] the significant risk that their products w[ill] be excluded outright from insurance coverage for tens of

[387] California Complaint, supra note 376, ¶¶ 156–158, 163.
[388] Id.
[389] Plaintiff's Original Petition ¶¶ 556–562, 581, Texas v. Eli Lilly & Co., No. D-1-GN-24-007940 (Tex. Dist. Ct. Oct. 3, 2024).
[390] Id. ¶ 8.
[391] Id. ¶ 25.
[392] U.S. Senate Comm. on Com., Sci. & Transp., supra note 128.

millions of patients."[393] The FTC terms the exclusionary act of negotiating preferred or exclusive status on the formularies the "chase-the-rebate strategy."[394]

Several decades ago, Richard Posner highlighted how oligopolies—markets dominated by a small number of firms—can produce anticompetitive outcomes such as higher prices and reduced output, even in the absence of explicit agreements or direct coordination among competitors.[395] Posner called for more aggressive enforcement of Section One of the Sherman Act when there was circumstantial evidence of collusion.[396] Posner critiqued this reliance on proving explicit agreements as overly narrow and disconnected from the economic realities of oligopolistic behavior.[397] As economists have underscored, oligopoly outcomes often mirror those of single monopolies or direct cartels but occur through tacit collusion, where firms independently align their behaviors rather than engage in direct coordination.[398] Posner argued that courts and enforcement agencies place undue emphasis on identifying formal collusion and ignore the structural conditions and market dynamics that enable coordinated behavior without direct

[393] FTC Complaint, supra note 20, ¶ 5.

[394] Id. ¶ 9.

[395] See Richard A. Posner, Oligopoly and the Antitrust Laws: A Suggested Approach, 21 Stan. L. Rev. 1562, 1575–80 (1969) [hereinafter Posner, A Suggested Approach] (arguing that treating explicit and tacit collusion dichotomously has obscured the similarities between the two kinds of anticompetitive behavior); see also Donald F. Turner, The Definition of Agreement Under the Sherman Act: Conscious Parallelism and Refusals to Deal, 75 Harv. L. Rev. 655, 656 (1962) (exploring the legality of "consciously parallel" decisions by a small group of dominant sellers to maintain a high noncompetitive price under the Sherman Act); Richard A. Posner, Oligopolistic Pricing Suits, the Sherman Act, and Economic Welfare: A Reply to Professor Markovits, 28 Stan. L. Rev. 903, 904 (1976) (noting that collusion could conceivably take place without leaving detectable traces of conspiracy or involving any overt communication between competitors). For a discussion of the impact of technology licensing on certain oligopolistic industries, see generally Ted Lindblom, Aineas Mallios & Stefan Sjögren, A Theoretical Analysis of Collusion Involving Technology Licensing Under Diseconomies of Scale, 24 B.E. J. Theoretical Econ. 263 (2024). On tensions between patent law and antitrust law, see generally Mark A. Lemley, The Economic Irrationality of the Patent Misuse Doctrine, 78 Calif. L. Rev. 1599 (1990).

[396] Posner, A Suggested Approach, supra note 395, at 1575.

[397] Id. at 1575–78.

[398] See, e.g., Louis Kaplow, Competition Policy and Price Fixing 183–84 (2013) ("[S]ometimes firms are able to charge coordinated supracompetitive prices (despite the absence of binding agreements), and successful coordinated behavior has been observed . . . . It is not surprising, therefore, that commentators have long offered reasons why firms in an oligopoly setting may indeed be able to sustain coordinated supracompetitive prices.").

communication.[399] This expanded framework of shifting toward evaluating market structure and behavior while considering indirect evidence of collusion, including parallel pricing and market conditions conducive to coordination, should serve as a lens in adjudicating the new lawsuits filed against the pharmaceutical manufacturers and PBMs.

Recognizing the compounded effects of an *oligopoly squared* market, courts should acknowledge that PBMs, in their intermediary role, operate through opaque agreements with other entities in the drug supply chain—creating precisely the kind of conditions that facilitate coordination and collusion. In previous work, I researched how market power should be understood in the aggregate and in relation to other cumulative effects of dominance.[400] I argued that courts need to consider the aggregate effects of collusive arrangements, contract clauses, and practices, which create what I termed "boilerplate collusion."[401] My collaborators and I further showed that the multiplicity and pervasiveness of restrictions in certain industries create an outsized compounded effect of monopolization.[402] Describing practices I termed "contract thicket[s]," I explained that "[u]nderstanding the aggregate effects of contractual arrangements between dominant market actors and individuals—consumers, employees, licensees, and tenants—is key to revamping antitrust policy and competition laws for the twenty-first century."[403] As the new state and federal lawsuits against the pharmaceuticals and PBMs move through litigation, the courts will need to address complex questions involving the application of antitrust and competition laws to multisided markets.[404] As

[399] Posner, A Suggested Approach, supra note 395, at 1575.

[400] See, e.g., Orly Lobel, The Law of the Platform, 101 Minn. L. Rev. 87, 162 (2016) (examining the rise of digital platforms that disrupt stagnant markets); Lobel, Knowledge Pays, supra note 102, at 557 (analyzing how information flow fuels labor market competition); Lobel, Gentlemen Prefer Bonds, supra note 102, at 676 (researching the rise of collusion among technology companies in the market for human capital); Lobel, Boilerplate Collusion, supra note 102, at 883 (researching how the parallel use of similar boilerplate restrictive clauses by competitors aggregates and impedes competition); Bamberger & Lobel, supra note 104, at 1069–70, 1085 (examining how two-sided digital platform models give rise to "category kings" (citation omitted)).

[401] Lobel, Boilerplate Collusion, supra note 102, at 877, 879.

[402] See, e.g., id. at 884–85 (explaining "the externalities and collusive effects of restrictions, such as noncompetes, which reduce mobility in an industry"); Bamberger & Lobel, supra note 104, at 1056–57.

[403] Lobel, Boilerplate Collusion, supra note 102, at 883, 908.

[404] See id. at 881 ("[S]urprisingly little thought has been given to the pervasiveness of identical contract clauses from the perspective of contract theory and, in turn, antitrust law is only now beginning to grapple with these realities as anticompetitive issues."); see also Ohio

intermediaries, the PBMs will assert that the courts must consider competitive effects on both sides of the market—manufacturers and plan providers. In other words, the PBMs will argue before the courts that even if rebates and other practices may harm certain actors along the supply chain—such as healthcare providers and pharmacies—they may increase the benefits to other actors, such as pharmaceutical manufacturers, by providing them with a predictable revenue stream that helps fund the research and development of new insulin formulations. This argument should be rejected.

As we saw in Sections II.B and II.C, PBMs negotiate with manufacturers for rebates that increase based on both volume and formulary exclusivity. The system creates incentives to exclude rather than include additional drugs. The system slows down the entry of generics, which in turn reduces incentives to compete and innovate. These rebates typically contain provisions that condition the highest rebate levels on maintaining preferred or exclusive formulary status.[405] The rebate system creates what has been established in the antitrust scholarly literature as "loyalty discounts" and "disloyalty penalties," where attempting to place a competing product on a formulary would trigger the

v. Am. Express Co., 138 S. Ct. 2274, 2276–77 (2018) (defining two-sided transaction platforms and holding that Amex's anti-steering provisions in its contracts with merchants did not violate federal antitrust law); Cristian Chica, Kenneth Chuk & Jorge Tamayo, Exclusive Dealing and Entry by Competing Two-Sided Platforms 1–2 (Harv. Bus. Sch., Working Paper No. 21-092, 2022) (studying the impact of the availability of both exclusive and nonexclusive contracts on two-sided market outcomes); David S. Evans, The Economic Analysis of Exclusive Contracts in Two-Sided Markets: Federal Trade Commission vs. Surescripts, Revue Concurrences, Mar. 1, 2024, at 1, 1 (Fr.) (analyzing the economic effects of exclusive contracts in two-sided health technology markets); Chris Sagers, Platforms, *American Express*, and the Problem of Complexity in Antitrust, 98 Neb. L. Rev. 389, 389–90 (2019) (arguing that the decision in *American Express* may severely limit antitrust enforcement in the future); John B. Kirkwood, Antitrust and Two-Sided Platforms: The Failure of *American Express*, 41 Cardozo L. Rev. 1805, 1811–13 (2020) (arguing that two-sided platforms can be properly analyzed with traditional methods as long as appropriate sensitivity is given to cross platform effects, anticompetitive conduct, market failure, and market power).

[405] Shepherd, supra note 167, at 377; 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 [https://perma.cc/3433-MZWP] ("Some formularies have as many as seven tiers. In developing a formulary, the PBM negotiates rebates with manufacturers, and rebates are contingent on securing a specific tier for the covered drug.").

loss of rebates.[406] Because rebates are based on a percentage of the list price, the manufacturers raise the list price to provide the highest rebate they can offer PBMs.[407] Meanwhile, generics and biosimilar drugs—drugs that have no clinically meaningful difference from the biologic drug they can replace—are excluded from the preferred tiers of formularies.[408] As Sanofi's Head of General Medicines Market Access admitted, "The narrower the formulary, the greater [the] discount that can be extracted from the manufacturer."[409] The litigation against manufacturers and PBMs represents a significant evolution in pharmaceutical antitrust enforcement, as well as cutting-edge frontiers in understanding competition in complex production chains. This surge of lawsuits highlights the increasing importance of antitrust enforcement in addressing pharmaceutical pricing practices. The actions of state attorneys generals and the FTC complaint demonstrate a willingness to advance novel theories of competitive harm and to challenge established industry practices.

Notably, antitrust enforcement could coincide with direct legislative prohibitions on conglomerate consolidation in health care. The Patients Over Profit legislation, a bipartisan bill that would bar health insurers

[406] See, e.g., Bruce H. Kobayashi, The Economics of Loyalty Discounts and Antitrust Law in the United States, 1 Competition Pol'y Int'l 115, 116 (2005) (applying law and economics principles to analyze loyalty rebates); Daniel A. Crane, Formalism and Functionalism in the Antitrust Treatment of Loyalty Rebates: A Comparative Perspective, 81 Antitrust L.J. 209, 219 (2016) (comparing European and American legal approaches to loyalty rebates); Daniel A. Crane, Bargaining Over Loyalty, 92 Tex. L. Rev. 253, 277–79 (2013) (arguing that loyalty agreements can be either anticompetitive or procompetitive depending on the circumstances); Richard A. Epstein, Monopoly Dominance or Level Playing Field? The New Antitrust Paradox, 72 U. Chi. L. Rev. 49, 68 (2005) (arguing that bundled rebates should be analyzed as exclusive dealing); Willard K. Tom, David A. Balto & Neil W. Averitt, Anticompetitive Aspects of Market-Share Discounts and Other Incentives to Exclusive Dealing, 67 Antitrust L.J. 615, 615 (2000) (arguing that market-share discounts are exclusive dealings); Andrew I. Gavil, Exclusionary Distribution Strategies by Dominant Firms: Striking a Better Balance, 72 Antitrust L.J. 3, 24 (2004) (analyzing loyalty discounts as vertical control devices).

[407] Press Release, U.S. Senate Comm. on Fin., Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs that Keep Prices High (Jan. 14, 2021), https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-insulin-investigation-uncovering-business-practices-between-drug-companies-and-pbms-that-keep-prices-high [https://perma.cc/V3KU-ZWEL].

[408] Laura Joszt, Margaret Rehayem: Rebates Remain Influential and a Barrier to Biosimilar Adoption for Employers, at 01:58 (AJMC TV, Apr. 28, 2023), https://www.ajmc.com/view/margaret-rehayem-rebates-remain-influential-and-a-barrier-to-biosimilar-adoption-for-employers [https://perma.cc/D3WA-SCAU].

[409] FTC Complaint, supra note 20, ¶ 114.

from owning or controlling healthcare providers under Medicare, thus requiring divestment of vertically integrated entities, was introduced in 2025.[410] Targeting conglomerates like UnitedHealth's Optum, the bill seeks to curb the kinds of conflicts of interest that are seen throughout this analysis and to restore competition in healthcare supply chains, although in its current form, the bill leaves PBM-pharmacy consolidation untouched.[411]

B. Cat-and-Mouse Evasion

Nearly a decade ago, anticipating the surge in public scrutiny over their activities, the three dominant PBMs created overseas entities. In 2020, CVS created a subsidiary entity, a "group purchasing organization" ("GPO") named Zinc Health Services, and charged it with the task of negotiating the rebates with the drug manufacturers.[412] The two other dominant PBMs quickly followed suit. Express Scripts established Ascent Health Services, and Optum Rx founded Emisar Pharma Services.[413] Each of these GPOs was founded outside the United States: two in Ireland and one in Switzerland.[414] These GPOs—Zinc, Ascent, and Emisar—now perform the same commercial contracting function that the PBMs had performed directly.[415] The PBMs also created companies in Ireland and the Cayman Islands to manufacture and market certain generics and biosimilars.[416] As a congressional report describes, these overseas locations are considered especially desirable to corporations for their lack of financial transparency.[417]

The pharmaceutical and PBM industries have been adept at finding legal loopholes and deploying novel anticompetitive tactics. They are

[410] Patients Over Profit Act, S. 2836, 119th Cong. (2025).

[411] Id.

[412] FTC Complaint, supra note 20, ¶ 17.

[413] Id. ¶¶ 22, 27.

[414] Deborah Abrams Kaplan, PBMs Are Creating GPOs, and Stirring Debate as to Why, Managed Healthcare Exec., July 2022, at 21, 21 ("In 2019, Express Scripts PBM . . . formed Ascent Health Services GPO . . . , based in Switzerland. In 2020, CVS Caremark formed Zinc GPO. And in 2021, OptumRx formed Emisar Pharma Services, based in Ireland.").

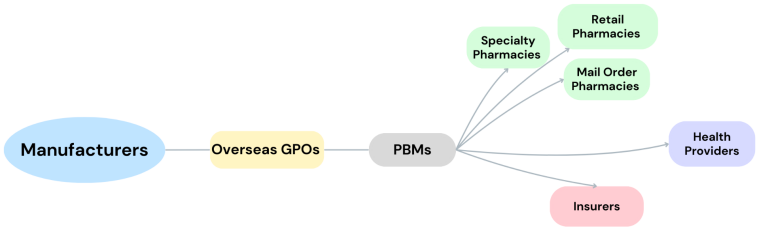
[415] Id.

[416] Adam J. Fein, What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars, Drug Channels Inst. (Sept. 6, 2023), https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html [https://perma.cc/7UYQ-CKK2].

[417] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 4 (describing companies formed by PBMs in Ireland and the Cayman Islands as "entities in locations well known for their lack of financial transparency and movement of operations").

now proving to be adept in relocating major functions into subsidiaries that are offshored. Relying solely on antitrust enforcement risks is, at best, a reactive and piecemeal solution that documents these practices after they have occurred. Moreover, antitrust litigation is notoriously slow and resource-intensive, often taking years to resolve.[418] During this time, consumers continue to face exorbitant prices, and the market remains uncompetitive. Antitrust lawsuits typically target specific practices or companies rather than address the broader structural issues in the pharmaceutical market. While litigation may result in fines or behavioral remedies, it does not necessarily foster competition or reduce prices in the long term. The lawsuits are important for bringing public attention to the issue and preventing some of the most egregious practices from continuing. They also serve as a good complement to legislative reforms, exposing the limits of existing competition and consumer protection laws. Yet, beyond litigation and legislative reforms, systemic changes are necessary to encourage new entry across the pharmaceutical supply chain in order to unsettle the *oligopoly squared* structures.

Figure V. Extended Chain of Drug Delivery



As the next Part illustrates, public and nonprofit production models represent a more radical departure from traditional market-based approaches. New strategies proactively restructure the market to reduce the opportunities for collusive behavior. By establishing government- or mission-driven entities capable of pharmaceutical drug production and delivery, these strategies seek to introduce a fundamentally alternative production paradigm and bypass profit-driven pricing actors and strategies.

[418] Tim Wu, The Curse of Bigness: Antitrust in the New Gilded Age 51 (2018).

V. MARKET DISRUPTION STRATEGIES

A. Direct Distribution Pharmacies: Removing the Middleman

"Everyone should have safe, affordable medicines with transparent prices."

- Mark Cuban[419]

New markets to disrupt the dominance and controls of PBMs are emerging. In 2022, billionaire entrepreneur Mark Cuban launched Cost Plus Drugs, a national drug distribution company designed to cut off the middleman, that is, the dominant PBMs.[420] According to Cuban, he received a cold email pitch from radiologist Alex Oshmyansky, in which he asked Cuban to invest in a pharmacy envisioned to skip the middleman wholesalers.[421] This new pharmacy model offers more straightforward and cost-effective alternatives. Like traditional PBMs, Cost Plus provides employers, insurers, and plan sponsors with prescription drug benefit services. However, it differs by employing transparent contracts, fair copays, frequent audit opportunities, and full pass-through of rebates.

In this model, Cost Plus bypasses the traditional PBMs and directly negotiates with drug manufacturers, setting prices based on production costs.[422] In other words, Cost Plus, as a direct mail pharmacy, serves as its own PBM, separate from the traditional models, to negotiate without distorting retail or wholesale prices.[423] In doing so, Cost Plus is able to substantially reduce the cost of prescription medications by eliminating the hidden fees and markups typically associated with PBM-managed

[419] Cost Plus Drugs Co., https://www.costplusdrugs.com/ [https://perma.cc/2275-7QMD] (last visited Nov. 4, 2025) (attributing the quote to Mark Cuban).

[420] See Ramez Kouzy, Molly B. El Alam, Kelsey L. Corrigan, Hussain S. Lalani & Ethan B. Ludmir, Patient-Level Savings on Generic Drugs Through the Mark Cuban Cost Plus Drug Company, JAMA Health F., June 14, 2024, at 1, 1 (estimating the out-of-pocket cost savings patients could achieve if generic drugs were purchased directly from the Mark Cuban Cost Plus Drug Company rather than through the use of their health insurance).

[421] Corin Cesaric, How Mark Cuban's Online Pharmacy Plans to Make Medications Affordable, NBC Chi. (Apr. 15, 2022, 11:53 AM), https://www.nbcchicago.com/news/health/how-mark-cubans-online-pharmacy-plans-to-make-medications-affordable/2807435/ [https://perma.cc/BN3C-JNJJ].

[422] Id.

[423] See Wall Street Journal, How Mark Cuban Is Trying to Disrupt Big Pharma, at 03:18 (YouTube, May 11, 2022), https://www.youtube.com/watch?v=qw2nx-I-jAA [https://perma.cc/L4RZ-TBL2] (short video on Mark Cuban Cost Plus).

drug distribution. Cost Plus's pricing structure is set by adding a standard fifteen percent markup on the production cost, a pharmacy labor fee of five dollars, and a shipping charge of five dollars.[424] For example, the leukemia drug Imatinib, which costs approximately between $2,000 and $8,000 at conventional pharmacies, is priced between $13.18 and $93.49, depending on tablet quantity and strength.[425] By 2023, Cost Plus expanded its inventory to over one thousand generic medications, offering savings on widely used drugs, such as those for diabetes and cholesterol management.[426] Additionally, Cost Plus has expanded vertically by building a manufacturing facility in Dallas to oversee drug production and distribution under its own brand.[427]

The company's mission is straightforward: to offer generic prescription drugs at transparent and significantly lower prices.[428] Intrinsic to this mission is its focus on serving the uninsured and underinsured.[429] According to some estimates, Medicare plan savings from using the model are over three billion dollars for a subset of seventy-seven generic drugs.[430] A 2024 economic analysis estimated the individual patient out-of-pocket cost savings of prescription pharmacy fills at 11.8% among 124 generic drugs.[431] The median estimated cost savings per prescription was $4.96 ($1.95–$11.39) while savings were highest for uninsured individuals at $6.08 ($1.87–$10.38).[432] Still, the analysis concludes that

[424] Joshua P. Cohen, Mark Cuban's Cost Plus Drugs Sparks Others to Change How Rx Meds Are Priced, Forbes (Jan. 2, 2024, 3:29 PM), https://www.forbes.com/sites/joshuacohen/2024/01/02/mark-cubans-cost-plus-drug-company-sparks-moves-to-change-how-rx-drugs-are-priced/.

[425] Imatinib (Generic for Gleevec), Cost Plus Drugs Co., https://costplusdrugs.com/medications/imatinib-100mg-tablet/ [https://perma.cc/UP54-XPJY] (last visited Nov. 4, 2025).

[426] Medications, Cost Plus Drugs Co., https://www.costplusdrugs.com/medications/ [https://perma.cc/MJM9-MP2J] (last visited Nov. 4, 2025) (indicating that Cost Plus Drugs has an inventory of over one thousand generic medications, offering savings on widely used drugs, including those for diabetes and cholesterol management).

[427] Heather Landi, Mark Cuban Says Cost Plus Drugs Targeting Generic Meds in Short Supply as It Opens Manufacturing Facility, Fierce Healthcare (Mar. 4, 2024, 6:00 PM), https://www.fiercehealthcare.com/health-tech/mark-cuban-says-cost-plus-drugs-has-couple-million-patients-2500-generic-drugs-it-moves.

[428] See Our Mission, Cost Plus Drugs Co., https://www.costplusdrugs.com/mission/ [https://perma.cc/6VTT-SV5Y] (last visited Nov. 4, 2025).

[429] Id.

[430] Kouzy et al., supra note 420, at 1.

[431] Id.

[432] Id.

> [w]ith generic drugs constituting 90% of all dispensed prescriptions, some patients can benefit from a transparent cost-plus pharmacy pricing model; however, for most, it is less expensive to use their health insurance benefits. Although [Cost Plus] sells most common generic drugs, only 26% of expensive generic drugs were available in May 2023.[433]

Several additional new studies empirically evaluate the cost-saving potential of such an alternative sourcing strategy. One study, with a specific focus on medications frequently prescribed within otolaryngology and utilizing Medicare Part D prescription data, identified the most commonly prescribed drugs in this specialty by filtering data based on prescriber type.[434] The selected medications were assessed for their availability on the Cost Plus platform, ensuring consistency in dosage forms to facilitate a robust comparison. The findings show substantial cost-saving opportunities. For otolaryngology alone, the researchers estimate that the adoption of Cost Plus prices could yield savings of $55.6 million annually.[435] Extrapolating this model across all medical specialties suggests a transformative potential for Medicare, with projected savings exceeding $1 billion.[436] These estimates are promising, suggesting the need for policy reforms that will support and scale such disruptive models competing within the current web of healthcare supply chains.

Cost Plus operates on a unique pricing model that underscores its commitment to transparency. As described above, the company sells medications at the actual cost of production, as determined by the manufacturer, adding a fixed fifteen percent markup and a pharmacy fee of five dollars.[437] This model starkly contrasts with the traditional system, where pricing involves a complex interplay of manufacturer rebates, PBM negotiations, and pharmacy pricing discretion, often leaving consumers

[433] Id. at 3.

[434] Zachary Buxo & John D. Cramer, Potential Cost-Saving Model Utilizing Mark Cuban Cost Plus Drug Company for Purchasing Common Otolaryngology Medications, 172 Otolaryngology—Head & Neck Surgery 693, 693 (2025).

[435] Id. at 695.

[436] Id.

[437] Cohen, supra note 424; Heather Landi, Mark Cuban Wants to Keep Shaking Up Healthcare. Here's Cost Plus Drug's Next Move, Fierce Healthcare (Aug. 15, 2024, 7:00 AM), https://www.fiercehealthcare.com/health-tech/mark-cuban-wants-keep-shaking-healthcare-heres-cost-plus-drugs-next-move.

unaware of the true cost of their medications.[438] By eliminating middlemen and publishing drug prices openly on its website, Cost Plus aims to empower consumers and reduce reliance on high-deductible insurance plans for affordable prescriptions. While these savings have made Cost Plus a viable alternative for many uninsured or underinsured patients, its limitations have also been noted. The company currently does not accept insurance, which means consumers must pay out of pocket and cannot apply purchases toward insurance deductibles.

Other such initiatives are underway. New private initiatives, collectively referred to as *transparent PBMs*, that take a similar approach to Mark Cuban's Cost Plus are on the rise. Instead of generating revenue from rebates or price markups, transparent PBMs primarily rely on flat administrative fees, eliminating conflicts of interest that often inflate prescription costs. This approach enables them to negotiate effectively with drug manufacturers, resulting in significant savings for patients. Armed with improved transparency, data access, and the ability to audit PBMs, payers can verify that they are avoiding hidden fees and fully benefiting from promised cost savings.[439] For example, SmithRx, founded in 2023, commits to a radically transparent, one hundred-percent pass-through model to secure the lowest-cost drugs possible for businesses and their employees.[440] Transparency-Rx, a coalition of transparent PBMs, reports savings of 163% on high blood pressure and heart medications, 184% on Type 2 diabetes drugs, and 195% on statins compared to traditional PBMs.[441] The coalition describes itself "[a]s a counterweight to the status-quo . . . confront[ing] stale and dated ideas, tak[ing] on corporate monopolies, and especially big PBMs and the insurance lobby."[442] The coalition contends that

> [f]or too long, these special interests have been the lone and loudest voice fighting against real policy changes on drug pricing and health care, protecting a broken system which hides profits and inflates

[438] See supra Section II.B.

[439] Staff of H. Comm. on Oversight & Accountability, supra note 85, at 26.

[440] SmithRx Introduces New PBM Evaluation Methodology Optimized for Drug Cost Savings, Bus. Wire (June 27, 2024, 5:41 PM), https://www.businesswire.com/news/home/20240627026506/en/SmithRx-Introduces-New-PBM-Evaluation-Methodology-Optimized-for-Drug-Cost-Savings [https://perma.cc/TDG6-5GB5].

[441] Transparency-Rx, https://transparency-rx.com/ [https://perma.cc/RW3X-P8LH] (last visited Oct. 9, 2025).

[442] Id.

> prescription costs, harming the interests of diverse communities, working families, and seniors. Just as transparency offers a better way to managing prescription drug benefits, Transparency-Rx represents a step forward to sound policy solutions, galvanizing true affordable prices.[443]

Cost Plus and other transparent, direct-to-patient PBMs have spurred broader conversations about pharmaceutical delivery reform. In 2022, then-FTC Chair Lina Khan delivered a powerful speech about the pharmaceutical market in which she stated, "There is nothing inevitable about the current structure of the market or the current business practices that occur and are permitted."[444] Since then, these new models have emerged, demonstrating that the traditional model is indeed not inevitable. The success, as well as limits, of the private initiatives highlight the discontent with the existing system while demonstrating the feasibility of alternative pricing structures. Whether the Cost Plus model can scale effectively remains uncertain, but its impact in challenging the status quo of prescription drug pricing is undeniable. The initiatives represent not only business innovations but also potential catalysts for more systematic equitable healthcare policies in the United States. These private alternative disruptive models require support by public reforms. They are further complemented by the revolutionary initiative of public manufacturing—StateRx—and the public-private governance models of drug development and delivery discussed in the next Section.

B. StateRx: Public Production

"What this does . . . is a game changer. This fundamentally lowers the cost. Period. Full stop."

- California Governor Gavin Newsom[445]

[443] Id.

[444] Lina M. Khan, Chair, Fed. Trade Comm'n, Remarks Before the American Economic Liberties Project and the National Community Pharmacists Association 3 (June 22, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Remarks-Lina-Khan-Economic-Liberties-National-Community-Pharmacists-Association.pdf [https://perma.cc/SWQ7-JCV9].

[445] Emma Bowman, California Enters a Contract to Make Its Own Affordable Insulin, NPR (Mar. 19, 2023, 2:16 PM) (internal quotation marks omitted), https://www.npr.org/2023/03/19/1164572757/california-contract-cheap-insulin-calrx [https://perma.cc/B3MG-Q5ZY].

A decade ago, insulin became so expensive that an entire community of do-it-yourself actors emerged, producing their own insulin outside the pharmaceutical industry.[446] In 2015, the Open Insulin Project was launched to develop a patent-free method for producing insulin, aiming to share the knowledge publicly.[447] The founders of the project, a team of biohackers, have been working on developing practical, small-scale, community-centered models for insulin production, collaborating with community biolabs in cities worldwide.[448] The team is working with cities and countries around the world, including Oakland, California, and Paris, France.[449] These grassroots efforts have inspired a greater revolution: now the action is moving to government-sponsored production.

California was the first state to launch a public-sector initiative aimed at producing prescription drugs.[450] On his first day in office in 2019, Governor Gavin Newsom signed an executive order to lower the cost of prescription drugs by leveraging California's market power.[451] The following year, the California Affordable Drug Manufacturing Act of 2020 was signed into law, establishing the CalRx program for the production and distribution of generic medications at affordable rates.[452] California chose insulin to be the first flagship drug of the program and has allocated fifty million dollars for the development of biosimilar insulin and an additional fifty million dollars to establish a state-based manufacturing facility.[453] The state invited forty stakeholders from four

[446] See Jenna E. Gallegos & Jean Peccoud, After a Century, Insulin Is Still Expensive—Could DIYers Change That?, The Conversation (Sept. 13, 2018, 10:32 AM), https://theconversation.com/after-a-century-insulin-is-still-expensive-could-diyers-change-that-99822 [https://perma.cc/6YZK-EXLZ] (arguing that by operating outside of the regulatory controls, patient do-it-yourself initiatives could lower insulin prices).

[447] Jenna E. Gallegos, Christopher Boyer, Eleanore Pauwels, Warren A. Kaplan & Jean Peccoud, The Open Insulin Project: A Case Study for 'Biohacked' Medicines, 36 Trends Biotechnology 1211, 1211–12 (2018).

[448] Id.

[449] Open Insulin Found., https://openinsulin.org/ [https://perma.cc/6AMA-D4G4] (last visited Oct. 29, 2025).

[450] California Enacts Law to Produce Generic Prescription Drugs, Nat'l Acad. for State Health Pol'y (Oct. 5, 2020), https://nashp.org/california-enacts-law-to-produce-generic-prescription-drugs [https://perma.cc/LZD5-NRLZ].

[451] Press Release, Off. of Governor Gavin Newsom, Governor Newsom Announces $30 Insulin Through CalRx (Mar. 18, 2023) [hereinafter $30 Insulin Through CalRx Press Release], https://www.gov.ca.gov/2023/03/18/governor-newsom-announces-30-insulin-through-calrx/ [https://perma.cc/F3KJ-TS8V].

[452] S.B. 852, 2020 Leg., Reg. Sess. (Cal. 2020).

[453] CalRx, https://calrx.ca.gov/ [https://perma.cc/RH82-TMRH] (last visited Oct. 9, 2025); see also Molly Grammel, CA Gov. Newsom Announces Budget Approval for Biosimilar

groups—patient advocates, healthcare providers, health insurers, and health policy / economic experts—to aid in ranking criteria for prioritizing drugs to be manufactured, drawing from academic research and public health reports, including pricing, spending, and public health impact.[454] The results of the study identified a need to prioritize drugs that serve large populations and carry high costs for payers and consumers.[455] In 2022, another bill was passed to prioritize the selection of generic drugs that have the greatest impact on consumers to lower costs and address shortages in the market.[456]

In March 2023, California officially contracted with Civica Rx under the CalRx program to set the cost of state-label insulins to no more than thirty dollars per ten-milliliter vial, and no more than fifty-five dollars per box of five pre-filled pen cartridges.[457] Founded in 2018 in Utah, Civica Rx is a nonprofit organization, funded through philanthropy and public grants, aiming to make essential medicines affordable and available, specifically by producing generic drugs in the face of supply shortages and access barriers.[458] For California's CalRx Biosimilar Insulin Initiative, Civica Rx planned to start production by 2024 at its 140,000-square-foot facility in St. Petersburg, Virginia, in collaboration with GeneSys Biologics, to develop three insulin biosimilars.[459] The facility has the capacity to produce ninety million vials and fifty million pre-filled

Insulin Initiative, Goodwin: Big Molecule Watch (July 13, 2022), https://www.bigmoleculewatch.com/2022/07/13/ca-gov-newsom-announces-budget-approval-for-biosimilar-insulin-initative/ [https://perma.cc/E3UU-996J].

[454] Mariana P. Socal et al., Developing Prioritization Criteria to Identify Target Drugs for CalRx, the California Generic Drugs Initiative, 26 Value Health 634, 635 (2023).

[455] See id. at 634 (describing the results of the study and proposing a more detailed ranking algorithm that will aid further development and inform public decisions to expand the CalRx model beyond insulin).

[456] Benjamin Ryan, California's Plan for Cheaper Insulin Collides with Big Pharma's Price Cuts, N.Y. Times (Mar. 24, 2023), https://www.nytimes.com/2023/03/24/health/insulin-prices-california.html; Ned Oliver, Utah-Based Nonprofit Set to Open $140M Insulin Plant in Petersburg, Axios Rich. (Feb. 8, 2023), https://www.axios.com/local/richmond/2023/02/08/petersburg-insulin-plant-nonprofit-prices [https://perma.cc/36VD-NTF4]; Bowman, supra note 445.

[457] Bowman, supra note 445.

[458] Dan Liljenquist, Ge Bai, Ameet Sarpatwari & Gerard F. Anderson, A Non-Profit Approach to Address Foreign Dependence of Generic Drugs, 49 J.L. Med. & Ethics 30, 33 (2021) (stating that support comes from philanthropic organizations, including Arnold Ventures, the Helmsley Charitable Trust, and others).

[459] Fact Sheet, CalRx 3, 4 [hereinafter CalRx Fact Sheet], https://calrx.ca.gov/uploads/2023/03/CalRx-Fact-Sheet.pdf [https://perma.cc/UPK8-4559] (last updated Mar. 17, 2023).

pens.[460] Civica Rx plans to file applications with the FDA for the approval of its biosimilar insulin products.[461] Unlike traditional pharmaceutical pricing models, CalRx's pricing model sets prices based on actual costs of production, development, and distribution.[462] A ten-milliliter vial of insulin, which typically retails for over three hundred dollars, will be priced at no more than thirty dollars, while a five-pack of insulin pens, which typically retails for over five hundred dollars, will cost no more than fifty-five dollars.[463] As we saw in the previous Sections, these prices represent a fraction of the current retail costs, providing a much-needed lifeline to millions of Americans who rely on insulin to manage diabetes.

Over the next few years, CalRx aims to bring to market the three most popular insulin products—Glargine, Aspart, and Lispro—under a CalRx-branded label.[464] These products will be available in pharmacies and through mail orders without the need for insurance coverage.[465] The state-led initiative targets not only price reduction, but also market disruption, by bypassing the traditional pricing structures led by the PBMs and their rebate system.[466] Civica Rx is committed to directly selling "its insulins to all consumers at single, low transparent prices, which aligns with the State's goals to ensure affordable insulins exist in the market."[467] Once CalRx's insulin is approved by the FDA, it will be made available at local pharmacies and retail outlets throughout California, ensuring that no

[460] Oliver, supra note 456.

[461] Medications, Civica Rx, https://civicarx.org/medications [https://perma.cc/4RBJ-PF77] (last visited Oct. 9, 2025) ("Our packaging line is fully compliant with the FDA's Drug Supply Chain Security Act . . . . Approximately three dozen Abbreviated New Drug Applications . . . are now in development.").

[462] CalRx, supra note 453.

[463] $30 Insulin Through CalRx Press Release, supra note 451 (stating that these prices lower the price of insulin by about 90%, which "sav[es] cash-paying patients between $2,000 and $4,000 annually").

[464] State of Cal., Cal. Health & Hum. Servs. Agency & Dep't of Health Care Access & Info., CalRx Status Update: Initial Progress Under the California Affordable Drug Manufacturing Act 4 (2023), https://calrx.ca.gov/uploads/2023/05/CalRx-Legislative-Report-Initial-Progress-Under-the-California-Affordable-Drug-Manufacturing-Act-April-2023.pdf [https://perma.cc/Q77J-5S4N].

[465] CalRx Fact Sheet, supra note 459, at 3; CalRx, supra note 453 (no insurance requirement).

[466] Audrey Stienon, Public Pharma's Biggest Barrier, Am. Prospect (Jan. 5, 2024), https://prospect.org/health/2024-01-05-public-pharmas-biggest-barrier/ [https://perma.cc/E65S-MPGX].

[467] CalRx Fact Sheet, supra note 459, at 3.

additional barriers—such as eligibility requirements or application processes—stand in the way of access.[468]

The history of government manufacturing of biologics can be traced to the late nineteenth and early twentieth centuries, when governments began producing vaccines in response to public health crises such as smallpox and diphtheria.[469] The tetanus contamination scandal triggered a debate about government intervention by way of regulation or production.[470] In 1901, a tragic incident in St. Louis, Missouri, resulted in the deaths of thirteen children who contracted tetanus from contaminated diphtheria antitoxin.[471] This incident, along with a similar tragedy involving contaminated smallpox vaccines in Camden, New Jersey,[472] underscored the critical need for federal regulation of biological products. The events catalyzed the enactment of the Biologics Control Act of 1902, marking the beginning of systematic government oversight in manufacturing biologics to ensure their safety and efficacy.[473] The federal government also played a critical role in the mass production of penicillin during World War II. While Alexander Fleming discovered penicillin in 1928, it was not widely available until the U.S. War Production Board coordinated large-scale production methods through federal labs and private pharmaceutical companies.[474] The government funded and managed the development of fermentation techniques that allowed penicillin to be manufactured in quantities sufficient for widespread use among Allied forces.[475] More recently, government entities have played

[468] $30 Insulin Through CalRx Press Release, supra note 451; CalRx, supra note 453 (outlining availability at retail outlets).

[469] Terry S. Coleman, Early Developments in the Regulation of Biologics, 71 Food & Drug L.J. 544, 547–48 (2016) (describing the early efforts of the New York City Board of Health in producing and distributing vaccines for these diseases).

[470] Id. at 549–50.

[471] David E. Lilienfeld, The First Pharmacoepidemiologic Investigations: National Drug Safety Policy in the United States, 1901–1902, 51 Persps. Biology & Med. 188, 192–93 (2008).

[472] See José Esparza, Seth Lederman, Andreas Nitsche & Clarissa R. Damaso, Early Smallpox Vaccine Manufacturing in the United States: Introduction of the "Animal Vaccine" in 1870, Establishment of "Vaccine Farms", and the Beginnings of the Vaccine Industry, 38 Vaccine 4773, 4775 (2020) (noting that tetanus contamination incidents in 1901 led to the promulgation of the Biologics Control Act of 1902).

[473] Lilienfeld, supra note 471, at 195–96.

[474] See Peter Neushul, Science, Government, and the Mass Production of Penicillin, 48 J. Hist. Med. & Allied Scis. 371, 372–73, 395 (1993) (examining the role of government initiatives in mass producing insulin during World War II).

[475] Id. at 371–73.

critical roles in accelerating biologics development in response to emerging infectious diseases, such as HIV and COVID-19.[476] This historical trajectory highlights the vital role of the government in fostering innovation, ensuring safety, and addressing market failures in drug and vaccine development and manufacturing. However, to date, these efforts have focused on vaccines and treatments for infectious diseases in states of emergency. Now, California is spearheading a far more systematic generic drug production effort without the pressure of an emergency outbreak or pandemic.

A few states are vying to follow in California's footsteps. Washington has authorized the development of a program for the public manufacturing of generic drugs.[477] Emulating the California model, it created a program in 2021 to partner with other states for public production of insulin and generic prescription drugs.[478] Maine created a bipartisan committee in 2022 to look into creating a similar program to publicly produce insulin.[479] New York and Illinois have introduced bills looking at producing generic prescription drugs.[480] In Michigan, lawmakers have also shown interest in pursuing this type of project.[481] At

[476] See Richard G. Frank, Leslie Dach & Nicole Lurie, It Was the Government that Produced COVID-19 Vaccine Success, Health Affs. Blog (May 14, 2021), https://www.healthaffairs.org/content/forefront/government-produced-covid-19-vaccine-success (describing the role of government in COVID-19 vaccine development).

[477] See Scott, supra note 36; see also Wash. State Health Care Auth., supra note 267, at 3–4, 6 (detailing the efforts of the state work group to reduce the cost of insulin and provide supply to individuals on an emergency basis).

[478] See Wash. State Health Care Auth., supra note 267, at 3–4.

[479] Scott, supra note 36; see also Letter from Jeanne M. Lambrew, Comm'r, Me. Dep't of Health & Hum. Servs., to Sen. Joseph Baldacci, Rep. Michele Meyer & Joint Standing Comm. on Health & Hum. Servs. (Feb. 17, 2023), https://www.legislature.maine.gov/doc/9743 [https://perma.cc/57TD-PDM3] (articulating the committee's task); Cristobal G. Alvarado & Sebastian E. Alvarado, Economic Impact Assessment of Production of Generic Insulin 5–14 (2023), https://legislature.maine.gov/doc/9820 [https://perma.cc/SFQ5-2CAD] (providing the Economic Impact Assessment for producing insulin in Maine).

[480] Arden Parrish, Opinion: The Insulin Crisis Is Far from Over. Public Pharma Could Be the Solution, Hartford Courant (Sept. 15, 2024, 5:00 AM), https://www.courant.com/2024/09/15/opinion-the-insulin-crisis-is-far-from-over-public-pharma-could-be-the-solution/; Press Release, N.Y. State Senate, New York Senate Passes Legislation to Make Prescription Drugs, Healthcare More Affordable and Accessible (May 20, 2025), https://www.nysenate.gov/newsroom/press-releases/2025/new-york-senate-passes-legislation-make-prescription-drugs-healthcare [https://perma.cc/675W-4SCU].

[481] See Scott, supra note 36; Press Release, Off. of Governor Gretchen Whitmer, Whitmer Signs Executive Directive Aimed at Lowering Costs, Manufacturing Insulin in Michigan (Oct. 3, 2022), https://www.michigan.gov/whitmer/news/press-releases/2022/10/03/whitmer-signs-executive-directive-aimed-at-lowering-costs [https://perma.cc/B2QU-78WU]. State

the federal level, Senator Elizabeth Warren and Congresswoman Jan Schakowsky introduced the Affordable Drug Manufacturing Act, proposing the creation of an Office of Drug Manufacturing within the Department of Health and Human Services to produce select generic drugs.[482] Like CalRx, this initiative aims at boosting generic competition in manufacturing to directly reduce drug prices.

At the global level, some governments have successfully entered the public production process of pharmaceuticals, suggesting the sustained potential of the CalRx initiative.[483] In Sweden, Apotek Produktion and Laboratorier is a public pharmaceutical manufacturer and one of the largest manufacturers in Europe for specialty medications.[484] Sweden publicly produced products sold in thirty-five countries, including the United States.[485] Each year, this public producer and Sweden's public pharmacy pay a dividend to the Swedish people as their only shareholder.[486]

Public manufacturing provides a safety net for critical medications, ensuring stability in supply and affordability in the face of future health crises and prioritizing drugs where market failures are most evident, such

production of insulin would align with Michigan's historical practice. Michigan produced vaccines through the Michigan Biologic Products Institute, which was run by the Michigan Department of Community Health until 1998. See Judith Miller, Company Led by Top Admiral Buys Michigan Vaccine Lab, N.Y. Times, July 8, 1998, at A19. And while the labs finally became privatized in 1998, Michigan's prior ability to produce biologics is recognized as a viable model. See, e.g., Robin Erb, With Insulin Costs Rising, Michigan Plots Early Steps to Produce Its Own, Bridge Mich. (Oct. 10, 2022), https://bridgemi.com/michigan-health-watch/insulin-costs-rising-michigan-plots-early-steps-produce-its-own [https://perma.cc/6SA6-T722] ("The idea of manufacturing drugs within a state-funded facility in Michigan is not without precedent: Michigan opened a facility to produce diphtheria vaccines in the 1920s, later expanding production to vaccines that protected against typhoid, tetanus, rabies and anthrax . . . .").

[482] Affordable Drug Manufacturing Act of 2023, S. 3398, 118th Cong. (2023); Press Release, Off. of Sen. Elizabeth Warren, Senator Warren, Representative Schakowsky Reintroduce Bicameral Affordable Drug Manufacturing Act (Dec. 5, 2023), https://www.warren.senate.gov/newsroom/press-releases/senator-warren-representative-schakowsky-reintroduce-bicameral-affordable-drug-manufacturing-act [https://perma.cc/XD6X-4XW6].

[483] See generally Dana Brown, Public Pharmaceuticals: Public Pharmaceutical Enterprises Are Developers, Manufacturers, and Distributors Owned by the Public, Rather than by Private Shareholders., Next Sys. Project (Oct. 2, 2020), https://thenextsystem.org/learn/stories/public-pharmaceuticals [https://perma.cc/BH3U-R6J4] (describing the benefits and challenges of incorporating public pharmaceutical development and manufacturing into national healthcare markets and providing Cuba and Sweden as successful examples of such incorporation).

[484] Id.

[485] Id.

[486] Id.

as insulin, cancer treatments, and antibiotics. These new initiatives directly disrupt monopolistic pricing power rather than merely regulating or litigating it. The public manufacturing model serves as a proactive intervention, offering a systemic solution to the entrenched problems of highly concentrated markets. By fostering competition, ensuring affordability, and addressing structural inequities, this approach lays the groundwork for a more resilient and equitable healthcare system.

The CalRx initiative can catalyze similar initiatives and lead the way to more accessible healthcare manufacturing and delivery models. Despite its promise, public or not-for-profit production models face several challenges. As analyzed throughout this Article, legal reforms are necessary to support and enable public manufacturing to operate effectively within the existing regulatory framework, including expedited approval processes for publicly produced generics and biosimilars. As discussed in Section I.D, biosimilar insulin is very similar, but not identical, to an original biologic product approved by the FDA.[487] The insulins will need to gain FDA approval, which can be a lengthy and costly process, potentially delaying their market entry by at least two years.[488]

These obstacles have had a material impact on the CalRx program. Despite Governor Newsom's promise of a 2024 delivery for publicly produced insulin in California, there is no date certain for its delivery.[489] In fact, the American Diabetes Association stated that the project is more than a year behind schedule with no end in sight—Californians could be waiting until 2030 or beyond to receive publicly produced insulin.[490] This production delay will have significant drawbacks, especially considering

[487] See Biosimilar Insulin Initiative, CalRx, https://calrx.ca.gov/biosimilar-insulin-initiative/ [https://perma.cc/3M2X-XYJA] (last visited Oct. 9, 2025) (describing California's initiative to manufacture affordable insulin).

[488] See Ryan, supra note 456 (suggesting that private pharmaceutical companies' lowering of insulin prices may undercut the California initiative to publicly manufacture and deliver insulin).

[489] Shortly before this Article went to press, Governor Gavin Newsom announced that the CalRx insulin pens "will be available to consumers in California beginning January 1, 2026." Press Release, Off. of Governor Gavin Newsom, Governor Newsom Announces Affordable CalRx Insulin, $11 a Pen, Will Soon Be Available for Purchase (Oct. 16, 2025), https://www.gov.ca.gov/2025/10/16/governor-newsom-announces-affordable-calrx-insulin-11-a-pen-will-soon-be-available-for-purchase/ [https://perma.cc/G8D3-4J2J].

[490] Senate Standing Committee on Budget and Fiscal Review, at 11:30–13:13 (Digital Democracy, Feb. 19, 2025), https://calmatters.digitaldemocracy.org/hearings/258513?t=740&f=432c924b0ae1af8bdcd4a0ab7a227014.

unforeseeable challenges to the regulatory process, as well as a potential clinical trial. Further, there have been no updates on the Civica Rx manufacturing facility, also promised in Newsom's CalRx initiative.[491] While industry professionals have stated that this delay is not unusual for such a complicated initiative, this delay will continue to have adverse effects on patients.[492]

In 2025, the California program suffered another setback: the fifty million dollars that had originally been allocated to support the in-state manufacturing facility were eliminated in a budget savings measure.[493] Tellingly, the California legislature, this time with the approval of Governor Newsom, enacted insulin caps, becoming the twenty-ninth state to do so.[494] The public production path thus became parallel to the regulation of for-profit pharmaceutical drug pricing. The California experience highlights that one of the greatest barriers to public production of pharmaceuticals are familiar budgetary constraints. Still, CalRx has the potential to be a "novel and historic" attempt at lowering prescription drug costs through state-sponsored manufacturing.[495] The initiative acts as a step in the right direction in directly disrupting concentrated, entrenched markets and reducing insulin costs for those who need this lifesaving medicine.

Before the state's recent price cap legislation, California's efforts to make insulin more affordable had fallen behind those of the federal government and other states.[496] Pharmaceutical companies have recently dropped insulin prices between sixty-five percent and eighty percent,[497]

[491] Kristen Hwang, California Made a Big Bet on Producing Its Own Insulin. There's No 'Date Certain' for Delivery, LAist (Mar. 3, 2025, 10:30 AM), https://laist.com/news/health/california-made-a-big-bet-on-producing-its-own-insulin-theres-no-date-certain-for-delivery [https://perma.cc/2ZXP-SFYB].

[492] Id.

[493] Andrew Oxford, Insulin Factory Funding Set for Cuts in California Budget Plan, Bloomberg L. News (May 20, 2025, 4:22 PM), https://news.bgov.com/bloomberg-government-news/insulin-factory-funding-set-for-cuts-in-california-budget-plan.

[494] See Am. Diabetes Ass'n, California Press Release, supra note 288.

[495] See Jacob S. Sherkow, Eli Y. Adashi & I. Glenn Cohen, Assessing—and Extending—California's Insulin Manufacturing Initiative, 329 JAMA 533, 533 (2023) (reviewing California's proposed CalRx initiative to manufacture insulin and highlighting the challenges facing the initiative).

[496] Id.

[497] See William B. Feldman & Benjamin N. Rome, The Rise and Fall of the Insulin Pricing Bubble, JAMA Network Open, June 14, 2023, at 1, 1, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2806020 [https://perma.cc/72P7-GXRU] ("The growing bubble between gross and net prices finally burst for several insulin products in March 2023, when

yet these price reductions have not benefited all patients who rely on insulin.[498] Twenty-eight other states and the District of Columbia have initiated monthly price caps for insulin; some Medicare users have costs capped at thirty-five dollars monthly.[499] To address these shortcomings, the American Diabetes Association had recommended that, in addition to the CalRx program, California implement an out-of-pocket cost cap for insulin, like models from other states, to make up for the deficits from the delayed CalRx program and to increase affordability for patients struggling to pay monthly for insulin.[500] After taking this recommendation to heart, California's new price cap legislation signals an intention to continue fighting for lower insulin prices across the state.[501]

C. Diversification as Strategy: An Emerging Legal Landscape

The long trajectory of high-priced insulin products underscores that market competition does not naturally emerge over time or through mere technological advancements. Rather, it shows the need for deliberate regulatory intervention, which involves addressing anticompetitive behaviors and incentivizing new entry. Moreover, it demonstrates the need to address problems and undesirable tactics at each stage of the pharmaceutical supply chain, from manufacturing to delivery. As this Article has uncovered, the high cost of pharmaceutical drugs in the United States stems not from a single issue but from a combination of factors, including market concentration, monopolistic pricing powers, ever-shifting patent protections, and stagnant regulatory frameworks that inadequately address affordability. The emerging legal landscape combines regulatory and legislative reform, antitrust and consumer protection enforcement, and direct market disruptions, including transparent pharmacy models and public pharmaceutical manufacturing. Publicly owned pharmaceutical manufacturing facilities that produce essential medications, particularly generics and biosimilars, not only ensure the availability of affordable alternatives, but also introduce direct

Eli Lilly, Novo Nordisk, and Sanofi—the 3 major insulin manufactures in the US—announced list price cuts of 65% to 80%, effective by January 2024.").

[498] Hwang, supra note 491.

[499] Id.; see supra Table I.

[500] Id.

[501] Am. Diabetes Ass'n, California Press Release, supra note 288; S.B. 40, 2025–2026 Leg., Reg. Sess. (Cal. 2025).

competition in markets dominated by a few companies. Alternative pharmacy models introduce new competition along the supply chain directly, further shifting market dynamics. The multilayered approach aligns with antitrust principles by addressing both horizontal and vertical restraints in the pharmaceutical supply chain. It further resonates with the contemporary insights on regulatory governance, which understand effective law reform as encompassing the participation of non-state actors, public and private collaboration, regulatory competition between bodies of state and federal policymakers, and the integration of policy domains to tackle complex socioeconomic issues that defy simple reforms.[502]

As this Article has shown, when a socioeconomic problem such as high drug prices stems from multiple market behaviors and structures, the solutions must also be multifaceted. Multiple actors should be considered and challenged as well. A central culprit lies in the market concentration on the manufacturing side—a concentration that is amplified by patent evergreening strategies. Another central source of the problem lies in the complex supply chain: there are multiple intermediaries between manufacturers and patients, primarily PBMs, that engage in strategies to increase profits and costs. This duality must therefore be tackled in tandem. Solutions must include increasing transparency across all of the supply, preventing collusions and market manipulation in the deals among the actors, instituting law reforms that will expedite generic drug entry into the market, and implementing stricter criteria for secondary patents on incremental innovations. Price caps also offer a direct, immediate regulatory response to constrain costs for patients. Finally, public manufacturing of essential drugs can create a virtuous circle of market pressure and disruption, complementing efforts to enhance competition with antitrust enforcement.

This Article demonstrates that the diversification of legal strategies and the parallel emergence of federal and state reforms are features, not bugs, of addressing a complex problem. While each strategy faces challenges, the combination of these approaches offers resilience to the constant resistance and shifting tactics of dominant for-profit market actors. Multimodal interventions recognize the complex ecosystem of pharmaceuticals and healthcare provision, avoiding the potential

[502] See generally Lobel, The Renew Deal, supra note 3 (describing both a conceptual and practical shift in federal and state regulation toward more collaborative governance models).

limitations of any single regulatory strategy. Together, these strategies offer more structural intervention, focusing on dismantling the existing *oligopoly squared* market structure within the healthcare delivery system.

CONCLUSION

The cost of drugs presents a complex regulatory puzzle demanding sophisticated policy design. The market concentration of pharmaceutical manufacturers, aided by flawed intellectual property and drug approval laws, is paired with the market concentration of PBMs, powerful middlemen who broker collusive deals between drug manufacturers, healthcare providers, pharmaceuticals, and pharmacies, to the detriment of patients. Successful intervention demands regulatory imagination, balancing immediate consumer needs with long-term market sustainability and innovation incentives.

Ultimately, the most effective regulatory strategy emerges not from a singular approach, but from a carefully calibrated, adaptive policy framework that can respond dynamically to evolving market conditions and technological developments in pharmaceutical production. Leveraging the interplay between direct law reforms, antitrust litigation, and public and nonprofit direct interventions can create a virtuous cycle: public production of generics and biosimilars could challenge anticompetitive tactics, and providers would be empowered to source drugs from public manufacturers when private suppliers refuse to offer competitive prices, thereby exerting downward pressure on pricing across the board and creating more accessibility and affordability in the market. By combining the spectrum of strategies analyzed in this Article, the United States can take a bold step toward addressing the systemic causes of high drug prices while fostering more equitable and competitive markets. Federalism should support, rather than impede, this multifaceted framework, which not only challenges the status quo in the pharmaceutical drug and delivery industry, but also demonstrates how public-private governance strategies can be transformative when powerful intermediaries dominate consumer markets.