NOTE

Don't Take the Blue Pill: A Law and Political Economy (LPE) Critique of the Pharmaceutical Industry

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INTRODUCTION

In February 2019, the Senate Committee on Finance summoned top executives from seven large pharmaceutical corporations for a hearing on drug pricing in America.[1] The hearing, one of several conducted on similar subjects by Congress in the past decade,[2] reflected widespread, even bipartisan, frustration with rising government spending on pharmaceutical products. The CEOs were predictably on message in their responses to questioning, reminding the Committee that pharmaceutical spending makes up a small share of all healthcare spending, shifting blame to insurance companies and pharmacy benefit managers (PBMs), and arguing that innovation in medicine requires robust incentives in the form of patent-protected monopoly periods.[3] As they put it, pharmaceutical corporations need the promise of massive profits to continue investing in innovative new drugs that require hundreds of millions of dollars to develop, because many development efforts fail during trials and research and development (R&D) requires capital expenditures.[4] Discounting these arguments, the House of Representatives in November 2021 passed a sprawling reconciliation bill that included provisions to radically alter how the federal government pays for pharmaceuticals.[5] After initially failing to pass the Senate, renewed negotiations over the summer resulted in the passage of the rebranded Inflation Reduction Act (IRA) on August 16, 2022.[6] The bill includes the most sweeping revisions in drug pricing policy since at least the Affordable Care Act in 2009 and arguably since the creation of the Part D program in 2003.[7]

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1. *Drug Pricing in America: A Prescription for Change, Part II: Hearing Before the S. Comm. on Fin.*, 116th Cong. (2019).

2. *See, e.g.*, *A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets: Hearing Before the Subcomm. on Competition Pol'y, Antitrust & Consumer Rts. of the S. Comm. on the Judiciary*, 117th Cong. (2021); *Unsustainable Drug Prices: Testimony from the CEOs (Part I): Hearing Before the H. Comm. on Oversight & Reform*, 116th Cong. (2020).

3. *See* Christopher Rowland, *Drug Executives Grilled in Senate Over High Prices*, WASH. POST (Feb. 26, 2019, 4:49 PM), https://www.washingtonpost.com/business/economy/drug-executives-grilled-in-senate-over-high-prices/2019/02/25/abc89c04-393f-11e9-aaae-69364b2ed137_story.html; *Drug Pricing in America: A Prescription for Change*, *supra* note 1, at 533.

4. *See Analysis*: *CEOs From Pfizer, Merck, AbbVie and Others Face Senate on Drug Prices*, WALL ST. J. (Feb. 26, 2019, 4:30 PM), https://www.wsj.com/articles/live-analysis-drug-company-ceos-take-the-hot-seat-before-congress-11551191988; *Drug Pricing in America: A Prescription for Change*, *supra* note 1, at 492, 495, 497.

5. H.R. 5376, 117th Cong. §§ 27001–27002 (as passed by House, Nov. 19, 2021); *infra* note 7.

6. Inflation Reduction Act, Pub. L. No. 117-169, 136 Stat. 1818 (2022). The IRA passed on entirely partisan lines, with all fifty Senate Democrats voting for the bill, all fifty Senate Republicans voting no, and Vice President Kamala Harris breaking the tie in favor of passing the bill. Melissa Quinn, *Senate Passes Democrats' Sweeping Climate, Health and Tax Bill, Delivering Win for Biden*, CBS NEWS (Aug. 8, 2022, 7:16 PM), https://www.cbsnews.com/news/inflation-reduction-act-senate-pass-climate-healthcare-tax-bill/ [https://perma.cc/CXU2-NV9G]; *see also Budget Reconciliation: The Basics*, HOUSE COMM. ON BUDGET (Aug. 11, 2021), https://democrats-budget.house.gov/sites/democrats.budget.house.gov/files/documents/Budget%20Reconciliation%20The%20Basics%20-%20Final%202021.pdf [https://perma.cc/VR6G-98DN] ("Instead of needing 60 votes, a reconciliation bill only needs a simple majority in the Senate.").

7. *See* Inflation Reduction Act secs. 11001–11408. Among other changes, the law allows the Secretary of Health and Human Services (HHS) to directly negotiate with pharmaceutical companies for some drugs purchased by the Medicare program, requires manufacturers to pay Medicare a rebate if the

These events, the first significant legislative fight lost by the pharmaceutical industry in a generation, represent a burgeoning reckoning with the consensus viewpoint on pharmaceutical development and spending, spurred by headlines of corporate rapaciousness,[8] soaring profits,[9] and set-your-watch-to-it yearly price hikes.[10] Patients report rationing insulin, occasionally resulting in death,[11] and more than forty percent of people diagnosed with cancer exhaust their life savings within two years of diagnosis.[12] It is well known that America pays, on average, more than twice what other Organisation for Economic Co-operation and Development (OECD) countries pay for the exact same pharmaceutical products.[13] Public support for drug pricing reform polls higher than nearly any other policy.[14] The passage of the IRA addresses some of these concerns for senior citizens enrolled in Medicare, albeit in a limited way. But the pharmaceutical industry continues to protest the bill, framing the legislation as a disaster for the industry and justifying its arguments with appeals to efficiency, innovation, and competition—the languages of neoliberalism.[15]

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price of a drug rises faster than the rate of inflation, and restructures the Part D benefit design. *See id.* secs. 11001, 11101, 11201; *see also infra* Part IV (discussing the drug pricing provisions of the IRA).

8. *See, e.g.*, Rebecca Robbins & Cecilia Kang, *Martin Shkreli Is Barred from the Drug Industry and Ordered to Repay $64.6 Million*, N.Y. TIMES (Jan. 14, 2022), https://www.nytimes.com/2022/01/14/business/martin-shkreli-barred.html.

9. *See* Fred D. Ledley, Sarah Shonka McCoy, Gregory Vaughan & Ekaterina Galkina Cleary, *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323 JAMA 834, 837 (2020) (finding that pharmaceutical companies "had significantly higher annual profit margins than S&P 500 companies"); *see also* Julia Kollewe, *Pfizer Accused of Pandemic Profiteering as Profits Double*, GUARDIAN (Feb. 8, 2022, 12:26 PM), https://www.theguardian.com/business/2022/feb/08/pfizer-covid-vaccine-pill-profits-sales [https://perma.cc/PS32-7LER].

10. *See generally* STAFF OF H. COMM. ON OVERSIGHT & REFORM, 117TH CONG., DRUG PRICING INVESTIGATION: MAJORITY STAFF REPORT (2021) (describing frequent and significant price increases).

11. *See* Drew Pendergrass, *How Insulin Became Unaffordable*, HARV. POL. REV. (Jan. 22, 2018), https://harvardpolitics.com/how-insulin-became-unaffordable [https://perma.cc/584X-MRG4]; *see also* Jean Fuglesten Biniek & William Johnson, *Out-of-Pocket Spending on Insulin Is Highest at the Beginning of the Year*, HEALTH CARE COST INST. (Sept. 10, 2019), https://healthcostinstitute.org/diabetes-and-insulin/out-of-pocket-spending-on-insulin-is-highest-at-the-beginning-of-the-year [https://perma.cc/9F57-CW4B] (detailing the high out-of-pocket costs of insulin).

12. Adrienne M. Gilligan, David S. Alberts, Denise J. Roe & Grant H. Skrepnek, *Death or Debt? National Estimates of Financial Toxicity in Persons with Newly-Diagnosed Cancer*, 131 AM. J. MED. 1187, 1189 (2018).

13. *See* ANDREW W. MULCAHY, CHRISTOPHER M. WHALEY, MAHLET GIZAW, DANIEL SCHWAM, NATHANIEL EDENFIELD & ALEJANDRO URIEL BECERRA-ORNELAS, RAND CORP., U.S. PRESCRIPTION DRUG PRICES ARE 2.5 TIMES THOSE IN OTHER OECD COUNTRIES (2021), https://www.rand.org/pubs/research_briefs/RBA1296-1.html [https://perma.cc/D6NG-CDR6].

14. *See* Amanda Michelle Gomez, *The Public Backs Medicare Rx Price Negotiation Even After Hearing Both Sides' Views*, KAISER HEALTH NEWS (Oct. 12, 2021), https://khn.org/news/article/poll-prescription-drug-price-negotiation-medicare-public-support [https://perma.cc/2G6N-38JX].

15. *See, e.g.*, Jake Johnson, *Big Pharma Bemoans 'Tragic Loss' as Democrats Take Modest Action to Curb Drug Prices*, COMMON DREAMS (Aug. 8, 2022), https://www.commondreams.org/news/2022/08/08/big-pharma-bemoans-tragic-loss-democrats-take-modest-action-curb-drug-prices [https://perma.cc/TVN6-W824]; Press Release, Pharm. Rsch. & Mfrs. of Am., PhRMA Statement on House Passage of Reconciliation Spending Bill (Aug. 12, 2022), https://phrma.org/resource-center/Topics/Economic-Impact/PhRMA-Statement-on-House-Passage-of-Reconciliation-Spending-Bill [https://perma.cc/Q5SC-J8CY]; Press Release, Michelle McMurry-Heath, President & CEO, Biotech. Innovation Org., New Drug Pricing

Yet the byzantine supply chain for branded pharmaceutical products in America reflects not the robust pricing mechanisms embraced by traditionally liberal economic theories, but rather regulatory capture, monopoly pricing, lack of meaningful consumer choice, and a dearth of information at all levels. In fact, despite a plethora of reporting and official analyses, it is hard to even clarify what the "price" of a drug really is. The pharmaceutical industry operates in one of the most heavily regulated sectors of the economy, relying on government research, funding, approval, and reimbursement at every level of development. The industry's outsized profit margins, among the largest of any industrial sector in the United States,[16] reflect successful efforts to shape each of these processes. Justifications that reference laissez-faire economics and appeals to efficiency are, therefore, misleading and disingenuous, and possess little explanatory power.

This Note will situate the current drug pricing debate in a theoretical framework established by the Law and Political Economy (LPE) Project. The LPE Project is a nascent intellectual movement "rooted in the insight that politics and the economy cannot be separated and that both are constructed in essential respects by law."[17] LPE scholars note that developments in legal and economic discourse over the past four decades have helped to facilitate rising inequality and seek to develop an alternative discourse and policy solutions aimed at building a more just and equitable economy.[18]

Part I will examine the current state of the pharmaceutical industry and the mainstream justifications of this status quo. Part II will sketch a detailed description of the pharmaceutical supply chain and discuss what the "price" of a drug is at each stage, with a focus on how patients perceive price (if at all). Part III will draw from LPE theories to demonstrate how the political economy of the pharmaceutical industry is constituted by specific laws and regulations, rather than defined by market-based competition, and will suggest that different legal configurations can result in better outcomes. Part IV will survey different policy options that would lead to more optimal societal outcomes, as well as briefly analyze relevant provisions of the IRA.

I. MAINSTREAM JUSTIFICATIONS

The textbook account of the economics of the pharmaceutical industry analyzes pharmaceutical corporations as "profit-maximizing firms with long time

Deal Could Propel Us "Light Years Back into the Dark Ages of Biomedical Research" (July 6, 2022) (available at https://www.bio.org/press-release/new-drug-pricing-deal-could-propel-us-light-years-back-dark-ages-biomedical-research [https://perma.cc/CM3R-4ZZ4]); Letter from Bd. of Dirs., Pharm. Rsch. & Mfrs. of Am., to Congress (Aug. 4, 2022) (available at https://static.politico.com/3b/ab/aed5886a49aaa3d2aec92cf5ab2c/08-04-2022-phrma-letter-to-congress.pdf [https://perma.cc/4G66-NDCX]).

16. *See* Ledley et al., *supra* note 9, at 839–40; U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 20 (2017), https://www.gao.gov/assets/gao-18-40.pdf [https://perma.cc/D7AS-6FCX].

17. *About*, LAW & POL. ECON. PROJECT, https://lpeproject.org/about/ [https://perma.cc/2TA4-SSPY] (last visited Apr. 16, 2023).

18. *See id.*; *see also infra* Section III.C for additional discussion of LPE concepts.

horizons [that] decide on investments in new products."[19] Though most basic research is funded by the federal government,[20] the R&D process for bringing new products to market is still costly, time-intensive, and uncertain.[21] The government grants patents through the intellectual property (IP) regime that gives corporations the exclusive right to market a drug for a certain period, which provides the branded drug with monopoly status for the duration of that period.[22] Using this monopoly pricing power, pharmaceutical corporations are able to set high prices to recoup the cost of their investments and earn profits.[23] Without monopoly pricing, "an innovator could not generally recoup the cost of R&D investment" and would lack incentives to make such investments.[24]

However, during the period of monopoly, potential consumers cannot access the drug due to its high cost, resulting in a loss in social welfare.[25] In America, one of the only countries that allows pharmaceutical corporations to set prices for their new products, the price of a new drug is determined by "demand conditions in the market."[26] In other countries, the government sets a regulated price "below the market price that firms would set in the absence of such regulation," which reduces corporations' incentives to invest in R&D.[27] There is a low fixed cost for competitors to develop a copy of a new drug (known as a "generic") by analyzing its chemical structure, so once a drug loses its patent-protected status, the market for the drug will become crowded with competitor drugs.[28] This competition results in lower prices for the drug.[29] Government policies that establish a certain

19. FRANK A. SLOAN & CHEE-RUEY HSIEH, HEALTH ECONOMICS 367 (2012).

20. *See id*. at 374–75 (citing research finding that two-thirds of a group of important drugs introduced between 1965 and 1992 "were developed with at least some government financial support").

21. *Id*. at 368–69 ("[T]he total amount of time required for developing new pharmaceutical products, from basic research to approval to market launch, is about 14 years on average in the United States.").

22. *Id*. at 367.

23. *Id*. at 379.

24. *Id*.

25. *Id*. at 380.

26. *Id.* at 382. In nearly every other OECD country, the government negotiates directly with pharmaceutical corporations to determine the price the government will pay for a new drug. *See id.* Germany technically allows corporations to set prices for newly launched pharmaceutical products. However, after a new drug is introduced in Germany, a quasi-governmental organization directly negotiates with the pharmaceutical corporation to determine the price of the drug into the future. That ultimate price is based on the organization's evaluation of the drug's effectiveness and cost compared to similar therapies and is used by all insurance companies operating in the country. *See* James C. Robinson, Patricia Ex & Dimitra Panteli, *How Drug Prices Are Negotiated in Germany*, COMMONWEALTH FUND (June 13, 2019), https://www.commonwealthfund.org/blog/2019/how-drug-prices-are-negotiated-germany [https://perma.cc/C939-TPJW]; James C. Robinson, Patricia Ex & Dimitra Panteli, *Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts*, COMMONWEALTH FUND (Jan. 23, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/drug-price-moderation-germany-lessons-us-reform-efforts [https://perma.cc/G76M-FJUM]. Canada has a single-payer system for most of its healthcare system, but not for pharmaceuticals, so its negotiation processes vary by province. *See* Jaden Brandt, Brenna Shearer & Steven G. Morgan, *Prescription Drug Coverage in Canada: A Review of the Economic, Policy and Political Considerations for Universal Pharmacare*, 11 J. PHARM. POL'Y & PRAC., no. 28, 2018, at 1, 2, 4.

27. SLOAN & HSIEH, *supra* note 19, at 377.

28. *Id*. at 379, 384.

29. *See id*. at 384–85.

number of years of patent protection on one hand and encourage generic development on the other navigate "a trade-off between preserving incentives for innovation . . . and reducing the welfare loss by removing barriers to generic competition."[30]

This standard account treats pharmaceutical products much like any other consumer product and assumes that market-based mechanisms will result in optimal outcomes. While acknowledging that the government sets some of the initial conditions of participation in the market, its rhetoric elevates the role of markets, pricing, and efficiency. This rhetoric is familiar in the United States as part of the neoliberal consensus—that is, the prevailing economic regime that prioritizes efficiency and separates questions of economy from questions of equality and liberty—that comprises the "Twentieth-Century Synthesis."[31] The rhetoric is echoed by the pharmaceutical industry, represented by the Pharmaceutical Research and Manufacturers of America (PhRMA). Widely recognized as the most powerful trade association in America,[32] PhRMA represents thirty-three large pharmaceutical corporations operating in the United States.[33] Its press releases, funded research, and public comments invariably justify the industry's pricing decisions with appeals to incentives for innovation, competition, and market-based solutions.[34]

These materials note the importance of America's IP laws but frame the legal regime's existence as a passive set of background conditions under which both the federal government and industry players operate. The industry's arguments take as their predicate that pricing mechanisms will lead to competitive markets and that competitive markets will lead to efficient outcomes. Baked into each press release and sworn Hill testimony is a shared set of baseline assumptions about the preconditions of the pharmaceutical market, which assumes that patent-

30. *Id.* at 381.

31. *See* Jedediah Britton-Purdy, David Singh Grewal, Amy Kapczynski & K. Sabeel Rahman, *Building a Law-and-Political-Economy Framework: Beyond the Twentieth-Century Synthesis*, 129 YALE L.J. 1784, 1794 (2020); *infra* Part III.

32. *See* Yeganeh Torbati & Jonathan O'Connell, *Pharmaceutical Industry Likely to Shatter Its Lobbying Record as It Works to Shape Democrats' Spending Bill*, WASH. POST (Nov. 5, 2021, 7:00 AM), https://www.washingtonpost.com/business/2021/11/05/pharmaceutical-industry-drug-price-lobbying; *see also* Alexander Zaitchik, *This Is How Big Pharma Wins*, N.Y. MAG.: INTELLIGENCER (Feb. 21, 2022), https://nymag.com/intelligencer/2022/02/this-is-how-big-pharma-wins.html.

33. *See About PhRMA*, PHARM. RSCH. & MFRS. AM., https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/About-PhRMA2.pdf [https://perma.cc/RYF7-FK6C] (last visited Apr. 16, 2023).

34. *See, e.g.*, PHARM. RSCH. & MFRS. OF AM., BUILDING A BETTER HEALTH CARE SYSTEM: PHRMA'S PATIENT-CENTERED AGENDA 15, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/Better-Way-Assets/Better-Way_Proactive-Agenda1.pdf [https://perma.cc/5TE6-LMBG] (last visited Apr. 16, 2023) (employing language such as "enhance competition," "competes on innovation," "[r]obust, competitive markets," and "incentives for continued biopharmaceutical innovation"); Gabby Migliara, *Government "Negotiation" Could Have Devastating Consequences for Medicare Enrollees*, PHARM. RSCH. & MFRS. AM. (July 23, 2021), https://catalyst.phrma.org/government-negotiation-could-have-devastating-consequences-for-medicare-enrollees [https://perma.cc/2L2F-HTGV] (defending "private negotiations" between pharmaceutical manufacturers and Part D insurance plans or PBMs); *see also* sources cited *supra* note 15.

protected monopoly pricing is a necessary incentive to spur innovation. These assumptions are "so deeply internalized in the field of IP law that [they are] typically taken for granted."[35]

II. THE PHARMACEUTICAL SUPPLY CHAIN & "PRICE"

In contrast to the textbook explanation of the pharmaceutical industry and the rhetoric used to bolster it, the dynamics of the industry, when examined closely, belie claims that the industry operates in a free market in any traditional sense. Section II.A will examine supply chains for pharmaceutical drugs. Section II.B will discuss the "price" of a given drug and how different players in the supply chain conceive of price. Section II.C will focus on how consumers, that is, sick patients who take brand name pharmaceuticals, conceive of the price of their drugs. This Part will conclude by contrasting the language of laissez-faire competition used by the industry to justify its behavior with the actual conditions of the industry.

A. SUPPLY CHAINS

What follows is an overview of U.S. pharmaceutical supply chains. Given the nature of this Note, the descriptions are generalized and do not address every exception and particularity of any given supply chain system. Many details, some important, are omitted.

Ninety percent of drugs prescribed in the United States are inexpensive generic drugs.[36] However, the bulk of spending on pharmaceutical drugs comes from brand name, patent-protected specialty drugs. These drugs account for only two percent of all prescriptions, but nearly half of all spending on pharmaceuticals.[37] This Note will primarily focus on brand name pharmaceuticals and will not discuss the generic pharmaceutical industry in detail. Brand name drugs can be separated into two main categories, which align with Medicare's payment system: Part B's physician-administered drugs (for example, intravenous chemotherapies that an oncologist administers while the patient is at a healthcare facility) and Part D's pharmacy-distributed prescription drugs (for example, an anti-blood-coagulation medication taken in pill form and picked up by the patient from a pharmacy).[38] The supply chain models vary considerably for these two types: Part B drugs are purchased by providers, who are later reimbursed by payers; Part

35. Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 975 (2012).

36. *See Generic Drugs*, FDA (Aug. 5, 2022), https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs [https://perma.cc/T7R9-N2PS].

37. Rujul Desai, Anna Kraus & Kristie Gurley, *USA*, *in* PRICING & REIMBURSEMENT 240, 243 (Grant Castle ed., 3d ed. 2020).

38. *See* PATRICIA A. DAVIS, CLIFF BINDER, JIM HAHN, SUZANNE M. KIRCHHOFF, PAULETTE C. MORGAN, MARCO A. VILLAGRANA & PHOENIX VOORHIES, CONG. RSCH. SERV., R40425, MEDICARE PRIMER 18, 23 (2020), https://crsreports.congress.gov/product/pdf/R/R40425/55 [https://perma.cc/ZZU3-U7XC].

D drugs are purchased by patients at the pharmacy counter and payment structures vary.[39]

Payment structures for pharmaceuticals also vary by which party is the "payer" for a drug. The term "payer" typically refers to the health insurer that reimburses a provider or pharmacy for healthcare goods and services.[40] The American payer system is highly fragmented, in contrast to European healthcare systems that typically have some variety of a single government payer.[41] In the United States, roughly 68% of the population is covered by private health insurance (employer-sponsored insurance is the most common type), while about 44% is covered by public insurance (Medicare, Medicaid, Veterans Health Administration of the Department of Veterans Affairs (VA), or TRICARE); nearly 10% of the population remains uninsured.[42] Government programs pay for drugs according to statute and regulation, and each varies widely in payment structures.[43] For instance, the VA directly negotiates with and pays pharmaceutical corporations, Medicare Part B reimburses physicians for their acquisition cost of a drug plus an add-on percentage to compensate for costs of handling and administration, Part D is administered by private health insurance plans (known as Part D Plans, or PDPs) that contract with PBMs to pay for drugs, and each state administers its own Medicaid program, but all states benefit from the federal Medicaid Drug Rebate Program (MDRP).[44] Payment structures involving pharmacy-distributed drugs typically involve retrospective rebate payments from the pharmaceutical company to the payer, which effectively lower the net price of a drug. Such rebate

39. *See id.* at 19, 23.

40. *See The Role of Payers*, BROOKINGS HEALTH SYS., https://www.brookingshealth.org/why-brookings-health/health-care-value/understanding-medical-prices/role-payers [https://perma.cc/WK49-XTV9] (last visited Apr. 16, 2023).

41. *See* SUZANNE M. KIRCHHOFF, AGATA BODIE, KAVYA SEKAR & SIMI V. SIDDALINGAIAH, CONG. RSCH. SERV., R44832, FREQUENTLY ASKED QUESTIONS ABOUT PRESCRIPTION DRUG PRICING AND POLICY 16 (2021), https://sgp.fas.org/crs/misc/R44832.pdf [https://perma.cc/Q6F8-2JZH].

42. RYAN J. ROSSO, CONG. RSCH. SERV., IF10830, U.S. HEALTH CARE COVERAGE AND SPENDING (2023), https://sgp.fas.org/crs/misc/IF10830.pdf [https://perma.cc/BQU2-RG5U]. Totals do not equal one hundred percent because some people have multiple sources of coverage. The uninsurance rate was 16% when the Affordable Care Act (ACA) passed, dropped to about 9% after the ACA was implemented, and rose to over 10% under the Trump Administration. *See* AIDEN LEE, JOEL RUHTER, CHRISTIE PETERS, NANCY DE LEW & BENJAMIN D. SOMMERS, U.S. DEP'T OF HEALTH & HUM. SERVS., NATIONAL UNINSURED RATE REACHES ALL-TIME LOW IN EARLY 2022, at 3 (Aug. 2022), https://aspe.hhs.gov/sites/default/files/documents/15c1f9899b3f203887deba90e3005f5a/Uninsured-Q1-2022-Data-Point-HP-2022-23-08.pdf [https://perma.cc/2MQS-QB82]. As of March 2023, the uninsurance rate was the lowest it had ever been due in large part to policies enacted in 2020 and 2021 in response to the COVID-19 Public Health Emergency, such as "continuous enrollment," which prohibits state Medicaid programs from un-enrolling beneficiaries even if they are not currently eligible. *See id.* at 8. However, as of April 1, 2023, Congress permitted states to resume Medicaid disenrollments. *See* Jennifer Tolbert & Meghana Ammula, *10 Things to Know About the Unwinding of the Medicaid Continuous Enrollment Provision*, KFF (Apr. 5, 2023), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-the-unwinding-of-the-medicaid-continuous-enrollment-provision/ [https://perma.cc/2DLC-ZMDX]. The uninsurance rate is expected to rise in the next year as millions of people lose their Medicaid coverage. *Id.*

43. *See, e.g.*, 42 U.S.C. §§ 1395w–101 to –154 (Medicare Part D); 42 U.S.C. § 1395w–3b (Medicare Part B); 42 C.F.R. § 414.904 (2021) (same); 42 U.S.C. § 1396r–8 (Medicaid).

44. *See* KIRCHHOFF ET AL., *supra* note 41, at 17.

agreements vary widely by payer and drug, are usually negotiated by PBMs on behalf of payers, and are almost always confidential.[45] Private health insurers also use PBMs to negotiate rebate agreements with manufacturers.[46]

Given the high degree of system complexity, the interactions between different stakeholders in any specific supply chain is best explained by diagram. The following diagram typifies a standard retail pharmacy drug distribution and payment chain; it does not account for physician-administered drugs (that is, it applies to Part D drugs, but not Part B drugs).[47]

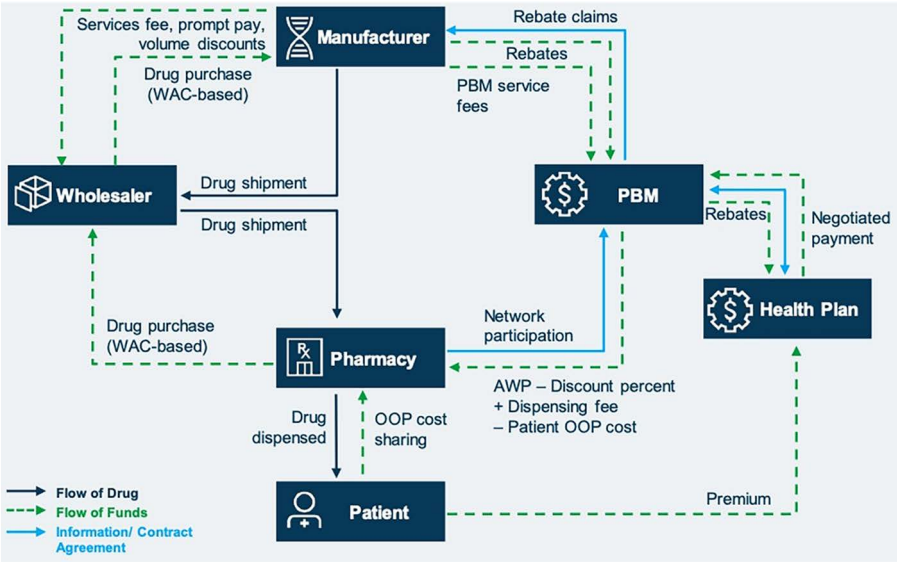

Figure 1.

The physical product, the actual drug, is transferred in three transactions: first from manufacturer to wholesaler, then from wholesaler to pharmacy, and finally from pharmacy to patient. The flow of money is more complicated. First, the wholesaler pays the manufacturer for the product. Then, the pharmacy pays the

45. *See* CHARLES ROEHRIG, ALTARUM, THE IMPACT OF PRESCRIPTION DRUG REBATES ON HEALTH PLANS AND CONSUMERS 2–4 (2018), https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf [https://perma.cc/6U74-2RN4].

46. *See* Elizabeth Plummer, Mariana P. Socal, Jeromie M. Ballreich, Gerard F. Anderson & Ge Bai, *Trends of Prescription Drug Manufacturer Rebates in Commercial Health Insurance Plans, 2015-2019*, JAMA HEALTH F., May 6, 2022, at 1, 3 (finding rebate increases in commercial health plans, and that "the growth of prerebate prescription drug costs (used for patients' cost sharing) outpaced the growth of postrebate drug costs for all 3 commercial plan types").

47. Megan West (Olsen), Daniel Nam, Brook Getachew, Lance Grady & Miryam Frieder, *Follow the Pill: Understanding the Prescription Drug Supply Chain*, AVALERE (May 20, 2020), https://avalere.com/insights/follow-the-pill-understanding-the-prescription-drug-supply-chain [https://perma.cc/S5DU-TZUR]. The diagram uses the following acronyms: "WAC" means wholesale acquisition cost, "AWP" means average wholesale price, and "OOP" means out-of-pocket. *Id.*

wholesaler. At the pharmacy counter, the patient pays some amount of money out-of-pocket (OOP), which is typically only a small percentage of whatever the pharmacy had paid for the drug. The rest of the pharmacy's reimbursement for the drug comes from PBMs, which operate on behalf of health insurance plans (Medicare PDPs, private health insurance corporations, or state Medicaid agencies, for instance) and essentially facilitate a payment from the health plan to the pharmacy. At some point in time well after the actual transaction of the drug from the pharmacy to the patient, pharmaceutical manufacturers pay retrospective rebates that are passed through PBMs to insurers.[48] PBMs thus function as payment facilitators between manufacturers and health plan payers, lowering the effective price paid by the insurer to the manufacturer. PBMs also maintain "formularies," which are lists of drugs for which a given health plan will provide reimbursement. PBMs use inclusion onto different tiers of formularies as leverage in negotiations with pharmaceutical manufacturers for greater rebates. This is because certain formulary tiers have different pricing incentives for patients (that is, a more favorable tier has a lower OOP cost for patients), which can lead to increased sales volume for drugs on preferred tiers.[49]

B. PRICE WITHIN SUPPLY CHAINS

In this complicated supply chain, there is no fixed meaning of "price" for any given drug. Pharmaceutical manufacturers establish a "list price" for brand name drugs, but this price is not paid by any stakeholder in the supply chain because the effective price paid is typically discounted via rebates and other fees.[50] Instead, there are a variety of pricing indexes used at different stages of transactions, including the average wholesale price (AWP), the wholesale acquisition cost (WAC), the average manufacturer price (AMP), and the average sales price (ASP).[51] Some "prices" are defined by federal law (such as WAC and AMP), while others are estimates of average prices paid calculated by healthcare IT companies (such as AWP); some include discounts and rebates, while others do not.[52] These indexes are used as reference points by federal payers in some instances. For instance, Medicare Part B reimburses providers at ASP plus 6%. Here, ASP reflects the average sales from manufacturers to all private health payers, after accounting for all rebates and discounts; the 6% is added as reimbursement to the provider for handling and storing the drug.[53] Medicare Part B thereby receives

48. *See id.*; *see also* Joey Mattingly, *Understanding Drug Pricing*, GENERIC DRUG REV., June 2012, at 40 (providing a similar supply chain overview with additional details relevant to pharmacies).

49. *See* Desai et al., *supra* note 37, at 257–58.

50. The main exception to this is uninsured patients, who may only be able to acquire brand name drugs at the full list price. Patient OOP contributions may also be calculated based on a percentage of list price. *See infra* Section II.C.

51. *See* Mattingly, *supra* note 48, at 41 tbl.1.

52. *See id.*

53. *See* Susan Weidner, Michael Diaz, Cass Schaedig & Lucio N. Gordan, *Observations Regarding the Average Sales Price Reimbursement Methodology*, 27 EVIDENCE-BASED ONCOLOGY 156, 156 (2021).

the benefit of the average rebate provided to private payers by manufacturers, while not actually receiving rebates.

The true "price" of a drug (that is, the ultimate net price after subtracting rebates paid by an insurer, through a PBM, to a pharmacy or provider) is likely to vary significantly depending on which payer is paying. Perhaps the starkest example of this is Medicaid, where the MDRP requires that manufacturers offer Medicaid either the "best" price offered to any private payer (excluding Medicare PDPs) or at least a 23.1% rebated discount.[54] In other words, Medicaid is guaranteed to have a net payment (that is, the list price minus a retrospective rebate payment) equal to or less than any other private payer. In other payment systems, such as Medicare Part D, the net price paid by any given PDP will depend on the rebate structure that the PDP's PBM is able to negotiate with a manufacturer. These negotiations typically depend on expected volume and formulary placement.[55]

To illustrate, consider a hypothetical situation[56] in which Plan A and Plan B are considering covering brand name drugs X and Y, which have similar clinical uses and are both introduced with list prices of $100. Plan A's PBM negotiates with X's manufacturer to give drug X a preferred spot on its formulary in exchange for a 40% rebate, resulting in a net price of $60. Because Plan A does not provide drug Y with a preferred formulary placement, Y's manufacturer provides Plan A only a 10% rebate (for a net price of $90). Plan B takes the opposite approach, placing drug Y in its preferred formulary tier and drug X in a less preferred tier. Plan B has fewer members than Plan A, however. The drug's expected volume is therefore lower, meaning that Plan B's PBM can only negotiate a 30% discount for drug Y ($70 net price) and a 5% discount for drug X ($95 net price). This hypothetical is represented in the chart below:

	Drug X			**Drug Y**		
	List Price	**Rebated Discount**	**Net Price**	**List Price**	**Rebated Discount**	**Net Price**
Plan A	$100	40%	$60	$100	10%	$90
Plan B	$100	5%	$95	$100	30%	$70

54. *See* KIRCHHOFF ET AL., *supra* note 41, at 17.

55. *See id.* at 7, 12, 18–19.

56. Note that this idealized hypothetical is solely for elucidation of the general pricing mechanisms, and therefore ignores other forms of discounts and fees that occur within the Part D supply chain. See *id.* for a more complete description.

Finally, many plans are required by law to cover certain drugs, which limits plans' ability to negotiate with pharmaceutical manufacturers. For instance, the Part D statute requires that PDP formularies cover all disease states, including at least two chemically distinct drugs in each drug class, as well as *all* drugs in "six so-called 'protected' classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics [medications used to treat cancer]."[57] This requirement effectively forces PDPs to cover new drugs in protected classes, even if they offer only marginal clinical improvement compared to older drugs, because the FDA will provide accelerated approval for drugs that "generally demonstrate an improvement over available therapy."[58]

While it is not unusual for different stakeholders in a supply chain to have different prices for the same good, the essential role of rebates in the pharmaceutical supply chain and the secretive nature of those rebates obfuscate pricing information. Rebate contract terms are trade secrets, so the net price of a drug (its true price to the payer) is not publicly available information.[59] The idealized form of pricing mechanisms suggests that price information collates consumer demand in the most efficient way possible, allowing for efficient economic coordination.[60] Any suggestions that pharmaceutical supply chains in their current state benefit from pricing discipline must contend with the reality that price information is nearly impossible to come by. Plans do not know what net prices other plans have negotiated with manufacturers, nor do patients know what net prices for specific drugs plans have negotiated when they are choosing their plan. Finally, and perhaps most importantly, the OOP amount paid by a patient at the pharmacy is most often determined by the design of their health insurance benefit rather than the "price" of the drug at any intermediary point in the supply chain.

C. PRICE AS PERCEIVED BY PATIENTS

Patients experience price in a different way than the other aforementioned industry stakeholders. When a patient goes to the pharmacy to pick up a drug their doctor has prescribed for them, the amount of money they will pay during that transaction depends on an interaction between the list price of the drug and the benefit design of the patient's insurance. The second half of that equation is absent for patients without insurance, who are required to pay the full list price of

57. *See An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 19, 2022), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/#:~:text=Spending%20and%20Financing-,Part%20D%20Spending,from%20premiums%20and%20state%20transfers [https://perma.cc/MF6U-8VMV].

58. FDA, U.S. DEP'T OF HEALTH & HUM. SERVS., CLINICAL TRIAL ENDPOINTS FOR THE APPROVAL OF CANCER DRUGS AND BIOLOGICS: GUIDANCE FOR INDUSTRY 2 (2018).

59. *See* Gabriela Dieguez, Maggie Alston & Samantha Tomicki, *A Primer on Prescription Drug Rebates: Insights into Why Rebates Are a Target for Reducing Prices*, MILLIMAN (May 21, 2018), https://www.milliman.com/en/insight/a-primer-on-prescription-drug-rebates-insights-into-why-rebates-are-a-target-for-reducing [https://perma.cc/EC6V-B9SP].

60. *See* F. A. Hayek, *The Use of Knowledge in Society*, 35 AM. ECON. REV. 519, 529–30 (1945) (analyzing the challenge of "designing an efficient economic system" when only in possession of "partial knowledge").

a drug (which, recall, is paid by no other stakeholders in the supply chain). This requirement renders many brand name drugs unaffordable for the uninsured, including most insulins, cutting-edge chemotherapies, and curative treatments for diseases such as Hepatitis C.[61] Some programs exist to provide uninsured patients with new pharmaceutical products, but the reach of those programs is limited.[62]

For patients with health insurance, the structure of the benefit design is critical. Benefit design dictates how much money the patient will be responsible for paying OOP at the point of sale. For many insurance plans, this sum is a function of the deductible, copay or coinsurance requirement, and maximum OOP limit.[63] However, benefit design varies widely across insurance types. In Medicaid, there is minimal cost sharing required of beneficiaries. When picking up drugs, Medicaid patients may have a nominal copay regardless of the type of drug (generic or brand name).[64] Still, even small differences in required OOP cost sharing at the point of sale have been shown to have meaningful impacts on Medicaid beneficiaries' ability to fill prescriptions.[65] In nearly half of private insurance plans, patients must spend down a deductible in order for the drug coverage to kick in, much like how deductibles work for other health spending. The patient is responsible for the list price of the drug until they have reached the deductible limit.[66] After that, or in plans

61. *See* ROBIN A. COHEN, PETER BOERSMA & ANJEL VAHRATIAN, NAT'L CTR. FOR HEALTH STAT., U.S. DEP'T OF HEALTH & HUM. SERVS., DATA BRIEF NO. 333, STRATEGIES USED BY ADULTS AGED 18–64 TO REDUCE THEIR PRESCRIPTION DRUG COSTS, 2017, at 3 (2019), https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf [https://perma.cc/4XLA-6G3W] (finding that a third of uninsured patients did not take their medications as prescribed); *see also* Anna Wells & Lauren Chase, *The Top 10 Most Expensive Popular Brand-Name Drugs in the U.S. (and How to Save)*, GOODRX HEALTH (July 14, 2021), https://www.goodrx.com/healthcare-access/drug-cost-and-savings/top-10-most-expensive-popular-brand-name-drugs-us-how-to-save [https://perma.cc/V2QX-KZ6W] (listing the average monthly cash price for the most expensive brand name drugs, ranging from $1,600 to more than $9,000); Olga Khazan, *The True Cost of an Expensive Medication*, ATL. (Sept. 25, 2015), https://www.theatlantic.com/health/archive/2015/09/an-expensive-medications-human-cost/407299 (noting that Sovaldi, which can cure Hepatitis C, costs $1,000 per day for the uninsured, rendering it unaffordable).

62. *See, e.g.*, *Ready, Set, PrEP*, HIV.GOV (Mar. 18, 2022), https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program [https://perma.cc/4U59-J7C3] (noting that "[a]n estimated 1.2 million people in the United States could benefit from PrEP medications, but fewer than 25% of them are taking it" and advertising a federal effort to provide free drugs); *How Much Does PrEP Cost?*, PREP DAILY (Aug. 17, 2020), https://prepdaily.org/how-much-does-prep-cost/ [https://perma.cc/8QXB-X95F] (surveying other payment plans). PrEP is used prophylactically to prevent HIV, must be taken daily, is highly effective, and has a list price of $22,000 per year. *See Preventing HIV Just Got a Lot Cheaper. What Took So Long?*, TRADEOFFS (Apr. 22, 2021), https://tradeoffs.org/2021/04/22/preventing-hiv-just-got-a-lot-cheaper-what-took-so-long [https://perma.cc/7EZB-YMSP].

63. *See* CAROL RAPAPORT, CONG. RSCH. SERV., R44014, AN INTRODUCTION TO HEALTH INSURANCE: WHAT SHOULD A CONSUMER KNOW? 6–7 (2015), https://sgp.fas.org/crs/misc/R44014.pdf [https://perma.cc/6D4U-SASB].

64. *See Cost Sharing*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/cost-sharing/index.html [https://perma.cc/7TH9-6J85] (last visited Apr. 16, 2023).

65. *See generally* LEIGHTON KU & VICTORIA WACHINO, CTR. ON BUDGET & POL'Y PRIORITIES, THE EFFECT OF INCREASED COST-SHARING IN MEDICAID: A SUMMARY OF RESEARCH FINDINGS (2005), https://www.cbpp.org/research/the-effect-of-increased-cost-sharing-in-medicaid [https://perma.cc/5RP8-EXTF] (surveying research and natural experiments of increased cost sharing).

66. *See* MASON TENAGLIA & MARCELLA VOKEY, IMS INST. FOR HEALTHCARE INFORMATICS, EMERGENCE AND IMPACT OF PHARMACY DEDUCTIBLES: IMPLICATIONS FOR PATIENTS IN COMMERCIAL

that do not have deductibles for pharmaceuticals, the patient's payment at the pharmacy counter is usually in the form of a copayment or coinsurance. A copayment is a flat fee that is unrelated to a drug's list price. A coinsurance payment is a payment calculated as a percentage of the list price of a drug; for drugs with high list prices, coinsurance payments can be extremely high (for example, for a drug with a list price of $1,000, a twenty percent coinsurance payment would be $200).[67] Whether a plan will require a copayment or coinsurance, and at what level for each, will depend on what formulary tier the plan's PBM has placed a drug on. Plans will typically try to steer patients to cheaper generic drugs, or brand name drugs that they receive large rebates for, by placing those drugs on formulary tiers that have low copay amounts and placing competitor drugs on less preferred tiers that require, for instance, a forty percent coinsurance payment.[68] As a result of the Affordable Care Act (ACA), most insurance plans are required to have annual maximum OOP limits.[69] Once a patient has spent, for example, $9,800 OOP within a plan year, the insurance company will pay the full amount of their remaining health expenditures, including drug costs. Medicare Part D statutorily defines the benefit design that PDPs offer, and suffice it to say that, until the IRA's changes occur, the design is complicated and illogical, and does not have a yearly cap.[70] Starting in 2025, Part D will revise the benefit design in multiple ways and cap yearly OOP expenses at $2,000.[71]

The combination of these factors means that patients typically pay the most for their drugs in the beginning of the year, when their deductibles have yet to be spent down and they are unlikely to have met their annual maximum OOP limit.[72] Research has demonstrated that patients are sensitive to their OOP costs at the pharmacy counter.[73] The following example illustrates this mechanism by

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HEALTH PLANS 3–4 (2015), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/emergence-and-impact-of-pharmacy-deductibles.pdf [https://perma.cc/8LBM-N8BK].

67. *See* RAPAPORT, *supra* note 63, at 6.

68. *See* Michael Bihari, *Understanding Your Health Plan Drug Formulary*, VERYWELL HEALTH (Sept. 27, 2022), https://www.verywellhealth.com/understanding-your-health-plan-drug-formulary-1738897 [https://perma.cc/4UY6-X52X]. *See generally* COLE WERBLE, FORMULARIES (2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000177/full/hpb_2017_09_14_formularies-1510940900977.pdf [https://perma.cc/43S3-N85B].

69. Pub. L. No. 111-148, § 1302(c), 124 Stat. 119 (2010) (codified at 42 U.S.C § 18022(c)); *see also* 45 C.F.R. § 156.130(c) (2021).

70. *See* AVALERE HEALTH, TRENDS IN PART D PROGRAM SPENDING: STABLE PREMIUMS & RISING REINSURANCE COSTS 2 fig.1 (2021), https://avalere.com/wp-content/uploads/2021/06/Direct-Subsidy-Blog_Revised_Avalere-White-Paper.pdf [https://perma.cc/8WZ9-38EN] (providing a helpful visualization of the current benefit design).

71. *See* Inflation Reduction Act, Pub. L. No. 117-169, secs. 11201–11202, 136 Stat. 1818, 1877–95 (2022). For additional discussion, see *infra* Part IV.

72. *See* Biniek & Johnson, *supra* note 11.

73. *See, e.g.*, ROBERT H. BROOK, EMMETT B. KEELER, KATHLEEN N. LOHR, JOSEPH P. NEWHOUSE, JOHN E. WARE, WILLIAM H. ROGERS, ALLYSON ROSS DAVIES, CATHY D. SHERBOURNE, GEORGE A. GOLDBERG, PATRICIA CAMP, CAREN KAMBERG, ARLEEN LEIBOWITZ, JOAN KEESEY & DAVID REBOUSSIN, RAND CORP., THE HEALTH INSURANCE EXPERIMENT: A CLASSIC RAND STUDY SPEAKS TO THE CURRENT HEALTH CARE REFORM DEBATE 2 (2006), https://www.rand.org/pubs/research_briefs/RB9174.html [https://perma.cc/2THB-CTYM]; Vera Lucia Luiza, Luisa A. Chaves, Rondineli M. Silva, Isabel Cristina M. Emmerick, Gabriela C. Chaves, Silvia Cristina Fonseca de Araújo, Elaine L. Moraes & Andrew D. Oxman, *Pharmaceutical Policies: Effects of Cap and Co-Payment on Rational Use of Medicines*, COCHRANE DATABASE SYSTEMATIC REVS., May 2015, at 1, 2 (surveying research to find that pharmaceutical OOP requirements may "reduce the use of life-

looking at a patient's OOP responsibility for two brand name drugs, A and B, at different points in time, January and June. The patient's two drugs are on different formulary tiers, so once the deductible is met, the patient's OOP for drug A is a flat copay, while the OOP for drug B is a percentage-based coinsurance. Because the patient's plan requires a $600 deductible be met before reducing the patient's OOP responsibility to only a copay, the patient's OOP payment is initially the combined list price of the drugs. Once the patient meets their deductible, their OOP amount shifts from the list price of the drugs to a copay or coinsurance amount. By April, the patient's OOP cost for their monthly trip to the pharmacy to pick up the two drugs has changed from $200 to $45. By the following January, a new plan year will begin, and the patient's deductible will reset. For a patient with a different insurance plan that does not have a deductible for pharmaceutical spending, the patient's OOP responsibility would vary according to the copay and coinsurance dynamics that the patient, represented in the chart below, experiences once their deductible is met.

	Jan	**Feb**	**Mar**	**Apr**	**May**	**June**
Drug A List Price	$100					
Drug B List Price	$100					
Drug A - Copay (flat fee)	-	-	-	$5	$5	$5
Drug B - Coinsurance (40% of list price)	-	-	-	$40	$40	$40
Patient OOP Responsibility	**$200**	**$200**	**$200**	**$45**	**$45**	**$45**
Deductible Remaining	$600	$400	$200	$0	$0	$0

In other words, the "price" a patient experiences in the course of a pharmacy transaction only sometimes reflects the list price of the drug and only indirectly relates to the negotiated net price of a drug via the formulary tiering system. Instead, the price is likely to vary widely according to a patient's coverage type, benefit design, and how much health care the patient has used during the year. Furthermore, pharmaceutical manufacturers, recognizing that high OOP costs deter patients from filling their prescriptions, frequently offer "coupons" that eliminate the patient's OOP responsibility at the point of sale.[74] These coupons

sustaining medicines" or medicines used for chronic illness, potentially "increas[ing] the use of healthcare services" by patients who do not take their drugs).

74. *See* Karen Van Nuys, Geoffrey Joyce & Rocio Ribero, *Prescription Drug Coupons: A One-Size-Fits-All Policy Approach Doesn't Fit the Evidence*, HEALTH AFFS. (Feb. 16, 2018), https://www.healthaffairs.org/do/10.1377/forefront.20180215.988517 [https://perma.cc/9D4B-LCPS]. PBMs and payers are vehemently opposed to the use of coupons because coupons circumvent plan designs meant to limit utilization (and thus control the payer's costs) by steering patients to certain drugs. There is an ongoing battle between manufacturers and PBMs around coupons and their PBM counterparts, known as copay accumulators and copay maximizers, conducted through state legislation efforts, federal rulemaking, and

further separate the patient from any experience of price. Accordingly, the "demand" that patients exert for drug products does not reflect demand in the traditional sense of willingness to pay for a product at the listed price. Patients with insurance do not often interact with the list price of a drug, nor do they play a role in any of the backend supply chain pricing dynamics described earlier in Section II.B.

Finally, it is worth mentioning in a discussion of the patient experience of drug pricing that patients are in a position of severe information asymmetry when it comes to drug purchases. Patients are prescribed drugs by their doctors, who attempt to match the patient with the most clinically effective drug for their ailment. Patients do not have the option to choose between competing brand name drugs or between brands and generics, and they lack the expertise necessary to make a meaningful choice even if they could. Accordingly, the patient experience of purchasing pharmaceutical products is multiple steps removed from normal market purchases. Patients are legally unable to choose which product they prefer, lack information to make a meaningful choice even if they were allowed to, and experience an OOP price that is likely more connected to the actions of their insurance company than it is to the product itself.

D. TOWARD A POSITIVE THEORY OF DRUG PRICING

This Part began by offering the textbook explanation of pharmaceutical political economy and surveying the rhetoric used by the industry to justify its actions. It then looked closely at the actual conditions of the industry, exposing the convoluted supply chain that complicates the standard explanation. Lastly, it analyzed the various definitions of price that exist within the supply chain, demonstrating that drug prices as perceived by patients are, for the most part, unrelated to the list price of a drug and instead reflect interactions between insurance benefit design and a patient's annual healthcare spending.

Together, these observations suggest that the standard economic explanation for the industry is insufficient to explain the current state of various branded pharmaceutical markets. The textbook explanations for pharmaceutical pricing do not delve into the intricacies of rebates and contracting, nor do they analyze how patients conceive of price, instead collapsing "demand" for a product into an idealized whole that reflects no real group's interests. Instead, demand is better understood as (at least) two separate forces.

The first is a patient's cost sensitivity at the pharmacy counter, which is primarily a function of benefit design, rather than reflecting the traditional sense of willingness to pay for an item's value. Further, patient demand does not reflect a

technological tools. *See* Mark Gooding, Daniel Nam, Kate Sikora, James Coffelt & Lance Grady, *Copay Accumulator and Maximizers: Evolving Policy Landscape*, AVALERE (Feb. 23, 2021), https://avalere.com/insights/copay-accumulator-and-maximizers-evolving-policy-landscape [https://perma.cc/2RLD-JUGS].

choice between competing products but is the result of the prescribing decisions of a patient's doctor. Patients do not "pay" for the real cost of a product, nor do they "choose" freely between products. From the patient perspective, consumption of pharmaceutical products is therefore not aligned with traditional economic assumptions.

The second is the demand that insurers and government payers face to cover certain drugs on certain formulary levels, which is predominantly a function of regulatory requirements and negotiating leverage, again in contrast to the typical sense of demand as willingness to pay for a product. There is an element of market forces at play in these transactions, because PBMs negotiate for discounts based on expected sales volume, even though pricing information is proprietary. But it is inaccurate to describe the net price that payers pay for a drug as primarily reflective of supply and demand. The key elements of pricing do not occur "within" a market; the crucial elements are instead decided a step prior, in the construction of the market's rules and requirements. Payers must reimburse for certain drugs, PBMs are permitted to withhold pricing information, and manufacturers receive government permission to sell their products and rely on protection of their patents to stake out monopoly selling positions. Each of these rules of the road is the result of political decisions. In this sense, the macroeconomic structure of the pharmaceutical market is inherently political–economic. As such, stakeholders exert collective influence to shape the rules of the market (for example, the tax system, the centralization of drug regulation at the federal level, the global IP regime) because they understand that corporate success is first a question of the framework itself, and only secondarily a question of competing within that framework—hence, the significant focus from industry stakeholders on lobbying and the revolving door from Washington to industry and back again.

The industry's appeals to rewarding innovation through monopoly pricing, the basis for the IP regime, are similarly lacking. The pharmaceutical industry intentionally discounts and downplays the role of the government in conducting basic research on which later development depends.[75] Pharmaceutical corporations typically spend more on advertising than they do on R&D, undermining their claims that current levels of monopoly pricing are required to sustain innovation.[76] The industry generates the highest profit margins of any American industry[77] and

75. *See, e.g.*, Biotech. Innovation Org., *Private and Public R&D Financing*, DRUG COST FACTS, https://www.drugcostfacts.org/drug-development [https://perma.cc/56V7-9HZJ] (last visited Apr. 16, 2023); *The Biopharmaceutical Research Ecosystem: The Role of NIH and Industry in the Research and Development of New Medicines*, PHARM. RSCH. & MFRS. AM., https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/The-Biopharmaceutical-Research-Ecosystem3.pdf [https://perma.cc/6TFE-37PX] (last visited Apr. 16, 2023).

76. *See New Study: In the Midst of COVID-19 Crisis, 7 out of 10 Big Pharma Companies Spent More on Sales and Marketing Than R&D*, AHIP (Oct. 27, 2021), https://www.ahip.org/news/articles/new-study-in-the-midst-of-covid-19-crisis-7-out-of-10-big-pharma-companies-spent-more-on-sales-and-marketing-than-r-d [https://perma.cc/3KYQ-R82H].

77. *See* Ledley et al., *supra* note 9, at 840–41.

zealously asserts its interests in the court system to extend patent protections on products well past the original term of those patents.[78] There is a real need in society to develop new medical technologies, but it does not follow automatically that the status quo of IP and pricing regimes is the best way to meet that need. In sum, a close examination of the current state of the pharmaceutical industry does not align with the industry's self-description and requires further explanation to truly analyze.

III. LPE CRITIQUES OF THE PHARMACEUTICAL INDUSTRY

There is no need to engage the industry on its own terms. LPE theories provide a broader, more critical look at the development of the current IP system and regulatory framework which enables the pharmaceutical industry to capture the largest profits of any industry. This Part will analyze and apply these theories. First, it will examine the broader shift in the U.S. economy away from industrial manufacturing to information- and IP-based companies and explain how brand name pharmaceutical corporations track with this trend. Second, it will examine how the pharmaceutical industry, despite its rhetoric, recognizes and participates in the construction of market rules, using the passage of Medicare Part D as an illustration. Finally, it will investigate neoliberal assumptions that underly the pharmaceutical industry's justifications by examining the constructive role of law and regulation in the industry. Together, these theories demonstrate that the current state of the brand name pharmaceutical industry is justified by assumptions of efficiency and competition that do not hold up to close scrutiny.

A. THE SHIFT FROM MANUFACTURING TO SERVICES AND IP

The pharmaceutical industry was not always a profit center in the United States. Rather, the rise of the industry aligns with the broader economic history of the past six decades in which the traditional manufacturing industry was replaced by modern technology companies. In the Fordist postwar era, manufacturing, oil, and chemical companies captured the bulk of profits.[79] These firms invested in physical capital to ensure full factory capacity and uninterrupted production, which maximized profits.[80] Firms vertically integrated with suppliers to ensure

78. *See generally* KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES (2020), https://sgp.fas.org/crs/misc/R46221.pdf [https://perma.cc/A3ZF-NT9N] (describing various strategies employed by pharmaceutical companies to extend their patent protections). As of May 11, 2023, the Senate Committee on Health, Education, Labor and Pensions (HELP) is considering legislation that would limit some of the pharmaceutical patent strategies that these companies and their lawyers can employ. *See Continuation: S. 1067, S. 1114, S. 1214, and S. 1339: Hearing Before the S. Comm. on Health, Educ., Lab. & Pensions*, 118th Cong. (2023); Angus Liu, *As Pharma Fights IRA, Senate Committee Advances Basket of Bills Aimed at Lowering Drug Prices*, FIERCE PHARMA (May 12, 2023, 10:40 AM), https://www.fiercepharma.com/pharma/pharma-fights-ira-senate-moves-forward-basket-bills-aimed-lower-drug-prices [https://perma.cc/BY5W-VZZT].

79. *See* Herman Mark Schwartz, *Mo' Patents, Mo' Problems: Corporate Strategy, Structure, and Profitability in America's Political Economy*, *in* THE AMERICAN POLITICAL ECONOMY: POLITICS, MARKETS, AND POWER 247, 260 fig.8.1 (Jacob S. Hacker et al. eds., 2022).

80. *See id.* at 248.

stable inputs and employed large numbers of unionized employees who worked in factories and production plants.[81] For a short period, firms placated a powerful labor movement by entering into compromise with their (predominantly white, male) workers to share in large manufacturing firms' outsized profits.[82] Following a series of strikes in the 1970s, however, the compromise was fractured as labor increased its wage share of value.[83] Manufacturers responded by outsourcing lower skill labor to markets with less protected workers and demerging vertically integrated aspects of business.[84] Firms also won legal victories that "remove[d] antitrust laws banning vertical restraints and . . . establish[ed] that franchisees, not franchisors, were the legal employer of the growing pool of low-wage labor."[85] This allowed firms to contract with branded franchises that were technically independently owned, while the parent firm retained control of most of the critical operational details of the franchise and its employees' day-to-day lives.[86]

Meanwhile, changes in U.S. antitrust and IP law led to increased concentration and monopoly power in certain high-tech industries.[87] Weaker enforcement of antitrust laws enabled more horizontal mergers resulting in increased market concentration, and both Congress and the "Supreme Court expanded the scope of IP protection in novel ways" to strengthen firms' control of new forms of IP.[88] Altogether, these changes resulted in a significant shift in U.S. profits from manufacturing firms to firms that gain their profits primarily from ownership of IP rights.[89] Herman Mark Schwartz, a political economist at the University of Virginia, describes an "ideal typical tripartite structure" of firms that exist in this new economy: (1) firms that solely design products; (2) firms that produce parts for those products; and (3) firms that assemble those parts.[90] Design firms, the first group, have "high human capital, low employee headcount, and low physical capital"; they are also highly profitable.[91] Part-producing firms, the second group, have high physical capital but are less profitable.[92] Assembling firms, the third group, have high employee headcount but low physical and human capital, and are the least profitable.[93]

The current state of the pharmaceutical industry aligns with this economic history. Pharmaceutical corporations gain the bulk of their profits from their IP-

81. *See id.*
82. *See id.* at 252.
83. *Id.*
84. *Id.* at 253 ("In the iconic Fordist automobile industry, employment moved steadily 'south' to non-union 'right-to-work' states in the US, then to Mexico, and finally to low-wage Asia.").
85. *Id.*
86. *Id.*
87. *Id.* at 254–55.
88. *Id.* at 255.
89. *See id.* at 259–60.
90. *See id.* at 249, 255–56.
91. *Id.* at 256.
92. *See id.*
93. *See id.*

protected brand name drugs. Indeed, a single "blockbuster" drug can generate large proportions of a pharmaceutical corporation's revenue for years on end.[94] These corporations extract their profits from the portion of their business model that is the "design firm" group of Schwartz's categories, and also operate "part-producing firm" specialty manufacturing plants. Despite the existence of the specialty manufacturing plants, these companies remain much smaller than the manufacturing behemoths of the Fordist era, and the bulk of their jobs are unavailable to less educated workers.[95] Further, pharmaceutical corporations increasingly contract out portions of their work, such as large-scale clinical trials, resulting in lower headcounts.[96] Although often labeled "manufacturers" in popular discourse, pharmaceutical corporations are different in kind than the industrial manufacturers of the Fordist period because their profits derive primarily from IP rights.

Increasingly, large pharmaceutical corporations do not conduct the original research—the basic science to discover new molecules as well as the initial trials to test the safety of new drugs—needed to create new medical discoveries.[97] They instead purchase IP that has been developed by small companies, often the product of research studies funded by federal grants from the National Institutes of Health (NIH).[98] "In 2018, such small firms accounted for nearly two-thirds of the brand new drugs patented in the United States and nearly three-quarters of drugs in the late stage of the development pipeline."[99] For instance, the blockbuster

94. *See, e.g.*, Kevin Dunleavy, *Humira Rings Up $20.7B in 2021, but AbbVie Still Mum on Post-Biosimilar Expectations*, FIERCE PHARMA (Feb. 2, 2022, 11:33 AM), https://www.fiercepharma.com/pharma/humira-rings-up-20-7-billion-sales-but-abbvie-still-mum-a-projection-for-2023-when-it-faces [https://perma.cc/74NY-B7DU] ("Overall, the company reported revenue of $14.9 billion for the quarter, roughly 36% of which was provided by Humira.").

95. *See* TECONOMY PARTNERS, LLC, 2021 LIFE SCIENCES WORKFORCE TRENDS REPORT: TAKING STOCK OF INDUSTRY TALENT DYNAMICS FOLLOWING A DISRUPTIVE YEAR 10 (2021), https://www.thbi.com/2021-workforce-trends.pdf [https://perma.cc/D89S-ES9Y] ("The life science industry employs a more highly skilled, STEM-intensive workforce compared with all industries nationally . . . . High-skilled jobs typically require a bachelor's or higher degree for entry . . . .").

96. *See* Esther Landhuis, *The Rise of Outsourcing*, 556 NATURE 263, 263 (2018) ("[T]oday, nearly anything that a pharmaceutical, biotechnology or medical-device business needs to do — from designing assays to planning and running clinical trials — can and may be outsourced to [contract research organizations].").

97. *See* David Blumenthal, Mark E. Miller & Lovisa Gustafsson, *The U.S. Can Lower Drug Prices Without Sacrificing Innovation*, HARV. BUS. REV. (Oct. 1, 2021), https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation ("Historically, many breakthrough products did originate with large pharmaceutical companies, but the innovation process in biomedicine has changed fundamentally. Truly innovative therapies — like the mRNA vaccines for Covid-19 . . . — now originate in small companies that are spinoffs of university research efforts mostly funded by the NIH and philanthropies.").

98. *See id.*; *see also* Emily H. Jung, Alfred Engelberg & Aaron S. Kesselheim, *Do Large Pharma Companies Provide Drug Development Innovation? Our Analysis Says No*, STAT (Dec. 10, 2019), https://www.statnews.com/2019/12/10/large-pharma-companies-provide-little-new-drug-development-innovation/ [https://perma.cc/LN7P-G99B] (finding that in 2017, "discovery and early development work were conducted in house for just 10 of Pfizer's 44 products" and "[o]nly two of J&J's 18 leading products (11%) were discovered in house").

99. Blumenthal et al., *supra* note 97.

drug Sovaldi (sofosbuvir), which is highly effective not only at treating but also fully curing Hepatitis C, was developed using various government research grants totaling over $60 million.[100] The biotech company Pharmasset developed the drug from this initial research, investing a comparable $62.4 million, some of which also came from federal funding sources.[101] Pharmasset was eventually acquired by Gilead in 2011 for more than $11 billion; Gilead quickly realized the return on its investment by setting the list price for the drug at $84,000 per year, resulting in $10.3 billion in sales during the first full year the product was marketed.[102]

In this way, pharmaceutical corporations engage in a form of offshoring, but for research risk. The largest corporations do not take on the large risk that basic research will not immediately pan out; the government does. Nor do they take on the risk that basic research will pass through an initial-stage clinical trial; start-up biotech companies do. Instead, they simply purchase the most promising biotech companies after successful initial trials. Of course, the large corporations pay a premium for those investments, and they are risky in their own right, but the largest risks are pushed outside the sanctum of the corporate entity, ensuring revenue and profit streams are as consistent as possible given the risky nature of the business.[103]

The process is in some ways akin to the Schumpeterian idea of "creative destruction" within capitalistic economies, with important caveats.[104] Schumpeter's theory describes creative destruction as an "organic process" of constant industrial evolution within capitalistic systems, in which each business attempts to achieve a monopoly position within a market by replacing its competitors through transformative technological innovation.[105] A capitalist system is thus in a constant state of flux, as businesses vying for a dominant place in the market "incessantly revolutionize[] the economic structure *from within*, incessantly destroy[] the old one, incessantly creat[e] a new one."[106] Reacting to these disciplining forces, capitalistic economies experience constant innovation within markets as new entrants seek monopoly power by offering goods that are better in kind than what was previously available.[107] Modern pharmaceutical corporations exhibit these economic patterns, in a certain sense, as they vie to develop the newest treatments, some of which are truly innovative in comparison to the current state of treatment.

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100. *See* Rachel E. Barenie, Jerry Avorn, Frazer A. Tessema & Aaron S. Kesselheim, *Public Funding for Transformative Drugs: The Case of Sofosbuvir*, 26 DRUG DISCOVERY TODAY 273, 273, 280 (2021).

101. *Id*. at 279.

102. *Id*. at 279–80.

103. *Cf*. Schwartz, *supra* note 79, at 249 ("The key difference is that [intellectual property rights-based] profit strategies combined with pressure from capital markets influenced by the shareholder-value model to drive vertical *disintegration* of commodity chains. Firms try to shed the risks inherent in fixed investments and a large labor force while using robust [intellectual property rights (IPRs)] to extract large shares of the value created in their commodity chain.").

104. *See generally* JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM & DEMOCRACY 81–86 (Routledge 2003) (1943).

105. *See id*. at 83–84.

106. *Id*. at 83 (footnote omitted).

107. *See id*. at 84.

However, the process by which pharmaceutical corporations develop monopoly positions is by no means "organic." Instead, the American IP system creates monopolies by design, seeking to provide incentives to reward expensive R&D.[108] Many new monopoly-protected pharmaceutical products offer only incremental improvement, or are merely reformulations of existing drugs that gain new patent protection, and are therefore not transformative innovations.[109] Nevertheless, the IP system provides the patent holder with monopoly pricing rights whether the new product is entirely curative or merely increases life expectancy by a few weeks compared to the current standard of care.[110] The pharmaceutical industry is further sheltered from the roiling sea of creative destruction because patients do not interact directly with the industry through their purchasing decisions.[111] For instance, if a new chemotherapy increases life expectancy by a month compared to the existing therapy and the standard of care is updated, oncologists may be motivated to prescribe the new product, even if the net price of the drug is much higher than the previous drug.[112] Patients, who experience price only indirectly through their insurance benefit design and who cannot prescribe themselves drugs, do not exert the same price discipline on the pharmaceutical industry as they do in other industries where consumption decisions are the result of an interaction between price and quality. Thus, the process of creative destruction exists in only a limited, institutionalized way within the pharmaceutical industry.

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108. *See supra* Part I.

109. *See* INT'L FED'N OF PHARM. MFRS. & ASS'NS, INCREMENTAL INNOVATION: ADAPTING TO PATIENT NEEDS 8 (2013), https://ifpma.org/publications/incremental-innovation-adapting-to-patient-needs [https://perma.cc/TU8N-KCHQ]; *see also* Ravi Gupta, Christopher J. Morten, Angela Y. Zhu, Reshma Ramachandran, Nilay D. Shah & Joseph S. Ross, *Approvals and Timing of New Formulations of Novel Drugs Approved by the US Food and Drug Administration Between 1995 and 2010 and Followed Through 2021*, JAMA HEALTH F., May 20, 2022, at 1, 2 ("[I]n some cases new formulations, particularly tablets and capsules, may not be clinically superior to the novel drug."); John-John B. Schnog, Michael J. Samson, Rijk O.B. Gans & Ashley J. Duits, *An Urgent Call to Raise the Bar in Oncology*, 125 BRIT. J. CANCER 1477, 1477 (2021) (noting that newly approved anticancer drugs "often offer limited benefits to patients").

110. There is certainly room to debate the true value of incremental improvements in pharmaceuticals. Any given patient and their family may place enormous value on the hope of additional weeks or months of life. Moreover, what even qualifies as "incremental" is a highly subjective determination. *See generally* Aaron S. Kesselheim & Jerry Avorn, Opinion, *The Most Transformative Drugs of the Past 25 Years: A Survey of Physicians*, 12 NATURE REVS. DRUG DISCOVERY 425 (2013) (sharing different perspectives among doctors as to what makes a drug transformative and innovative). That being said, there is unarguably a big difference between a drug that cures a patient's illness entirely and a drug that extends the life of a patient by a relatively short amount of time. Most European single-payer purchasing institutions account for the improvement of a drug compared to existing therapies in their calculation of the drug's value. *See supra* note 26 and accompanying text.

111. *See supra* Section II.C.

112. *See* Mark J. Ratain, Editorial, *Oncology Drug Prescribing: The Influences of Greed and Fear*, 18 JCO ONCOLOGY PRAC. e1384, e1384 (2022) ("Thus, a financially motivated physician interacting with a scared patient often leads to administration of an expensive drug, particularly since a discussion about less toxic or less expensive treatment options (or a watch and wait approach) is time-consuming, yields no revenue related to prescribing, and scores no key opinion leader prescribing points.").

Recognizing the key importance of monopoly-protected IP in their business models, pharmaceutical companies employ and retain many lawyers, paying handsome sums to zealously defend their patent rights.[113] The motivation underlying these large expenditures (statistics for which are not readily available to the public)[114] is that legal control of a patent results in potentially massive revenues. For instance, in 2019 the pharmaceutical company Juno (a subsidiary of Bristol-Myers Squibb-Celgene) and the cancer hospital Memorial Sloan Kettering (MSK) brought suit against Kite (a subsidiary of Gilead) alleging patent infringement related to a new "CAR-T" therapy.[115] These new medical technologies have the potential to significantly improve cancer treatment, but come with eye-popping list prices—as high as $373,000 per treatment.[116] The jury found that Kite had violated Juno and MSK's patent rights and awarded nearly $780 million in damages, which was then increased to $1.2 billion by a district court judge.[117] Kite appealed the ruling, and the Federal Circuit Court of Appeals vacated the jury verdict; the Supreme Court declined to hear June and MSK's appeal.[118] Because ownership of IP rights comes with such large projected revenues—indeed, it is the main driver of revenues—pharmaceutical companies are understandably willing to spend large sums on legal actions to protect their IP rights. As the profits generated by IP-based firms continue to rise, the amount of money spent jockeying in courts for a share of those profits will likely also rise.

PBMs, the intermediaries between payers and manufacturers that negotiate rebates, are also creatures of an information-based economy. PBMs maintain formularies, design prescription drug benefits, and negotiate rebate agreements with pharmaceutical corporations on behalf of payers. In the pharmaceutical supply chain, PBMs never actually handle the physical product—the drugs. Instead, they control and exchange confidential information and use that information as leverage to negotiate the net prices ultimately paid from payer to manufacturer.

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113. *See* RICHARDS ET AL., *supra* note 78, at 1–2; Brian Baxter, *A Look at What Some of Big Pharma's Top Lawyers Earned in 2019*, BLOOMBERG L. (Apr. 1, 2020, 5:30 AM), https://news.bloomberglaw.com/esg/a-look-at-what-some-of-big-pharmas-top-lawyers-earned-in-2019. To note, as of May 11, 2023, the Senate HELP Committee is considering legislation that would limit some of these pharmaceutical patent strategies. *See Hearing Before the S. Comm. on Health, Educ., Lab. & Pensions*, *supra* note 78; Liu, *supra* note 78.

114. *See* Damien Conover, *What Litigation Risk Means for Big Pharma and Biotech Valuations*, MORNINGSTAR (Sept. 10, 2021), https://www.morningstar.com/articles/1057502/what-litigation-risk-means-for-big-pharma-and-biotech-valuations [https://perma.cc/9N3R-QA8N] ("In aggregate, the 18 large-cap drug and biotech companies under Morningstar coverage have paid nearly $4 billion a year on average in litigation fees from 2016 to 2020. However, company disclosures of legal fees are very ambiguous.").

115. Juno Therapeutics, Inc. v. Kite Pharma, Inc., No. 17-cv-07639, 2020 WL 10460622, at *2 (C.D. Cal. Mar. 24, 2020), *rev'd*, 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022) (mem.).

116. *See* Inmaculada Hernandez, Vinay Prasad & Walid F. Gellad, Letter, *Total Costs of Chimeric Antigen Receptor T-Cell Immunotherapy*, 4 JAMA ONCOLOGY 994, 994 (2018).

117. *See* Angus Liu, *Gilead Wins Reversal of $1.2B Fine in CAR-T Patent Fight with Bristol Myers*, FIERCE PHARMA (Aug. 26, 2021, 11:59 AM), https://www.fiercepharma.com/pharma/gilead-reverses-1-2b-fine-car-t-patent-fight-against-bristol-myers [https://perma.cc/P6ZL-VPQQ].

118. *Juno Therapeutics*, 10 F.4th at 1342.

Rebate contract terms are trade secrets, so firms with larger market shares are able to collate more information to better inform their contracting tactics and increase leverage.[119] Accordingly, the industry is highly and increasingly consolidated, with three firms controlling nearly ninety percent of the market.[120]

PBMs are an institution "peculiar" to the United States.[121] In countries with single-payer systems, where the government negotiates directly with manufacturers, there is no need for an intermediary to negotiate pricing between payers and manufacturers or maintain different formularies.[122] Although PBM profit margins tend to be slimmer than those of pharmaceutical corporations,[123] PBMs are a source of profit extraction in the industry and a key force responsible for obfuscating comprehensible pricing information, all without handling physical product. Because their business is designed around keeping information confidential, PBMs are not forthcoming, to say the least, when asked to disclose information. Louisiana recently filed suit against Optum (the PBM subsidiary of UnitedHealth Group), which provides PBM services for Louisiana's Medicaid program, alleging that Optum had overcharged the state by billions of dollars.[124] Prior to filing the lawsuit, the Louisiana Attorney General requested that UnitedHealth hand over PBM contracts for an audit; five months later, UnitedHealth provided 2,200 pages of documents—but eighty-three percent were fully redacted.[125]

In these ways, the political economy of the pharmaceutical industry is reflective of and contributes to the rise in income and wealth inequality in the United States. Profits are increasingly concentrated among firms, such as pharmaceutical corporations, that derive their profits from control of IP rights. These firms do not have large employee bases with which they may feel pressure to share profits, increasing wealth concentration.[126] A crucial input for these firms is information: IP-protected scientific information, legal services, and trade secret-protected pricing information. Large pharmaceutical corporations are increasingly entities that

119. *See* Dieguez et al., *supra* note 59. The Senate HELP Committee began considering legislation that would require increased transparency of PBM business practices on May 11, 2023. *See Hearing Before the S. Comm. on Health, Educ., Lab. & Pensions*, *supra* note 78; Liu, *supra* note 78.

120. *See Pharmacy Benefit Managers*, NAIC (Apr. 11, 2022), https://content.naic.org/cipr-topics/pharmacy-benefit-managers [https://perma.cc/M483-7JKQ].

121. *See* Rena M. Conti, Brigham Frandsen, Michael L. Powell & James B. Rebitzer, *Common Agent or Double Agent? Pharmacy Benefit Managers in the Prescription Drug Market* 1–2 (Nat'l Bureau of Econ. Rsch., Working Paper No. 28866, 2022).

122. *See supra* note 26 and accompanying text.

123. BILL HEAD, PHARM. CARE MGMT. ASS'N, PBMS AND THEIR ROLE IN THE DRUG SUPPLY CHAIN 9 (2019), https://www.dmhc.ca.gov/Portals/0/Docs/DO/Final%20PCMA%20AB%20315%20TF%20Presentation%20Sept%202019.pdf?ver=2019-09-27-111859-027 [https://perma.cc/KY7K-2CHK].

124. *See* John Tozzi, *UnitedHealth Inflated Drug Costs, Louisiana Attorney General Alleges in Suit*, BLOOMBERG (Apr. 20, 2022, 3:04 PM), https://www.bloomberg.com/news/articles/2022-04-20/unitedhealth-inflated-drug-costs-louisiana-ag-alleges-in-suit.

125. Shelby Livingston (@ShelbyJLiv), TWITTER (Apr. 20, 2022, 5:50 PM), https://twitter.com/ShelbyJLiv/status/1516897203918454787.

126. *Cf.* Schwartz, *supra* note 79, at 264 ("The concentration of profits into low-headcount, IPR-rich firms also directly and indirectly affects income distribution, and through that growth and politics.").

exist to purchase, protect, and profit from IP rights, rather than the exclusive drivers of innovation they claim to be.

B. THE DOUBLE MOVEMENT AND PART D

On December 8, 2003, President George W. Bush signed Medicare Part D into law, expanding Medicare to include coverage of prescription drugs for American seniors.[127] The issue had been floated under the Clinton Administration and had gained enough political momentum that the Bush Administration (and the pharmaceutical industry) realized they were better off expanding a government benefit under their own terms rather than risk a Democratic administration designing a program.[128] The bill passed the House at 5:53 AM after Republican Representative Billy Tauzin, then ranking member of the GOP, called a vote on the bill for 3:00 AM.[129] This was done, according to one of Tauzin's Republican House colleagues, because there were "a lot of shenanigans . . . going on that night (that) they didn't want on national television."[130] Former Democratic Representative Louise Slaughter asserted that the "political process used to pass Part D was the worst abuse of the legislative process I have seen during my 20 years in Congress" and noted that Democrats were "physically barred" from negotiations while pharmaceutical lobbyists were "invited in."[131] Members from both parties acknowledge that "the pharmaceutical lobbyists wrote the bill."[132] Indeed, pharmaceutical lobbyists were physically on the floor of the House during the witching-hour vote, helping GOP leadership whip the final votes it needed to pass the bill.[133] Less than a year after the bill's passage, two of the chief negotiators of the bill, Representative Tauzin and Centers for Medicare and Medicaid Services (CMS) Administrator Thomas Scully, were working as lobbyists for the pharmaceutical industry. Tauzin accepted a job as chief lobbyist for PhRMA that came with an annual salary of $2 million, "one of the largest salaries ever paid to any advocate by an industry."[134] Scully launched

127. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, tit. I, 117 Stat. 2066.

128. *See generally* Josh Rosmarin, Winning the Battles, Losing the War: Business Power and the Case of the American Pharmaceutical Industry (Apr. 16, 2012) (B.A. thesis, Yale University) (charting the political and legislative histories of Medicare drug benefit proposals under Clinton and Bush).

129. *See* Wendell Potter & Nick Penniman, *The Lobbyist Who Made You Pay More at the Drugstore*, BILLMOYERS.COM (Mar. 18, 2016), https://billmoyers.com/story/the-man-who-made-you-pay-more-at-the-drugstore/ [https://perma.cc/5UYC-6VYH].

130. *Id.*

131. Louise M. Slaughter, *Medicare Part D—The Product of a Broken Process*, 354 NEW ENG. J. MED. 2314, 2314 (2006).

132. Potter & Penniman, *supra* note 129 (quoting Republican Representative Walter Jones); *see also* Michelle Singer, *60 Minutes: Under The Influence*, CBS NEWS (July 23, 2007), https://www.cbsnews.com/news/under-the-influence/ [https://perma.cc/B2QV-9NJS] (quoting former Democratic Representative John Dingell: "I can tell you that when [Part D] passed, there were better than 1,000 pharmaceutical lobbyists working on [the bill]. . . . And it's probably also true that [the bill] was written by their lobbyists.").

133. *See* Potter & Penniman, *supra* note 129.

134. *Washington's Revolving Door*, LEDGER (Dec. 19, 2004, 11:01 PM), https://www.theledger.com/story/news/2004/12/20/washingtons-revolving-door/26136474007.

a lobbying and legal career with a focus on pharmaceutical clients.[135] In short, the pharmaceutical industry strongly supported the passage of Part D and exerted heavy influence in its passage.

Medicare Part D represented a massive expansion of the government's role as a health insurer.[136] Why, then, did the pharmaceutical industry so strongly influence the passage of the bill? After all, the pharmaceutical industry "frame[s] their arguments[s] within the standard language of market freedom" and "insist[s] that they invested scarce resources in developing new medications and it is only fair that they be able to profit from their discovery wherever there is demand for that product."[137] This market-based language is in tension with support for a large expansion of the role of government. Indeed, in the lead up to Part D's enactment, ideologically libertarian groups "attacked the new benefits as a burden to taxpayers," pointing to forecasted increases in government expenditures for drugs that were previously purchased privately.[138] Rather than have the government step in, these groups suggested, a better policy would be to let individual consumers and the market dictate how these drugs would be purchased.

As Austro–Hungarian economic anthropologist Karl Polanyi noted long ago, however, "the market system [does] not and [can]not exist independently of government action."[139] Instead, the state must at the very least define the outer edges of the market by protecting property rights, establishing a money supply, and managing labor inputs.[140] Thus, proponents of laissez-faire, market-based economics state a "political goal—a fully self-regulating market economy—[that] is fundamentally impractical and incoherent."[141] This logical incoherence leaves a "substantial gap between the ideology and the reality" that opponents of self-regulating markets can use "to win incremental changes that help protect society from the market."[142] For Polanyi, capitalism results from this "double movement": a constantly shifting tension between proponents of laissez-faire economics and movements of protection.[143] Medicare Part D, designed to pay for important medications for the nation's vulnerable seniors, represented such a political opportunity for protective incremental change.

While the pharmaceutical industry invoked the "vision of a self-regulating market system" through its rhetoric, they recognized "their own dependence on

135. *See id.*; *see also* Peter H. Stone & Louis Jacobson, *Former Medicare Chief Soldiers on in Wake of Ethics Investigations*, GOV'T EXEC. (Apr. 9, 2004), https://www.govexec.com/management/2004/04/former-medicare-chief-soldiers-on-in-wake-of-ethics-investigations/16439 [https://perma.cc/S7TS-6LK4].

136. *See* Potter & Penniman, *supra* note 129 (noting that spending estimates for Part D ranged from $400 billion to $530 billion over ten years).

137. Fred Block, *Polanyi's Double Movement and the Reconstruction of Critical Theory*, 38 PAPERS POL. ECON. 20, 25 (2008).

138. Thomas R. Oliver, Philip R. Lee & Helene L. Lipton, *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK Q. 283, 320 (2004).

139. Block, *supra* note 137, at 21.

140. *See id.*

141. *Id.*

142. *Id.*

143. *See id.* at 20.

the . . . exercise of the state's coercive powers to protect their property . . . and manage the market system [themselves]."[144] They must, of course, because their IP-dependent business model is reliant on the state for its very existence:

> First, the firm's home government must grant the firm a patent, essentially a monopoly over the production of a particular product for a given time period. Second, that home government, or one of its allies, must make clear to governments in other parts of the world that they are determined to protect the firm's property rights overseas. Third, other governments must agree to enforce that patent and interdict any competitor's product that infringes on that patent. In short, the property right is not self-enforcing; it requires political action in multiple sites.[145]

Therefore, disguised in the language of market-based freedom, the industry recognized the political opening, co-opted the protective movement, and literally wrote the law to develop new forms of drug "markets" that catered to pharmaceutical corporations' interests.

A key issue during the legislative debate around Part D was whether Medicare would be able to directly negotiate with pharmaceutical corporations to determine what the government would pay for a given drug. If given that ability, Medicare would be able to function much like European single payers do and use its huge purchasing power to negotiate lower prices.[146] Alas, the final legislation, shaped by lobbyists, explicitly forbade the government from directly negotiating with pharmaceutical corporations.[147] Instead, privately operated PDPs would contract with PBMs to negotiate individually with pharmaceutical corporations. The (paper-thin) argument in support of this policy is that allowing private firms to negotiate individually will result in a more efficient, market-based outcome. This ban on government price negotiations, supposedly designed to use competition to reach efficient outcomes, "has been derided by critics as a giant gift to the drug industry."[148] The drug industry is able to benefit from this restriction because no single PDP represents more than twenty-one percent of Part D enrollees, and the leverage of any individual plan is limited by the size of its enrollee base.[149] Any given PDP, therefore, possesses far less leverage in negotiations with pharmaceutical corporations than the U.S. government would and accordingly cannot negotiate

144. *Id*. at 25.

145. *Id*.

146. *See infra* Section IV.B.

147. *See* 42 U.S.C. § 1395w–111(i) ("Noninterference—*In order to promote competition* under this part and in carrying out this part, the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." (emphasis added)).

148. Stuart Silverstein, *This Is Why Your Drug Prescriptions Cost So Damn Much*, MOTHER JONES (Oct. 21, 2016), https://www.motherjones.com/politics/2016/10/drug-industry-pharmaceutical-lobbyists-medicare-part-d-prices/ [https://perma.cc/EX7K-LDAH].

149. MIKE MCCAUGHAN, MEDICARE PART D 2 (2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000172/full/ [https://perma.cc/K4Y9-CAWR].

lower prices. Additionally, this policy has resulted in a proliferation of complicated, opaque supply chains with many opportunities for profit extraction, as illustrated in Part II.

The Part D program has undoubtedly made an important difference in the lives of millions of seniors, despite its bizarre and costly benefit design.[150] It also provides a massive profit opportunity for pharmaceutical corporations. Part D will spend $119 billion in 2023, the bulk of which is revenue for pharmaceutical corporations.[151] The pharmaceutical industry understands that its continued profitability is contingent on government policies—development funding, IP law enforcement, payment policies—that define the markets in which it operates. The text of the Part D statute states that the purpose of the noninterference clause is "to promote competition," but this is misleading rhetoric; the purpose is to ensure that the full weight of Medicare's negotiating power cannot be exerted against any pharmaceutical corporation.[152] Hence, the industry participates in the "double movement" of development of market society to shape the rules of the game to their liking.

The intellectual cadre of the LPE movement note that our current moment in history presents a series of crises: rising inequality, economic precarity, and impending climate chaos. In the inaugural LPE text, the authors assert that these crises cannot be addressed without altering how political power is allocated: "The political response to these problems has proven insufficient. Our democratic structures of decision-making are hollowed out. Government enacts the policy preferences of the rich over those of the majority."[153] The details surrounding the enactment of the Part D benefit support these observations. Although the passage of the IRA suggests that positive action is possible in the current political climate, it is limited in scope by design and its enactment will almost certainly face significant political and litigation pushback.[154]

C. INVESTIGATING NEOLIBERAL ASSUMPTIONS

Though the structure of the pharmaceutical market is defined by law and regulation, the industry and its supporters repeatedly employ neoliberal language of markets and competition, despite the structural incoherence of these claims. Such language mistakenly separates questions of law from questions of economics, reflecting the "prevailing models of legal thought and scholarship, which have

150. *Id.* at 1–3 (noting that Part D provided benefits to more than forty million people in its first decade; stating that beneficiaries have no OOP limit in PDPs; and describing the "donut hole" in the benefit which left a gap between "the initial insurance coverage and the trigger point for catastrophic coverage"—the hole was fixed by the ACA); *see also* AVALERE HEALTH, *supra* note 70, at 2 (describing phases of the Part D benefit design).

151. *See An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 57.

152. 42 U.S.C. § 1395w–111(i).

153. Britton-Purdy et al., *supra* note 31, at 1788–89 (footnote omitted).

154. *See infra* Sections IV.A–B; Peter Sullivan & Victoria Knight, *House GOP Eyes Repeal of Dems' Drug Pricing Law*, AXIOS (Sept. 23, 2022), https://www.axios.com/2022/09/23/gop-drug-price-repeal-target [https://perma.cc/TU42-UF7W].

been profoundly shaped by a misconception of the relationship between politics and the economy."[155] Instead, these questions are inextricably linked because markets are neither self-creating nor self-enforcing, but rather rely on the background set of rules and regulations established by the state.

This misconception is seen in the "division of labor" among legal fields, in which "some legal subfields have been reoriented around versions of economic 'efficiency.'"[156] Efficiency is defined as a form of wealth maximization, inherently prioritizing the interests of those with wealth over those without.[157] By focusing myopically on efficiency, the discourse around how society might be structured is severely limited: "This methodological approach offers no framework for thinking systematically about the interrelationships between political and economic power. Its commitment to summative conceptions provides it no means to analyze, let alone counter, contemporary concentrations of wealth and power, except insofar as they interfere with overall efficiency."[158] The field of IP law developed in tandem with the emergence of the neoliberal consensus and ascension of the field of law and economics.[159] Indeed, "[t]he term 'intellectual property' itself was hardly used before the 1960s, and its use exploded only in the 1980s and 1990s."[160] IP law combined a variety of distinct legal regimes, including patent, copyright, and trademark and trade secrets, into a single field designed around information production.[161] While each originally sought to promote the advancement of society in a specific way to realize political values, "economic thinking . . . joined these radically different legal regimes together into one subject and rendered the pursuit of efficiency their aim."[162] The putative appeal of this market approach is that it can deliver a "rough approximation[] of distributive justice" even while ignoring theoretical problems of distributive justice and practical problems about the fulfillment of needs.[163]

However, this approach does not adequately address questions of distribution or coercion.[164] Instead, it assumes that markets are the most efficient ordering device, and that by extending property right protections (foundational to IP law) as widely as possible, individual actors will internalize externalities to maximize efficiency.[165] The LPE founders note that "[t]his assumption epitomizes law and economics: it simultaneously recognizes and embraces the fact that law makes

155. Britton-Purdy et al., *supra* note 31, at 1789.
156. *Id.* at 1790. These legal subfields include "contracts, property, antitrust, intellectual property, [and] corporate law." *Id.*
157. *See id.*
158. *Id.*
159. *See id.* at 1802.
160. *Id.*
161. *Id.*
162. *Id.*
163. *Id.* at 1813.
164. *See id.* at 1813–14.
165. *See id.* at 1799.

markets, while demanding that the satisfaction of markets becomes the aim of politics."[166]

IP law, central to the pharmaceutical industry, reflects these assumptions. Even though monopoly pricing attached to exclusive patent rights comes with acknowledged deadweight loss, the patent regime is presumed to be "more efficient than government production, largely because of the way that exclusive rights in information guide decisions about the allocation of inventive resources."[167] Assigning property rights to information allows for the use of pricing mechanisms to transmit information between consumers and creators, linking "production of information to consumer demand, and, by extension, to social welfare."[168] In other words, the key assumption is that patents will enable consumers to exert their preferences through pricing mechanisms, which will guide R&D producers to develop breakthroughs that are most desired by the widest body of people.

This assumption is just that—an assumption—but it forms the basis for modern IP law, in which IP rights are the "privileged means of promoting scientific . . . production."[169] The consensus around this assumption forces the bulk of inquiry into IP law to stay within those defined boundaries. Because the IP system is presumed to be the most efficient system, mainstream IP law questions are "internal" to the IP system: the academy debates about the extent of patent rights or how to best administer them, not whether the IP system is truly the optimal system for information production.[170] In the pharmaceutical context, this phenomenon is demonstrated by the many arguments over the questionable ways that pharmaceutical corporations legally protect their patent rights,[171] despite mainstream hesitancy to question the sanctity of patent rights in the first place.[172] But it is not obvious from first principles nor from empirical evidence that IP is more efficient than other commons-based approaches to the production of knowledge.[173]

166. *Id.*

167. Kapczynski, *supra* note 35, at 974.

168. *Id.* at 974–75. As demonstrated in Part II, this theoretical claim is belied by the realities of the pharmaceutical supply chain and patients' experience of price.

169. *Id.* at 975.

170. *See id.*

171. *See* RICHARDS ET AL., *supra* note 78, at 1–2.

172. *See, e.g.*, Ed Silverman, *Drug Makers Urge Biden to Reject Proposal to Waive Patent Rights on Covid-19 Products*, STAT (Mar. 8, 2021), https://www.statnews.com/pharmalot/2021/03/08/biden-covid19-coronavirus-vaccine-wto-who-covax-pfizer-merck-jnj/; Sarah Lazare, *Documents Reveal Biden Admin Not Fighting for a Covid Vaccine Patent Waiver, Despite Public Statements*, IN THESE TIMES (Nov. 29, 2021), https://inthesetimes.com/article/biden-omicron-wto-trips-waiver-intellectual-property-patents [https://perma.cc/P2FS-5639] (describing the lack of urgency from the Biden Administration in World Trade Organization negotiations resulting in "a slowing down of negotiations," despite the Biden Administration's public rhetoric suggesting that COVID vaccine IP should be shared).

173. *See* Kapczynski, *supra* note 35, at 977; *see also* Nick Warino, *The Nordic Model Invents the Goods*, PEOPLE'S POL'Y PROJECT (2022), https://www.peoplespolicyproject.org/projects/nordic-state-innovation [https://perma.cc/68DR-FTU7] (examining Nordic state institutions that direct innovation activities and arguing that these models are superior to the American innovation model).

The history of the United States' policy of technology transfer—crucial to the pharmaceutical industry—demonstrates that the current neoliberal consensus on the subject, based on IP justifications, was not inevitable but the result of industry influence trumping other ideas on how to organize the production of information.[174] The Reagan Administration passed the Bayh-Dole Act and follow-on legislation in the early 1980s, creating the "legal framework that determines ownership rights to state-backed inventions."[175] This framework creates a "striking distributive logic"[176] in the interactions between the government, which provides federal funding for R&D, and the corporations that come to own patent rights:

> Collectively, the federal government's set of R&D agencies channel massive amounts of public funding into privately owned assets. The key institutional mechanism through which this occurs is the transfer of government-funded patent rights to the private R&D contractors that participate in research projects. Upon completion of a successful R&D project, private contractors assume ownership of the IP generated through state-funded research. *At this juncture, a public resource is transformed into a source of private profit*.[177]

This exact dynamic is central to the pharmaceutical industry, in which most initial funding for basic research is provided by the NIH, turned into private patent rights by small biotech companies, and purchased for huge sums of money by large pharmaceutical corporations.[178] The rationale underlying this policy, now the conventional wisdom of the Twentieth-Century Synthesis, reflects the same rationales underlying the price-centric IP regime. Efficiency and patent utilization are the key justifications for making commercialization spin-offs the chief aim of the federal R&D system.[179] This neoliberal rhetorical consensus, although dominant, "eclipses a longer and more politically significant story" about a "set of broader value claims and policy concerns" regarding the "relationship between business and the state in technological development."[180] Prior to the emergence of this consensus, New Deal progressives "conceptualized government-funded research and public patent ownership as a counterweight to private research power and as a means of redistributing the social benefits of innovation."[181] As federal R&D spending continued to expand during World War II and the Cold War, this broader conception of patent rights remained prevalent.[182] Though initially opposed, "private industry eventually accommodated the federal R&D

174. *See* Daniel Traficonte, Property and Power on the Endless Frontier 63–64 (Aug. 9, 2021) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3901914 [https://perma.cc/42LL-DVTF].

175. *Id.* at 3.

176. *Id.*

177. *Id.* (emphasis added).

178. *See supra* Section III.A.

179. *See* Traficonte, *supra* note 174, at 4.

180. *Id.* at 4–5.

181. *Id.* at 5.

182. *See id.*

system and ultimately came to depend on it," resulting in industry's push to promote commercialization as a key goal of IP policy.[183] Eventually, industry interests won out, and "more expansive conceptions of government patent policy were abandoned," leaving only the commercialization rationale.[184] This dynamic is again reflective of Polanyi's "double movement" of politics in market-based economies.[185] Law professor and political economist Daniel Traficonte concludes that this history demonstrates that "the technology transfer consensus reflects the success of private industry in steering major policy choices toward its own ends and in shaping the policy discourse in a pro-business direction."[186]

Traficonte's history of the emergence of the technology transfer consensus tracks with an understanding of neoliberalism as the intentional "encasement" of markets.[187] Rather than a "liberation" of markets, which implies that markets exist in some independent sense, "the real focus of neoliberal proposals is not on the market per se but on redesigning states, laws, and other institutions to protect the market."[188] Even Friedrich Hayek, often thought of as the prototypical pro-market libertarian theorist, recognized the need for governments to construct a framework in which the economy would operate.[189] Neoliberal thought recognizes that "the market does not and cannot take care of itself."[190] Instead of seeking to liberate markets, neoliberal policies design institutions to encase markets and "inoculate capitalism against the threat of democracy" on a global scale.[191] Democratic governance presents a potential threat to capital because the masses might vote for policies of progressive distribution.[192] The global IP regime that the pharmaceutical industry relies on is an example of this type of market encasement. To join the World Trade Organization, countries must agree to the patent protection laws contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[193] Capital, which owns and extracts profits from its IP,[194] is protected by this agreement because it provides constraints on countries that might prefer to, for instance, share IP in a more distributive manner.

The Twentieth-Century Synthesis can be seen in IP price internalism, in commercialization-centric R&D policies, and in a global encasement of market-

183. *Id.*
184. *Id.*
185. *See supra* Section III.B.
186. Traficonte, *supra* note 174, at 65.
187. *See* QUINN SLOBODIAN, GLOBALISTS: THE END OF EMPIRE AND THE BIRTH OF NEOLIBERALISM 13 (2018).
188. *Id.* at 5–6.
189. *See id.* at 7.
190. *Id.* at 2.
191. *Id.*
192. *See id.* at 4.
193. *See Pharmaceutical Patents and the TRIPS Agreement*, WORLD TRADE ORG. (Sept. 21, 2006), https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm [https://perma.cc/2K7J-4QCP]; Block, *supra* note 137.
194. *See supra* Section III.A.

protecting policies. As the LPE founders explain it, the purpose of this neoliberal consensus is to obfuscate and limit what appears to be politically possible by hiding the real questions:

> We lost the ability to see certain commitments in our law . . . as either reflecting or calling forth certain kinds of political values, or as taking a side in disputes that were inevitably struggles for power. That move, of course, was not neutral. It expressed a particular view of power and legitimacy . . . .[195]

For many years, the debate about pharmaceutical pricing has been limited by this false neutrality of market supremacy. As large pharmaceutical industries gained increasing power within the U.S. economy, they insisted that their outsized profit margins were absolutely necessary to incentivize innovation because that is how innovation is created in a market-based society. In actuality, the industry helped to shape many of the laws and regulations that encase various pharmaceutical markets in ways that helped their own interests.[196] The industry conducted less and less of their own R&D, preferring to outsource the risky initial stages of research to the government and small biotech companies; the history of the technology transfer regime shows that this, too, was the result of the neoliberal consensus that prioritized business interests.[197] Shrouded in the cloak of the Twentieth-Century Synthesis, these large-scale shifts long escaped mainstream notice.

However, recent events, such as Purdue Pharma's criminal role in the opioid crisis[198] and the federal government's huge investment in the rapid development of COVID vaccines,[199] may have finally cracked the industry's impenetrable shell of neoliberal rhetoric. Indeed, the passage of the IRA may represent the first step in reforming the industry. As policymakers consider the next steps in drug pricing policies beyond moderate changes to the Medicare program, an LPE-influenced framework will help to ensure that reform is optimized for the general public by directly considering questions of equity.

IV. POLICIES FOR REFORM

There are many ideas for how to reform the pharmaceutical industry. Some are transformative; others would provide patients with financial relief while leaving the basic structure of the industry unchanged. This Part, which is by no means comprehensive, will survey some of these proposed ideas. The IRA includes

195. Britton-Purdy et al., *supra* note 31, at 1806.

196. *See supra* Section III.B.

197. *See supra* Section III.A.

198. *See, e.g.*, Jan Hoffman, *Purdue Pharma Is Dissolved and Sacklers Pay $4.5 Billion to Settle Opioid Claims*, N.Y. TIMES (Sept. 17, 2021), https://www.nytimes.com/2021/09/01/health/purdue-sacklers-opioids-settlement.html.

199. *See* Richard G. Frank, Leslie Dach & Nicole Lurie, *It Was the Government That Produced COVID-19 Vaccine Success*, HEALTH AFFS. (May 14, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210512.191448 [https://perma.cc/D9FX-P2FX].

provisions to modify the Medicare Part D benefit design and to allow Medicare to negotiate with manufacturers for the prices of some drugs. This Part will also briefly analyze the extent and possible impacts of these new, not-yet-implemented policies.

A. REDUCE PATIENT OOP RESPONSIBILITIES

Patients, especially low-income patients, are sensitive to the perceived cost of a drug during a pharmacy counter transaction.[200] Many patients with high deductibles or who are uninsured "literally need to decide if they will pay for their insulin or for their housing and food."[201] Higher perceived costs at the point of sale lead to patients rationing use of, or forgoing altogether, potentially life-critical drugs. Many of these drugs, such as insulin or anticoagulants, are prophylactic in nature, designed to prevent the onset of a more debilitating health event such as diabetic ketoacidosis or a stroke. If a diabetic who cannot afford their insulin winds up in the emergency room, it is a failure of the medical system in two regards. The first is a basic moral failure: health care is a right, and it is unjust that a person will end up in a life-threatening, painful situation merely because they cannot afford an OOP payment. The second is a failure of system efficiency: each emergency room trip is extremely expensive, meaning that the healthcare system as a whole pays more than it would have if the patient could have simply had their medication in the first place.[202] A variety of policy changes, some supported by the pharmaceutical industry, would alleviate these issues by changing the way that patients experience price at the pharmacy counter.

The IRA includes provisions to redesign the Part D benefit to limit patients' exposure to OOP costs.[203] The benefit will now include a maximum yearly OOP limit of $2,000 and will restructure how the costs of drugs are borne at different stages of the benefit.[204] This policy is supported by patient interest groups and the pharmaceutical industry alike because the industry recognizes that patients are more likely to fill their prescriptions if their personal costs are lower, resulting in

200. *See* Luiza et al., *supra* note 73.

201. Geoff Colvin, *Insulin's Deadly Cost: Ultrahigh Prices in the U.S. Mean Many Diabetics Can't Afford the Medication They Need to Survive*, FORTUNE (Dec. 6, 2021, 3:15 PM), https://fortune.com/longform/insulin-cost-diabetes-treatment.

202. *See* ASPEN INST., BUDGETING FOR DISEASE PREVENTION AND HEALTH PROMOTION: IMPROVING THE FEDERAL SCOREKEEPING PROCESS 14–15 (2022), https://www.aspeninstitute.org/wp-content/uploads/2022/03/REPORT-Budgeting-for-Disease-Prevention-and-Health-Promotion.pdf [https://perma.cc/A665-SJC2]. Although the long-term budgetary projections for preventative services are complicated due to the inherent difficulty in making projections beyond a short timeframe and the inescapable economic implication that patients who die early cost the system less, it is widely accepted that certain preventative services are net savers even under current budgetary practices. *See id.* at 15.

203. *See* Inflation Reduction Act, Pub. L. No. 117-169, secs. 11201–11202, 136 Stat. 1818, 1877–95 (2022).

204. *See* DAVID J. FARBER, PREEYA NORONHA PINTO, JOHN D. SHAKOW, EVA A. TEMKIN & CHRISTINE CARLETTA, KING & SPALDING, PRICE NEGOTIATION, MEDICARE REBATES, AND BENEFIT REFORM: KEY DRUG PRICING IMPLICATIONS OF THE INFLATION REDUCTION ACT OF 2022, at 7–9 (Aug. 15, 2022), https://www.kslaw.com/attachments/000/009/841/original/Price_Negotiation__Medcare_Rebates__and_Benefit_Reform.pdf?1660584404 [https://perma.cc/62QN-ZY36].

higher sales volumes.[205] This policy change will only impact seniors, however, so its scope is limited—everyone with insurance coverage from a source other than Medicare will be unaffected.

Another recently proposed change, focusing on insulin, would have a wider reach in terms of population, impacting all group and individual health plans as well as Part D.[206] The bill would require all plans to structure their benefits such that diabetics would not have to pay more than $35 per month for insulin.[207] Although this policy would apply to a broader swath of the population, it would only apply to those patients who require insulin, so it is narrower than the Part D redesign in that sense. A more far-reaching policy extending to all drugs across all payer plans would have a much larger impact upon a broader patient population.

The government's decision to offer the COVID-19 vaccine for free to all Americans reflects an understanding of the logic that patients who experience receiving a drug for "free" are more likely to take it and that in some instances the positive externalities of maximizing uptake are huge. This logic should extend to all or most drug products, because the COVID vaccine is not qualitatively different from drugs that treat other diseases that kill many people per year. While the timeline and urgency of the pandemic made these arguments more appealing to many, there is little difference between a patient dying of COVID because the vaccine was unaffordable and a patient dying of diabetes or cancer because their insulin or chemotherapy was unaffordable.

The basic premise of cost sharing in insurance design is to limit consumption, reflecting the traditional economic idea that as the price of a product increases, demand for that product decreases.[208] But in the context of medicine, this model does not fit. Patients do not consume drugs like they do other products; there is no inherent satisfaction derived from taking insulin or chemotherapy (in fact, taking chemotherapies, and many other drugs, is an intensely painful experience). Instead, patients are told that if they do not take their prescribed medications, they might die. Imposing cost sharing to reduce consumption of essential drugs cannot be reconciled with a belief that every person has an equal right to stay alive.

Broader reforms that target benefit design across all types of insurance, for all types of prophylactic drugs, would address these issues in a more comprehensive way because they would reduce OOP pressures for a much larger swath of patients. However, these reforms would not address the prices in the pharmaceutical industry's supply chain and would likely increase the total amount of money

205. *See Medicare Part D*, PHARM. RSCH. & MFRS. AM., https://phrma.org/policy-issues/Medicare/partd [https://perma.cc/DRB3-NCRY] (last visited Apr. 16, 2023) (advocating for a cap on annual OOP costs and lower, more predictable cost sharing).

206. *See* Affordable Insulin Now Act, H.R. 6833, 117th Cong. (as passed by House, Mar. 31, 2022).

207. *See id.*

208. *See* BROOK ET AL., *supra* note 73, at 1–2.

spent by insurers and the government on pharmaceuticals.[209] A single-payer system, which would include a more expansive version of Medicare negotiation, would address both of these issues, but a discussion of various single-payer proposals is beyond the scope of this Note.

B. MEDICARE NEGOTIATION

Payers in the United States pay more than twice, on average, what those in other OECD countries pay for the same pharmaceutical products.[210] This disparity is in large part due to the fractured payer landscape that forces each relatively small payer to negotiate individually with pharmaceutical corporations to determine the net price of a drug.[211] The IRA changes the way that Medicare will pay for drugs in both Part B and Part D by allowing the Secretary of Health and Human Services (HHS) to directly negotiate with manufacturers for certain drugs and impose rebates if the list price of a single-source drug increases faster than inflation.[212] Although the inflationary rebates apply to all single-source drugs (drugs without generic competitors), the Secretary will only be able to negotiate the price of a limited set of drugs. Starting in 2026, the Secretary can choose ten drugs to negotiate, then fifteen additional drugs in both 2027 and 2028, and twenty additional drugs in 2029 and each following year.[213] Drugs are eligible for negotiation only if they have been on the market for a certain number of years (seven or eleven, depending on drug type), do not have any competitors, and represent a top-spending drug for the Medicare program; additional restrictions also apply.[214] The IRA provides only limited instructions for how the Secretary could propose a price for a drug but does provide a process for the negotiations.[215] If the pharmaceutical corporation and the Secretary fail to reach an agreement at the end of the process, the pharmaceutical corporation will be subjected to a ninety-five percent excise tax on gross sales of the relevant drug, a powerful incentive pushing pharmaceutical corporations to reach agreement.[216]

As Centers for Medicare and Medicaid Services (CMS) begins to implement these provisions, there are significant questions regarding how the Secretary will approach the negotiation process, the responses from pharmaceutical corporations subject to negotiation, and potential legal challenges to the negotiation process and excise tax. The particular impact of the Medicare negotiation provisions will depend on the interplay between these factors. Ultimately, the reach of the

209. With reduced OOP costs, patients would be likely to consume more drugs, costing payers more in reimbursement. *See id.*

210. *See* Mulcahy et al., *supra* note 13.

211. *See* MCCAUGHAN, *supra* note 149.

212. *See* Inflation Reduction Act, Pub. L. No. 117-169, secs. 11001–11002, 136 Stat. 1818, 1833–62 (2022); *see also* FARBER ET AL., *supra* note 204, at 2–7.

213. FARBER ET AL., *supra* note 204, at 2.

214. *See id.*

215. *Id.* at 4–5; Inflation Reduction Act sec. 11001, § 1194(e) (instructing the HHS Secretary to include in negotiations factors such as R&D costs, unit production costs, prior federal financial support, patent information, and revenue data).

216. FARBER ET AL., *supra* note 204, at 5.

bill is fairly limited because it only empowers the Secretary to negotiate for drugs that have been on the market for a long time, leaving untouched the initial list price of a drug when it is launched. Still, the IRA represents an important first step to expand the power of Medicare to negotiate, and the Secretary's power could conceivably be broadened to make the negotiation process more impactful.

An alternative strategy for bringing manufacturers to the negotiating table, considered in earlier legislation but not included in the IRA, would be for the government to engage in "competitive licensing" for drugs for which the negotiation process has failed.[217] This strategy would empower the Secretary to override the patent rights for the original pharmaceutical corporation's drug (while providing reasonable compensation) and contract with a third-party manufacturer to produce a generic version of the drug at a reduced price.[218]

Direct negotiations with a pharmaceutical corporation require the payer (here, Medicare) to approximate the value of a drug. Many OECD countries, which negotiate directly with pharmaceutical corporations for all drugs, conduct "health technology assessments" (HTAs) as part of their negotiation processes to assign a monetary value to new drugs based on clinical value, existing treatment availability, and other factors.[219] In America, the nonprofit Institute for Clinical and Economic Review (ICER) performs a similar, though nonbinding, function by reviewing "evidence to help align a treatment's price with how well it improves the lives of patients and their families."[220] Although subject to a variety of complications including how to assign value to clinical improvement, assess value relative to specific populations, and maintain transparency, these types of assessments could help the government appropriately price pharmaceutical products in any negotiation process. The IRA instructs the Secretary to consider some similar factors in the course of negotiations, but it does not specifically tie the negotiation process to the result of any sort of HTA.

Strategies resulting in lower negotiated prices would, of course, result in lower profit margins for pharmaceutical corporations impacted by the policies. The industry argues that these reductions will negatively impact innovation.[221] But even if these approaches result in "diminished incentives for research to some degree, the efficiency gains might still be large if the access gains were

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217. *See* Christopher J. Morten & Amy Kapczynski, *Assessing Drug Pricing Reform Proposals: The Real Leverage and Benefits of Competitive Licensing*, HEALTH AFFS. (Nov. 4, 2019), https://www.healthaffairs.org/do/10.1377/forefront.20191101.594551/full [https://perma.cc/M6WZ-325W].

218. *See id.* For a discussion of similar policies, see *infra* Section IV.C.

219. *See* Ting Wang, Neil McAuslane, Lawrence Liberti, Helga Gardarsdottir, Wim Goettsch & Hubert Leufkens, *Companies' Health Technology Assessment Strategies and Practices in Australia, Canada, England, France, Germany, Italy and Spain: An Industry Metrics Study*, FRONTIERS PHARMACOLOGY, Dec. 3, 2020, at 1, 3.

220. *Who We Are*, INST. FOR CLINICAL & ECON. REV., https://icer.org/who-we-are [https://perma.cc/EM52-9YB4] (last visited Apr. 16, 2023).

221. *See supra* note 15 and accompanying text.

substantial."[222] Further, by defining what a drug should cost according to its clinical value, the government could potentially "improve research efficiency if existing profits are too high and induce wasteful 'racing'—in which multiple companies chase similar compounds, dissipating resources that could be dedicated to other worthy unmet medical needs."[223] In other words, the government could intentionally construct incentives to encourage innovation in areas where improved clinical outcomes would have the broadest impact, in contrast to the current system which incentivizes innovation in areas that reimburse the most, regardless of whether the added utility is greatest.[224]

C. CREATIVE USES OF GOVERNMENT-HELD IP

The U.S. government funds much of the basic research that results in new pharmaceutical products.[225] Due to the technology transfer framework established by the Bayh-Dole Act and a general hesitancy to take any action to contest patent rights, however, the government rarely asserts any ownership to patent rights by the time a new product is available for widespread use.[226] Instead, pharmaceutical corporations have complete control over IP rights for most drugs. A 2019 complaint filed by HHS in Delaware federal district court involving PrEP, a prophylactic for HIV,[227] bucked this trend.[228] In the complaint, HHS asserted its patent rights to PrEP, alleged that Gilead had infringed those rights, and sought damages.[229] The U.S. government exclusively holds the "method of use" patent for prophylactic once-a-day PrEP, but this was not widely known until the existence of the patents was publicized by an HIV patient interest group.[230] Although Gilead recently prevailed in a trial on the issue, the United States' plans for

222. Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFS. 791, 793 (2016) (discussing impact to innovation incentives in the context of a comparable competitive licensing policy).

223. *Id.*

224. *See* Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75, 119–21 (2020) (noting that for "patentable products with short commercialization lags, market-based rewards underestimate social value for drugs with positive externalities (such as vaccines, drug addiction treatments, or innovations generating technological spillovers)" and that "Medicare Part D drove R&D on drugs with a large Medicare market share, but not on other drugs").

225. *See supra* Section III.A.

226. *See supra* Section III.C.

227. *See* sources cited *supra* note 62.

228. *See* Complaint, United States v. Gilead Scis., Inc., 515 F. Supp. 3d 241 (D. Del. Nov. 6, 2019) (No. 19-cv-2103), 2019 WL 5942984. On May 9, 2023, Gilead prevailed in a jury trial. *See* Judgment Following Jury Verdict, United States v. Gilead Scis. Inc., No. 19-cv-2103 (D. Del. May 15, 2023) (describing the May 9 jury verdict); *see also* Spencer Kimball, *Gilead Sciences Defeats U.S. Government Lawsuit Alleging HIV Drug Patent Violations*, CNBC (May 9, 2023, 12:43 PM), https://www.cnbc.com/2023/05/09/gilead-did-not-violate-patents-hiv-prevention-drug.html [https://perma.cc/A42G-WEZH]. The United States' plans for appeal are unknown as of the time of publication.

229. Complaint, *supra* note 228, at 75; *see also* Christopher J. Morten & Amy Kapczynski, United States v. Gilead*: Can a Lawsuit Yield Better Access To PrEP?*, HEALTH AFFS. (Nov. 18, 2019), https://www.healthaffairs.org/do/10.1377/forefront.20191118.218552 [https://perma.cc/X82A-GQ2N].

230. *See* Morten & Kapczynski, *supra* note 229.

appeal are unknown, and the United States could potentially use the threat of damages in similar lawsuits to lower the prices of other drugs.[231] "Finally, this example suggests that the U.S. government should do more to consider how and when it uses patents to increase access to medicines for the public, beyond this one case."[232] The Executive Branch can, if it chooses, take the initiative to research whether the government possesses valid patent rights on expensive drugs and consider litigation if warranted.

Another preexisting but little-used government power is codified in Section 202 of the Bayh-Dole Act.[233] So-called "march-in rights" enable the government to require "research grantees that obtain patents claiming federally funded inventions to confer a nonexclusive, royalty-free license back to the US government, which permits the government to practice the invention or to have it practiced on the government's behalf."[234] In other words, the United States can assert its patent rights on a product, license a generic manufacturer to produce the product, and purchase that generic product at a reduced price. Because generics are significantly cheaper to consumers than brand name drugs, this strategy could make a drug more widely available to the public. The United States has never exercised this power, though many stakeholders called for the government to exercise it on COVID-19 vaccines and treatments.[235] A similarly underutilized statutory power is found in 28 U.S.C. § 1498, which empowers the government to use "patents at any time without permission of the patent holder, as long as reasonable compensation is provided."[236] The United States threatened to exercise this right during the anthrax crisis of 2001, but ultimately extracted concessions from the manufacturer to procure the needed antibiotic without using the provision.[237]

CONCLUSION

The current state of the pharmaceutical industry has human costs. On a micro level, individuals who cannot afford their life-sustaining medications suffer needlessly. Diabetic patients go without insulin, a drug that has existed in its current form for a century, because the OOP costs linked to rapidly rising list prices render the drug unaffordable.[238] The field of oncology has generated a new term,

231. *See supra* note 228.

232. Morten & Kapczynski, *supra* note 229.

233. 35 U.S.C. § 202; Alfred B. Engelberg & Aaron S. Kesselheim, Opinion, *Use the Bayh-Dole Act to Lower Drug Prices for Government Healthcare Programs*, 22 NATURE MED. 576, 576 (2016).

234. Engelberg & Kesselheim, *supra* note 233.

235. *See* Michael Liu, William B. Feldman, Jerry Avorn & Aaron S. Kesselheim, *March-in Rights and Compulsory Licensing—Safety Nets for Access to a COVID-19 Vaccine*, HEALTH AFFS. (May 6, 2020), https://www.healthaffairs.org/do/10.1377/forefront.20200501.798711/full [https://perma.cc/4XG5-JLBF].

236. Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 280 (2016); *see also* Liu et al., *supra* note 235 (describing governmental powers under § 1498).

237. *See* Brennan et al., *supra* note 236; Liu et al., *supra* note 235.

238. *See* Tara O'Neill Hayes & Josee Farmer, *Insulin Cost and Pricing Trends*, AM. ACTION F. (Apr. 2, 2020), https://www.americanactionforum.org/research/insulin-cost-and-pricing-trends [https://perma.

"financial toxicity," to study and measure the impact of drug prices on cancer patients' outcomes.[239] On a macro level, high drug costs to payers mean that everyone included in an insurance risk pool pays more in their monthly premiums. Further, every dollar spent on a new brand name drug that may only add, on average, a few additional months of life expectancy is a dollar not spent on other, more impactful treatments. The profit-driven U.S. healthcare system prioritizes, at every turn, expensive treatments, rather than cost-cutting preventative measures. As the adage goes, "an ounce of prevention is worth a pound of cure"—but when each pound generates substantial profits for shareholders, attempted cures are what we get.

The pharmaceutical industry is by no means the only stakeholder extracting profits at the expense of patient well-being in the U.S. healthcare system. But the story of the transformation of the industry is indicative of larger trends in the United States that comprise the neoliberal consensus of the twentieth century in which profits are prioritized over patients and the healthcare industry has become nearly twenty percent of the United States economy.[240] As policymakers grapple with shifts in economic loci from industrial manufacturing to care work supplemented by high-tech drugs,[241] a clear-eyed view of the forces at work is needed. The provision of health care, much like the development of new pharmaceutical therapies, is a vital part of an advancing society. But from that premise, it does not follow that the neoliberal status quo is optimal. "For faithful neoliberals, the idea of effective price controls is paradoxical: there is no redeeming a policy that stifles the informational function of the price system. For the rest of us, a more complex calculus is required."[242] Although markets and pricing mechanisms can be a useful tool to apportion health care, they must be controlled in ways that best serve the masses, not the privileged few shareholders. Reforming the pharmaceutical industry is merely a starting point in the journey to create a more just, equitable healthcare system.

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cc/H8NK-RJD6] ("The average list price of insulin increased 11 percent annually from 2001 to 2018, with average annual per capita insulin costs now nearing $6,000.").

As previously noted, the IRA improved how Medicare beneficiaries will pay for insulin by limiting their OOP costs. *See supra* Section IV.A; *Insulin*, MEDICARE.GOV, https://www.medicare.gov/coverage/insulin [https://perma.cc/23NZ-9HTT] (last visited Apr. 16, 2023). These changes do not impact any patients who are not on Medicare, that is, nearly everyone under sixty-five in the United States.

239. *See generally* Pricivel M. Carrera, Hagop M. Kantarjian & Victoria S. Blinder, *The Financial Burden and Distress of Patients with Cancer: Understanding and Stepping-up Action on the Financial Toxicity of Cancer Treatment*, 68 CA: CANCER J. FOR CLINICIANS 153 (2018) (describing negative impacts of financial burdens on cancer patients).

240. *See* Ryan Nunn, Jana Parsons & Jay Shambaugh, *A Dozen Facts About the Economics of the US Health-Care System*, BROOKINGS (Mar. 10, 2020), https://www.brookings.edu/research/a-dozen-facts-about-the-economics-of-the-u-s-health-care-system [https://perma.cc/KQ8A-7Q4A].

241. *See generally* Gabriel Winant, *A Place to Die: Nursing Home Abuse and the Political Economy of the 1970s*, 105 J. AM. HIST. 96 (2018) (tracking the changes in the political economy of Pittsburgh as it shifted from unionized male steel workers supporting single families to underpaid, diverse female care workers running nursing homes and other healthcare centers).

242. Note, *Price and Sovereignty*, 135 HARV. L. REV. 755, 775 (2021).