

# ARTICLE

## PERVERSE INCENTIVES: WHY EVERYONE PREFERS HIGH DRUG PRICES—EXCEPT FOR THOSE WHO PAY THE BILLS

ROBIN FELDMAN\*

### ABSTRACT

*Health care spending rarely follows an ordinary, rational model. Yet even in that context, prescription drug prices are rising at a puzzling rate. What is causing the phenomenon? Quite simply, incentives percolating throughout the prescription drug market push players toward higher prices. At the center lies the highly secretive and concentrated Pharmacy Benefit Manager (PBM) industry—middle players who negotiate between drug companies and health insurers by arranging for rebates and establishing coverage levels for patients. Contracts between drug companies and the middle players are closely guarded secrets. The PBM customers, including Medicare, private insurers, and even their auditors, generally are not permitted access to the terms. And the middle players are not alone; everyone is feeding at the trough.*

*Markets, like gardens, grow best in the sun. They wither without information. Thus, one should not be surprised to see competitive distortions and suboptimal outcomes.*

*Despite the extreme secrecy, details have begun to seep out—through case documents (including recent contract disputes among parties), government reports, reports to shareholders, and industry insider reports. Piecing together these sources, this Article presents a full picture of incentive structures in which higher-priced drugs receive favorable treatment, and patients are channeled towards more expensive medicines. In exchange for financial incentives structured in different ways to appeal to hospitals, insurers, doctors, and even patient advocacy groups, drug companies ensure that lower-priced substitutes cannot gain a foothold. It is a win-win for everyone, except of course for taxpayers and society. This Article also analyzes popular proposals that are unlikely to work and suggests approaches for aligning incentives.*

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\* Arthur J. Goldberg Distinguished Professor of Law & Director, Center for Innovation (C4i), University of California Hastings Law; Visiting Professor, UCLA Law. Research for this piece was funded in part by a generous grant from the Laura and John Arnold Foundation. With the permission of Harvard Journal on Legislation, this Article has been expanded into a book, *DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES* (2019).

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## I. INTRODUCTION

Prescription drug prices are rising at an alarming and puzzling pace. Prices for branded drugs rose 12.4% in 2015 alone;<sup>1</sup> between 2014 and the

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<sup>1</sup> Neeraj Sood, Dana Goldman & Karen Van Nuys, *Follow the Money to Understand How Drug Profits Flow*, STAT (Dec. 15, 2017), <https://www.statnews.com/2017/12/15/prescription-drug-profits-pbm/> [perma.cc/W8ZJ-RRM6] (citing MURRAY AITKEN, QUINTILES IMS INST., *MEDICINES USE AND SPENDING IN THE U.S.: A REVIEW OF 2015 AND OUTLOOK TO 2020* 2, 8 (2016)); see also Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, A

end of 2018 prices increased 60%.<sup>2</sup> Federal government reports show that price jumps were particularly dramatic for many drugs, with some prices increasing up to 500%.<sup>3</sup> The list price of drugs tells only part of the story, given the many rebate and discount processes that exist within the industry.<sup>4</sup>

Nevertheless, real spending for drugs is rising as well. The government Centers for Medicare and Medicaid Services (CMS) projects that the increase in national drug spending will more than double in 2018 from the prior year's significant rise.<sup>5</sup> In 2017, this increase in spending outpaced increased health care spending as a whole and the 2017-2018 consumer price

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*Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 284 (2016) (describing soaring drug prices caused by profit margins reaching an estimated 42%); Jordan Paradise, *A Profile of Bio-Pharma Consolidation Activity*, 25 ANN. HEALTH L. 34, 41 (2016) (noting that the price for "the type 2 diabetes drug Glumetza . . . rose 800 percent"); Carly J. Goeman, Note, *The Price Isn't Right: Shareholder Proposals as Opportunities for Institutional Investors to Restore Firm Value and Reduce Pharmaceutical Prices*, 2017 COLUM. BUS. L. REV. 748, 755 n. 22 (2017) (stating that "Valeant's product Nitropress rose by 525% in price" and "Isuprel rose 212%"); Brendan Murphy, Note, *Getting High On Profits: An Analysis of Current State and Federal Proposals to Rein in Soaring Drug Prices*, 12 J. HEALTH & BIOMED. L. 37, 37 (2016) (criticizing Martin Shkreli's decision to hike the price of Daraprim by 5,000% overnight); Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in the Pharmaceutical Markets* 34 (Hutchins Ctr. On Fiscal & Monetary Pol'y at Brookings, Working Paper No. 30, 2017).

<sup>2</sup> Rabah Kamal et al., *What are the Recent and Forecasted Trends in Prescription Drug Spending?*, PETERSON-KAISER HEALTH SYS. TRACKER (Feb. 20, 2019), [https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-prices-for-common-generic-drugs-have-dropped-by-37-since-2014-while-branded-drug-prices-have-increased-by-over-60\\_2019](https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-prices-for-common-generic-drugs-have-dropped-by-37-since-2014-while-branded-drug-prices-have-increased-by-over-60_2019) [https://perma.cc/83DM-WAHU].

<sup>3</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-201, BRAND-NAME PRESCRIPTION DRUG PRICING: LACK OF THERAPEUTICALLY EQUIVALENT DRUGS AND LIMITED COMPETITION MAY CONTRIBUTE TO EXTRAORDINARY PRICE INCREASES 11 (2009) [hereinafter 2009 GOV'T ACCOUNTABILITY OFFICE REPORT]; see also Michael G. Daniel, Timothy M. Pawlik, Amanda N. Fader, Nestor F. Esnaola & Martina A. Makary, *The Orphan Drug Act: Restoring the Mission to Rare Diseases*, 39 AM. J. CLINICAL ONCOLOGY 210, 211 (2015) (citing the example of imatinib, a treatment for chronic myelogenous leukemia, which cost \$30,000 a year when it was introduced in 2001, but whose price had more than tripled to \$92,000 a year by 2012).

<sup>4</sup> Dylan Scott, *Inside the Impossibly Byzantine World of Prescription Drug Prices*, STAT (Dec. 21, 2015), <https://www.statnews.com/2015/12/21/prescription-drug-prices-confusion/> [https://perma.cc/W62W-UE4E] (describing secretive discount and rebate systems and explaining that the list price is the company's opening bid).

<sup>5</sup> Ed Silverman, *Spending Growth on Prescription Drugs Will Double This Year*, STAT (Feb. 14, 2018), <https://www.statnews.com/pharmalot/2018/02/14/prescription-drugs-spending-cms/> [https://perma.cc/V6B6-MAHP] (citing Cuckler et al., *National Health Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth*, 37 HEALTH AFF., 3, 5 (Feb. 2018)); see also NORMAN R. AUGUSTINE, GURU MADHAVAN & SHARYL J. NASS, MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 75 (The Nat'l Acads. Press 2017) [hereinafter NAS REPORT] (showing that although the rate of increase in spending for prescription drugs in 2016 slowed from the year before to an increase of only 5.8%, that growth rate was still double the rate of increase in 2013; spending rates in 2014 and 2015 rose 10.3% and 12.4% respectively).

index.<sup>6</sup> All of this, despite the fact that roughly 80% of the prescriptions in this country are filled using generic drugs.<sup>7</sup>

This Article analyzes and explains this phenomenon, which has puzzled modern commentators and policymakers alike. Many academic analyses to date have focused on entry barriers and activities that prevent lower-priced generic drugs from getting to market—such as extensions of patent and non-patent exclusivities, attempts to block generic approval at the Food and Drug Administration (FDA), and Pay-for-Delay court settlements that keep lower-cost drugs off the market.<sup>8</sup> In contrast, this Article focuses on a more troubling section of market activity that occurs after generics clear the patent and regulatory hurdles. Having finally cleared those substantial hurdles, generics face a new threat from the shadowy and byzantine system of drug distribution, data ownership and manipulation, and reimbursement schemes.

Why do drug prices stubbornly continue to rise, despite the promise of competition after patents expire? Quite simply, the phenomenon occurs because internal incentives push every market participant in the chain of custody toward behaviors that push prices higher. At the center of the system lies the highly secretive and highly concentrated industry known as Pharmacy Benefit Managers or PBMs. These middle players negotiate prices between branded drug companies and those who pay the bills, arranging for rebates from various drug companies. They also establish what are known as the formularies, schedules that set the terms on which patients can access particular drugs and the reimbursement rates patients will get. The contracts

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<sup>6</sup> Compare BUREAU OF LABOR STATISTICS, U.S. DEP'T OF LABOR, PRESCRIPTION DRUGS IN THE U.S. CITY AVERAGE, ALL URBAN CONSUMERS, SEASONALLY ADJUSTED (2018) (showing a 2.4% increase in the Consumer Price Index for prescription drugs from January 2017 to January 2018) with Silverman, *supra* note 5 (noting a 2.9% increase in spending on prescription drugs in 2017).

<sup>7</sup> See *How Critics Say Drug Companies Play "Games" to Stave Off Generic Competitors*, CBS NEWS (Feb. 2, 2018) <https://www.cbsnews.com/news/drug-companies-alleged-tactics-delay-cheaper-generic-drugs/> [perma.cc/526J-HSGA] (quoting industry spokesperson); see also RACHEL SCHMIDT & SHINOBU SUZUKI, MEDICARE PAYMENT ADVISORY COMM'N, THE MEDICARE PRESCRIPTION DRUG PROGRAM (PART D): STATUS REPORT 11 (2018) (showing that growth in brand price more than offset effects of generic use in Medicare Part D).

<sup>8</sup> See generally ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 16, 86, 97 (2017); Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171 (2008); Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249 (2016); Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7 (2014); Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009 (2010); Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471 (2008); Robin Feldman, *May Your Drug Price be Evergreen*, 5 J.L. & BIOSCI. 590 (2018); Robin Feldman & Connie Wang, *A Citizen's Pathway Gone Astray – Delaying Competition from Generic Drugs*, 376 N. ENG. J. MED. 1499 (2017); Robin Feldman et al., *Empirical Evidence of Drug Pricing Games – A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39 (2017); Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499 (2016); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009).

between drug companies and the PBMs are a closely-guarded secret, with the details known only to the drug companies and the PBMs. Government entities and the private insurers who pay the bills are not permitted to see the full terms of the contracts. Even health plan auditors generally are not permitted full access to the contract terms.<sup>9</sup> PBMs provide periodic rebates to the health plans without providing full information regarding the actual net pricing for any particular drugs. Markets thrive on information, and from the standpoint of competition, such an industry design is less than ideal.

Through a variety of sources—government reports, state Medicaid actions, industry insider reports, case documents—the terms of these secret contracts are seeping into public view. Piecing together information from these original sources, this Article for the first time presents a full picture of the perverse profit-taking incentive structures and demonstrates how using drugs with higher prices operates in the interests of so many players—including doctors, clinics, hospitals, group purchasing organizations, wholesalers, PBMs, brand drug companies, health plans, patient assistance programs, and patient advocacy groups. Payment flows are structured so that higher prices benefit the intermediaries. These structures also lead to circumstances in which higher priced drugs receive more favorable reimbursement treatment, and patients are channeled towards more expensive drugs.

In addition, the system operates to support competition-free zones for pharmaceutical companies. The perverse incentive structures allow pharmaceutical companies to share monopoly rents with parties at each level of the market in an effort to maintain their position at the top of the market. In exchange for financial payoffs,<sup>10</sup> structured in different ways to appeal to different groups, drug companies can ensure that as lower-priced substitutes

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<sup>9</sup> See Linda Cahn, *Don't Get Trapped By PBMs' Rebate Labeling Games*, MANAGED CARE (Jan. 1, 2009), <https://www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games> [perma.cc/3G3X-9EHF] (explaining that audit materials are limited to client-specific materials, and given that rebates are not client-specific, the PBM can refuse to provide information about them); Michael Hiltzik, *How 'Price-Cutting' Middlemen Are Making Crucial Drugs Vastly More Expensive*, L.A. TIMES (June 9, 2017), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html> [perma.cc/7ZSL-DC9N] (quoting, in part, an industry consultant to explain that “insurers generally don’t have the right to audit PBMs’ collections and distributions . . . . ‘The PBMs will say the rebate contracts are between them and the pharmaceutical companies, and it is none of our business.’”); see also Stephen Barlas, *Employers and Drugstores Press for PBM Transparency*, 40 PHARMACY AND THERAPEUTICS 3, 206–08 (2015) (quoting an accredited health care fraud investigator, “PBMs make it near impossible to audit both their ‘secret agreements’ for rebates with pharmaceutical companies and retail network agreements with pharmacy chains.”); Neil Weinberg & Robert Langreth, *Inside the ‘Scorpion Room’ Where Drug Price Secrets are Guarded*, BLOOMBERG (May 4, 2017), <https://www.bloomberg.com/news/articles/2017-05-04/in-scorpion-room-auditor-gets-scant-look-at-drug-contracts> [perma.cc/R7YA-YEVQ] (“PBMs still often put auditors in secure rooms, limit the number of contracts they can see and restrict and review note-taking, according to people in the industry and contracts reviewed by Bloomberg.”).

<sup>10</sup> See *infra* note 108 and accompanying text.

enter the market, these firms cannot gain a foothold.<sup>11</sup> It is a win-win for everyone, except of course for consumers, taxpayers, and society in general.

This Article describes the way in which, at most levels, the system operates to create incentives for prices to rise and ultimately for consumers and taxpayers to experience harm. The Article also proposes approaches to better align incentives and analyzes some popular proposals that are unlikely to solve the problem. Specifically, Part II of the Article describes the extent of the rising prices and economic effects. Part III describes the incentive structures in place at each level of the market. Part IV suggests solutions to begin realigning the industry's incentives with society's interests and creating greater competition in pharmaceutical markets.

## II. THE LANDSCAPE

The following section describes the current landscape of the prescription drug industry, including pricing trends. This section also details the byzantine world of negotiating prices and establishing reimbursement levels for patients. The term “drug company” is used throughout this Article to refer to drug manufacturers—that is, companies who make the medicines—as opposed to wholesalers. This section explains the way in which the general health care market is an imperfect market and that, even in the context of such market imperfections, spending on drugs defies rationality. Finally, this section introduces the Pharmacy Benefit Manager, a main actor in the health care space and one who plays a key role in rising prices.

### A. Branded Prescription Drugs

#### 1. Overview of Drug Market

Research and development in the pharmaceutical industry is a long and arduous affair. Although scholars disagree over the full extent of costs to bring a drug to market, no matter how one slices the numbers, estimated costs range from \$161 million to \$2.5 billion.<sup>12</sup>

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<sup>11</sup> See *infra* note 112 and accompanying text.

<sup>12</sup> A 2014 study from the Tufts Center for the Study of Drug Development found that developing a new drug costs approximately \$2.5 billion, which includes the costs of compound failures. See DiMasi JA, Grabowski HG & Hansen RA. *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 27 (2016). Moreover, this study focuses only on the development of new drugs, while many released drugs are merely repurposed old ones. See Feldman, *supra* note 8, at 625. This finding has been challenged on multiple fronts. See Steve Morgan et al., *The Cost of Drug Development: A Systematic Review*, 100 HEALTH POL'Y 4 (2011) (analyzing 13 different studies to estimate that drug development costs range from \$161 million to \$1.8 billion); Aaron E. Carroll, *\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, N.Y. TIMES (Nov. 18, 2014), [www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html](http://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html) [perma.cc/J5BQ-V95Z] (suggesting that the disparity in the findings stem from methodological mistakes in the Tufts study, and noting that the Tufts Center is funded by pharmaceutical

The pharmaceutical industry in this country has introduced extraordinary health care advances. One cannot overemphasize the major life improvements over the last century that flow from innovation in prescription medications, including new life-saving antibiotics, treatments for pain, psychopharmacological treatments, and cancer drugs. Pharmaceuticals also constitute a major export for the United States,<sup>13</sup> with domestic companies accounting for 45% of the global market.<sup>14</sup>

To incentivize this substantial and uncertain investment, new drugs are generally protected by a patent, which prevents others from copying the drug and competing in the market. Other regulatory awards, for activities such as engaging in new studies or pediatric analyses, can extend the protection for additional, limited periods of time.<sup>15</sup> When the various patent and regulatory protections that allow a period of time for recoupment of investment have expired, the Hatch-Waxman system for approval of generic drugs is designed to expedite the entry of generic competitors.<sup>16</sup>

Not all patent-protected drugs represent major health care innovations. Some are merely combinations of existing medications that can be purchased for less individually.<sup>17</sup> Others are tweaks of existing medicines, al-

companies); TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, FINANCIAL DISCLOSURE, <https://csdd.tufts.edu/financial-disclosure> [perma.cc/37HF-GBQN]. Additionally, a study analyzing the SEC filings for 10 cancer drugs found that the average cost of developing a single cancer drug was \$648.0 million. See Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, 177 JAMA INTERN. MED. 1569 (2017).

<sup>13</sup> See MICHAEL FINN, U.S. DEP'T OF COM., 2016 TOP MARKETS REPORT PHARMACEUTICALS 8 (2016) ("With \$47 billion in exports in 2015, pharmaceuticals rank as one the top [sic] exporting sectors for IP-intensive industries in the United States.").

<sup>14</sup> Matej Mikulic, *U.S. Pharmaceutical Industry – Statistics & Facts*, STATISTA (May 9, 2017), <https://www.statista.com/topics/1719/pharmaceutical-industry/> [https://perma.cc/SD6Y-HTWS].

<sup>15</sup> See Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 67–68 (2016) (detailing the history of more than a dozen forms of non-patent exclusivities).

<sup>16</sup> For detailed descriptions of the Hatch-Waxman system, see generally FELDMAN & FRONDORF, *supra* note 8, at 21–22, 26–33 (citing WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RES. SERV., *THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER I* (2011); Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 178 nn.55–56 (2008)).

<sup>17</sup> Treximet is a migraine medicine that combines sumatriptan and naproxen in multilayer tablets. Janet Freilich, *Patent Infringement in the Context of Follow-On Biologics*, 16 STAN. TECH. L. REV. 9, 42 n.186 (2012). Soon after Treximet was brought to market, GlaxoSmithKline sold the branded drug for \$18 per pill when the individual components sumatriptan and naproxen were available for approximately \$5 apiece. Tracy Staton, *Treximet: Cautionary Tale of Payer Price Revolt*, FIERCEPHARMA (June 19, 2009), <https://www.fiercepharma.com/pharma/treximet-cautionary-tale-of-payer-price-revolt> [https://perma.cc/4WAF-YHPX]. Pernix later acquired the drug and more recent sources indicate that the average cost for a Treximet prescription of 9 tablets is \$1,050.15, but this can vary depending on the pharmacy. Press Release, Pernix Therapeutics, Pernix Signs Agreement to Acquire Treximet Tablets for Migraine from GSK (May 14, 2014), <https://www.businesswire.com/news/home/20140514005549/en/PERNIX-Signs-Agreement-Acquire-TREXIMET-Tablets-Migraine> [https://perma.cc/R2XA-GFEV]; Drug Price Search for Treximet, GOODRX, <https://www.goodrx.com/treximet> [https://perma.cc/GZ49-DRA3] (search for "Treximet" in search bar). There is currently no generic version of the drug available, and generic manufacturers have been blocked from

tered in dosage or delivery system in an effort to obtain additional protection.<sup>18</sup> Such alterations generally cost far less to produce than the original pharmaceutical formulation, and yet they receive new protections of the same length as the original. The patent and exclusivity system, unfortunately, incentivizes this type of suboptimal behavior.

The price of a generic drug averages 75% to 90% below the cost of the original branded drug.<sup>19</sup> This price reduction tends to happen across time, with the largest reduction occurring as multiple generic drugs are available on the market.<sup>20</sup> This, of course, is when the generic market works at its best, although some scholars have observed generic drugs experiencing high prices or sharp price increases.<sup>21</sup>

During the period of protection for a branded drug, however, monopoly pricing reigns. There may be drugs within the same general class of medications that can serve as therapeutic alternatives, but most branded drug companies enjoy considerable freedom in setting the price in the United States.

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entering the market for patent infringement claims. See *Treximet Prices, Coupons and Patient Assistance Programs*, DRUGS.COM (2018), <https://www.drugs.com/price-guide/treximet> [<https://perma.cc/Y6TL-5ZBP>]; Christopher M. Holman, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination*, 50 IND. L. REV. 759, 801 (2017) (noting that “[v]arious generic drug companies sought to bring a generic version of Treximet to the market, and were sued . . . for infringement”). See also *Pozen Inc. v. Par Pharma, Inc.*, 800 F. Supp. 2d 789, 809 (E.D. Tex. 2011).

<sup>18</sup> Feldman, *supra* note 8, at 597 (observing that “[r]ather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones[.]” referring to empirical data that on average, “78% of the drugs associated with new patents were not new drugs [coming on the market], but existing ones”).

<sup>19</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-16-706, *GENERIC DRUGS UNDER MEDICARE: PART D GENERIC DRUG PRICES DECLINED OVERALL, BUT SOME HAD EXTRAORDINARY PRICE INCREASES 1* (2016) [hereinafter 2016 GOV’T ACCOUNTABILITY OFFICE REPORT].

<sup>20</sup> Under Hatch-Waxman, a first filing generic that submits an abbreviated new drug application with a complete paragraph IV certification receives a six-month period (180 days) in which no other generic company may receive approval to enter the market. 21 U.S.C. §355(j)(5)(B)(iv) (2018). Paragraph IV certification refers to an ANDA applicant’s certification that the original patent is either “invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. §355(j)(2)(A)(vii)(IV). During this period, the only versions on the market will be the original brand and the first-filing generic, along with any generic versions that the branded company might choose to introduce or authorize. See FELDMAN & FRONDORF, *supra* note 8, at 59 (describing the concept of “authorized generics”: generic, unbranded versions of a drug introduced by the brand-name company).

<sup>21</sup> MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: *MEDICARE PAYMENT POLICY 408-09* (2017) [hereinafter *MEDPAC 2017 REPORT*] (citing *Why Are Some Generic Drugs Skyrocketing in Price? Hearing Before the Subcomm. on Primary Health and Aging of the S. Comm. on Health, Educ., Labor, and Pensions*, 113th Cong. 50-55 (2014) (statement of Aaron S. Kesselheim, Associate Professor, Medicine, Harvard Medical School); Jonathan D. Alpern et al., *High-Cost Generic Drugs – Implications for Patients and Policymakers*, 371 NEW ENG. J. MED. 1859, 1859-62 (2014); Adam Fein, *Retail Generic Drug Inflation Reaches New Heights*, DRUG CHANNELS (Aug. 12, 2014), <http://www.drugchannels.net/2014/08/retail-generic-drug-inflation-reaches.html> [<https://perma.cc/T5UD-R8GR>]; see also 2016 GOV’T ACCOUNTABILITY OFFICE REPORT, *supra* note 19, at 13 (showing 351 cases over history of extraordinary price increases for generic drugs within a single year); Chintan V. Dave et al., *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, 167 ANALS INTERNAL MED. 145, 145 (2017).



With any commodity in a monopoly price setting, of course, the upper bounds of pricing are set by the limits of the budgetary capacity of those consuming the product.<sup>22</sup> No budgets are endless, and all goods must compete to some extent with other items in the consumer's basket. After all, I can only pay what I am willing to (I want to provide for my family and go to the movies once in a while) and what I can afford to (I need to secure food, a roof over my head, and a coat for the winter).

Health care, however, is no ordinary expenditure, and the industry experiences unusual effects. Key aspects of this odd market include the following.<sup>23</sup> First, although patients are the ultimate consumers of prescription medication, they lack full information and may be insulated from the full costs in a variety of ways.<sup>24</sup> Employer-provided health insurance is subsidized by federal and state governments, in the form of tax advantages for the employers and employees.<sup>25</sup> Insurance itself can insulate users from the full costs of their care, spreading the cost across a pool of other workers and across time. For many of those without a connection to employment, Medicare, Medicaid, government health plans, and other government programs absorb much or all of the cost.

Second, the patient is at an information disadvantage in health care, relying on the expertise of health care professionals. With prescription medication in particular, consumers are not even able to make the purchasing choice, with the physician making the ultimate decision on what to pre-

<sup>22</sup> Thomas J. Campbell, *Labor Law and Econ.*, 38 STAN. L. REV. 991, 1005 (1986) (citing EDWIN MANSFIELD, *MICROECONOMICS* 251 (4th ed. 1982)); Kenneth M. Casebeer, *Unemployment Insurance: American Social Wage, Labor Organization & Legal Ideology*, 35 B.C. L. REV. 259, 280, 298 (1994); Brian A. Hearn, Nicola Amendola & Giovanni Vecchi, *On Historical Household Budgets*, (Inst. for New Econ. Thinking, Working Paper No. 45, 2016).

<sup>23</sup> For a full description of buying distortions in the health care market see generally FELDMAN & FRONDORF, *supra* note 8, at 13 (noting that the "pharmaceutical market does not operate much like a standard market at all"); Abigail Moncrieff, *Understanding the Failure of Health-care Exceptionalism in the Supreme Court's Obamacare Decision*, 142 CHEST 559, 559 (2012) (arguing that the Supreme Court's failure to employ health-care exceptionalism in a constitutional challenge to the Patient Protection and Affordable Care Act was an "odd" holding that disregards the uniqueness of the health care market); Clifford D. Stromberg, *Health Law Comes of Age: Economics and Ethics in a Changing Industry*, 92 YALE L.J. 203 (1982) (reviewing WILLIAM J. CURRAN & E. DONALD SHAPIRO, *LAW, MEDICINE AND FORENSIC SCIENCE* (3d ed. 1982)).

<sup>24</sup> Morton & Boller, *supra* note 1, at 7 (explaining that externalities and information asymmetries prevent consumers from optimal substitution because they do not bear full costs and lack medical expertise or reliable information to identify therapeutic equivalents).

<sup>25</sup> Nicholas Drew, *Two Federally Subsidized Health Insurance Programs Are One Too Many: Reconsidering the Federal Income Tax Exclusion for Employer-Provided Health Insurance in Light of the Patient Protection and Affordable Care Act*, 54 B.C. L. REV. 2047, 2056 (2013) (describing the government subsidy for employer-provided health care created by Section 106 of the Internal Revenue Code); Max Huffman, *Competition Policy in Health Care in an Era of Reform*, 7 IND. HEALTH L. REV. 225, 261 (2010) (observing that health care costs are paid with "before tax dollars"); Yair Listokin, *Equity, Efficiency, and Stability: The Importance of Macroeconomics for Evaluating Income Tax Policy*, 29 YALE J. ON REG. 45, 49 (2012) (noting a government subsidy excluding "employer-provided health insurance from income tax").

scribe. And, as will be described in detail below,<sup>26</sup> that prescription decision may be influenced by the insurance plan's willingness to reimburse for the medication, as well as by less savory aspects including direct-to-consumer advertising<sup>27</sup> and drug companies courting physicians.<sup>28</sup> Accurate information on both price and quality of health care services can benefit consumers, both by helping them become better shoppers and also by spurring competition among providers along both price and quality dimensions.<sup>29</sup> Delivering that information in an easily understandable format—and one that is not drowned out by other messages such as advertising—can be challenging.<sup>30</sup>

Most important, buying decisions for health care do not follow ordinary economic logic—stretching the boundaries of rationality.<sup>31</sup> My own life may

<sup>26</sup> See *infra* n. 82 and accompanying text.

<sup>27</sup> The United States and New Zealand are the only two industrialized nations that allow direct-to-consumer advertising for prescription medication. See Bruce Patsner, *Problems Associated with Direct-to-Consumer Advertising (DTC) of Restricted, Implantable Medical Devices: Should the Current Regulatory Approach be Changed?*, 64 FOOD DRUG L.J. 1, 3 (2009) (“[A]side from New Zealand, DTCA is banned in every other Western industrialized nation except the United States.”); see also Erin J. Asher, Note, *Lesson Learned from New Zealand: Pro-Active Industry Shift Towards Self-Regulation of Direct-to-Consumer Advertising Will Improve Compliance with the FDA*, 16 ALB. L.J. SCI. & TECH. 599, 614 (2006) (“New Zealand is currently the only other industrialized country in the world besides the United States to allow DTC advertising.”).

<sup>28</sup> Ctrs. For Medicare & Medicaid Servs., *Open Payments* (Mar. 4, 2020), <https://www.cms.gov/openpayments/> [<https://perma.cc/MN6F-WB79>] (noting that Open Payments is a government program under the Affordable Care Act that details the value and nature of payments made from companies to physicians).

<sup>29</sup> See Marina Lao, Deborah L. Feinstein & Francine Lafontaine, Fed. Trade Comm’n, Comment Letter on Amend. to the Minn. Gov’t Data Prac. Act, 4-5 (June 29, 2015), [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702min-nhealthcare.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702min-nhealthcare.pdf) [<https://perma.cc/F9CZ-X352>]. See generally *High Prices, Low Transparency: The Bitter Pill of Health Care Costs: Hearing Before the S. Comm. on Finance*, 113th Cong. 8 (2013) (statement of Paul B. Ginsburg, Ph.D., Center for Studying Health System Change and National Institute for Health Care Reform); U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-791, HEALTH CARE PRICE TRANSPARENCY: MEANINGFUL PRICE INFORMATION IS DIFFICULT FOR CONSUMERS TO OBTAIN PRIOR TO RECEIVING CARE 2 (2011) [hereinafter GAO REPORT], <http://www.gao.gov/assets/590/585400.pdf> [<https://perma.cc/SE4L-KDL7>]; Christopher Whaley et al., *Association Between Availability of Health Service Prices and Payments for These Services*, 312 JAMA 1670, 1670-76 (2014); Video: Public Workshop to Study to Examining Health Care Competition, held by the Fed. Trade Comm’n (Mar. 20–21, 2014), available at <https://www.ftc.gov/news-events/eventscalendar/2014/03/examining-health-care-competition> [<https://perma.cc/2KV4-4B79>].

<sup>30</sup> See GAO REPORT, *supra* note 29, at 23.

<sup>31</sup> See generally Wendy Netter Epstein, *Revisiting Incentive-Based Contracts*, 17 YALE J. HEALTH POL’Y L. & ETHICS 1 (2017) (addressing skewed economic incentives in health care); William P. Kratzke, *Tax Subsidiaries, Third-Party-Payments, and Cross-Subsidization: America’s Distorted Health Care Markets*, 40 U. MEM. L. REV. 279 (2009) (citing DAVID GRATZER, THE CURE: HOW CAPITALISM CAN SAVE AMERICAN HEALTH CARE 42 (2006)); ARNOLD KLING, CRISIS OF ABUNDANCE: RETHINKING HOW WE PAY FOR HEALTH CARE 53–54 (2006); E. Haavi Morreim, *Diverse and Perverse Incentives of Managed Care: Bringing Patients into Alignment*, 1 WIDENER L. SYMP. J. 89, 95, 139 (1996); Jennifer Prah Ruger, *Health, Capability, and Justice: Toward a New Paradigm of Health Ethics, Policy and Law*, 15 CORNELL J.L. & PUB. POL’Y 403, 476 (2006) (noting efforts to manufacture economic incentives through “inappropriate” and “deleterious” insurance deductibles and copayment schemes to

be of incalculable value to me, well beyond what my budget or society's budget can rationally afford. That may be true even when the likelihood of success is low or the additional lifespan provided is no more than weeks or months.<sup>32</sup> When someone else is paying the bill, the value to me, measured by my willingness to consume the good, becomes infinite. Of course, not all prescription drug buying decisions are matters of life and death, but the general irrationality of health decisions can distort ordinary purchase choices in a society whose citizens generally exist beyond the subsistence level. All of this suggests that the normal budgetary limitations a monopolist might face have less force in the health care system.

## 2. Prices

Even within the distorted world of health care, however, prescription drug prices stand out, rising faster than any other form of health care spending, including hospitalization and nursing home care.<sup>33</sup> In a 2017 report to Congress, the non-partisan legislative branch agency called the Medicare Payment Advisory Commission (MedPAC) reported that between 2006 and 2014, drug prices in Medicare Part D rose by an average of 57% cumulatively, with dramatic increases in 2013-2014 in particular.<sup>34</sup> One industry report for 2016 projected that prescription drug prices would rise 11.6% for

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help health care purchases mimic typical economic rationality); Clive Crook, *The Slippery Economics of Health Care*, NAT'L J. MAG. 3249, 3249–50 (2005) (discussing the lack of consumer incentives in health care decision making); Uwe E. Reinhardt, *Reorganizing the Financial Flows in American Health Care*, 12 HEALTH AFF. 172, 176 (1993); see also Paige Kelton, *Some Pharmacists Barred from Helping Patients Save Money*, ACTION NEWS JAX (Feb. 22, 2018), <http://www.actionnewsjax.com/news/local/some-pharmacists-barred-from-helping-patients-save-money/705277162> [<https://perma.cc/PS2S-2N6R>] (quoting one commentator that “key question is not: What’s it worth to save a child’s life . . . if that was the question, the polio (vaccine) they gave me when I was 6 years old would have cost a million dollars. The right question is: What is the price that will maximize accessibility and affordability, while maintaining a robust R&D pipeline?”).

<sup>32</sup> In the U.S., 8.5% of total health care spending is for individuals in the last year of life. See Alan R. Weil, *Advanced Illness and End-Of-Life Care*, 36 HEALTH AFF., 1167, 1167 (2017).

<sup>33</sup> See MURRAY AITKEN QUINTILES IMS INST., UNDERSTANDING THE DYNAMICS OF DRUG EXPENDITURE (2017), [http://www.imshealth.com/files/web/IMSH%20Institute/Reports/Understanding\\_the\\_Dynamic\\_Composition\\_of\\_Drug\\_Expenditure/QIIHI\\_Understanding\\_the\\_Dynamics\\_of\\_Drug\\_Expenditure\\_Shares\\_Levels\\_Compositions\\_Drivers.pdf](http://www.imshealth.com/files/web/IMSH%20Institute/Reports/Understanding_the_Dynamic_Composition_of_Drug_Expenditure/QIIHI_Understanding_the_Dynamics_of_Drug_Expenditure_Shares_Levels_Compositions_Drivers.pdf) [<https://perma.cc/ZU79-YSRZ>] (noting that net drug expenditure in the U.S. increased from \$377 per person in 1995 to \$974 per person in 2015); Aimee Picchi, *Martin Shkreli-Style Drug Price Hikes are Everywhere*, CBS NEWS (Feb. 2, 2016, 3:43 PM), <https://www.cbsnews.com/news/martin-shkreli-style-drug-price-hikes-are-everywhere/> [<https://perma.cc/4LPR-3NHR>] (citing Robert Langreth & Rebecca Spalding, *Shkreli Was Right: Everyone’s Hiking Drug Prices*, BLOOMBERG (Feb. 2, 2016, 1:06 PM), <https://www.bloomberg.com/news/articles/2016-02-02/shkreli-not-alone-in-drug-price-spikes-as-skin-gel-soars-1-860> [<https://perma.cc/8YKT-5GMS>], to note that “[a]bout 20 of the top prescription drugs have at least quadrupled” their prices from 2014 to 2016).

<sup>34</sup> MEDPAC 2017 REPORT, *supra* note 21, at 408–09.

Americans younger than 65 and 9.9% for older adults, compared to wages increases projected for that year of 2.5%.<sup>35</sup>

These price increases have played a significant role in drug company profits in recent years. For example, the Wall Street Journal reported in 2015 that 80% of the growth in profits for the 20 largest drug companies were due to increasing prices on existing drugs, not new drugs or increased drug sales.<sup>36</sup>

Some drug price rises stand out in particular. A report from the U.S. Government Accountability Office estimated that between 2000 and 2008 alone, 416 branded products displayed extraordinary price increases.<sup>37</sup> Those increases ranged from 100% to 499%.<sup>38</sup>

Such price increases are driven by rising prices in branded medications. Although branded drugs account for only 11% of prescription volume in the country, they account for 74% of the spending.<sup>39</sup> Thus, although the pharmaceutical industry correctly points out that generic medications represent most of the prescription volume in this country and the FDA approves a vast number of new generics every year,<sup>40</sup> the year-to-year increase in the prices of branded drugs along with higher prices for the new branded drugs are swamping the savings from generic competition.<sup>41</sup>

As described below, rising list prices play an important role in driving up patient out-of-pocket costs as well as overall spending. In the case of branded medications, these list prices continue to rise sharply. List prices for branded drugs rose 12.4% in 2015 and increased 10% or more annually for each of the prior three years.<sup>42</sup> Although there may be some moderation in pricing due to public pressure, the general trend of increasing prices appears

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<sup>35</sup> EXPRESS SCRIPTS HOLDING CO., VALUE BEYOND: 2016 ANNUAL REPORT, DELIVERING MORE THAN MEDICINE (FORM 10-K) 4 (Dec. 31, 2016).

<sup>36</sup> Joseph Walker, *For Prescription Drug Makers, Price Increases Drive Revenue*, WALL STREET J. (Oct. 5, 2015, 9:59 PM), [www.wsj.com/articles/for-prescription-drug-makers-price-increases-drive-revenue-1444096750](http://www.wsj.com/articles/for-prescription-drug-makers-price-increases-drive-revenue-1444096750) [<https://perma.cc/5RDJ-9BDZ>]; see also Lydia Ramsey, *We Just Got a Better Idea of How Much Drug Companies Rely on Price Hikes, and It Doesn't Look Good*, BUS. INSIDER (Apr. 19, 2017, 12:24 PM), <http://www.businessinsider.com/drug-price-increases-represented-pharma-earnings-growth-2017-4> [<https://perma.cc/QA3Q-PLS2>].

<sup>37</sup> 2009 GOV'T ACCOUNTABILITY OFFICE REPORT, *supra* note 3, at 9.

<sup>38</sup> See *id.*; see also Brenda Goodman & Andy Miller, *The High Cost of Surviving Rabies*, WEBMD (Feb. 20, 2018), <https://www.webmd.com/a-to-z-guides/news/20180220/the-high-cost-of-surviving-rabies> [<https://perma.cc/82EU-2VL3>] (noting that the cost of the rabies shot regimen increased nearly 400% between 2008 and 2018).

<sup>39</sup> *Generic Drug Access and Savings in the U.S.*, Ass'n for Affordable Medicines 33 (2017).

<sup>40</sup> *How Critics Say Drug Companies Play "Games" to Stave Off Generic Competitors*, *supra* note 7 (quoting representative of the pharmaceutical industry group PhRMA that 90% of all medicines are generic and that over 1,000 new generics were approved in 2017, the highest of anywhere in the world).

<sup>41</sup> See MEDPAC 2017 REPORT, *supra* note 21, at 408 (concluding that price increases in the brands are overwhelming the effects of using lower-cost generic drugs, even as the use of generics continues to climb).

<sup>42</sup> Sood, Goldman & Van Nuys, *supra* note 1; Murray Aitken, *supra* note 1, at 8.

likely to hold for the foreseeable future.<sup>43</sup> For example, Eli Lilly's transparency report noted that the company raised list prices 14% on average in 2016;<sup>44</sup> Allergan increased its list prices for eighteen medications by 9.5%.<sup>45</sup>

In general, the price rises are most dramatic in a category called specialty drugs. The definition of specialty drugs varies, but the category tends to include high-cost drugs, particularly ones that are used to treat a rare condition, require special handling, use a limited distribution network, or require ongoing clinical assessment.<sup>46</sup> Some drugs are categorized as "specialty," however, simply because their cost exceeds \$10,000 a year.<sup>47</sup> The National Academy of Sciences reports that over the last five years, spending on specialty medicines has nearly doubled, outpacing the consumer price index from 2011 and 2013 and composing more than two-thirds of growth in drug spending between 2010 and 2015.<sup>48</sup> The 2016 annual report from Express Scripts PBM projects that 1% of all drugs will account for 50% of the drug spending by 2018 due to higher-cost specialty medicines.<sup>49</sup> In institutional and retail settings, specialty drug spending as a share of net spending accounted for 24.7% in 2008 increasing to 46.5% in 2017,<sup>50</sup> while specialty

<sup>43</sup> *Health Affairs: Health Spending Projections Through 2027*, HEALTH AFF. BLOG (Feb. 22, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190221.997607/full/> [https://perma.cc/ZTH2-PAUQ].

<sup>44</sup> See ELI LILLY & CO., 2016 LILLY INTEGRATED SUMMARY REPORT 15 (2016).

<sup>45</sup> Silverman, *Several Drug Makers Just Raised Their Prices by Nearly 10 Percent, and Buyers Expect More Price Hikes*, STAT (2018), <https://www.statnews.com/pharmalot/2018/01/02/price-hikes-inflation-survey/> [https://perma.cc/Z458-F4XV].

<sup>46</sup> MEDPAC 2017 REPORT, *supra* note 21, at 427 n.37; see also Juliette Cubanski, Wyatt Kom & Tricia Neuman, *The Out of Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019*, KAISER FAM. FOUND. 1 (Feb. 01, 2019), <https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/> [https://perma.cc/LM2X-2U64] (noting that Medicare set a floor of at least \$670 per month in 2019 to define a drug as "specialty"). Most biologics fall within a subset of specialty medicines. See *id.*

<sup>47</sup> *Fact Sheet: Specialty Drugs & Health Care Costs*, PEW CHARITABLE TR. (2015), <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2015/11/specialty-drugs-and-health-care-costs> [https://perma.cc/NM7F-FD4M].

<sup>48</sup> See NAS REPORT, *supra* note 5, at 77 (citing AMERICA'S HEALTH INSURANCE PLANS, SPECIALTY DRUGS: ISSUES AND CHALLENGES: ADVANCING EFFECTIVE STRATEGIES TO ADDRESS SOARING COSTS WHILE ENSURING ACCESS TO EFFECTIVE TREATMENTS AND PROMOTING CONTINUED MEDICAL INNOVATION 6 (2015)); MURRAY AITKEN, QUINTILES IMS INST., MEDICINES USE AND SPENDING IN THE U.S.: A REVIEW OF 2015 AND OUTLOOK TO 2020 13 (2016), <https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf> [https://perma.cc/5C39-4XKL]. Spending increases of specialty drugs are reported on an invoice price basis, referring to the amounts that pharmacies and hospitals pay to distributors for medicines. See, e.g., 2009 GOV'T ACCOUNTABILITY OFFICE REPORT, *supra* note 3 at 2, 11 (noting that between 2000 and 2008, a few specialty drugs used to treat conditions such as fungal or viral infections or heart disease experienced price increases of 1,000% or more).

<sup>49</sup> EXPRESS SCRIPTS, *supra* note 35, at 4 (Express Scripts, the institutional author of this report, is a pharmacy benefit manager).

<sup>50</sup> MURRAY AITKEN & MICHAEL KLEINROCK, IQVIA INST. FOR HUMAN DATA SCI., *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022* 6 (2018), [https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?\\_id=1582048573615](https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_id=1582048573615) [https://perma.cc/46FA-BN3J].

drugs accounted for ~2% drugs in retail and non-retail settings.<sup>51</sup> In other words, more of the drug spending is flowing into this category.

List prices, of course, are only the beginning of the story. Drug companies enter into a variety of contracts that provide for rebates from the list price. Although these price concessions are a closely-guarded secret, and it is difficult to tease out the actual net price different entities pay along the drug chain,<sup>52</sup> the net price to the drug company is substantially less than the list price. Defending against complaints about rising drug prices, the industry interest group PhRMA reported at a Federal Trade Commission (FTC) roundtable that after accounting for rebates and discounts, prices grew only 3.5% in 2016.<sup>53</sup> Similarly, a leading industry analysis group estimates that although list prices increased 13.5% in 2014, the net price increase was only 5.5%.<sup>54</sup> Even these net price increases, however, outstrip the inflation rate over the last five years, which has ranged from a low of under one percent in 2014 and 2015 to a high of 2% for 2016 and 2017, with the same projected for 2018.<sup>55</sup>

Many people, however, do pay the full list price or an amount based on the list price. Private insurance plans often require that patients contribute an amount based on a percentage of the full list price of the drug, a contribution known as co-insurance. Other plans require that patients pay for medications in full at the list price until meeting an individual or family deductible.<sup>56</sup> For example, in 2016, nearly 30% of those enrolled in employer-sponsored plans were enrolled in high-deductible plans that require patients to pay 100% of

<sup>51</sup> See *id.* (indicating specialty drugs are 1.9% of prescriptions in retail, while they account for 2.3% of drugs).

<sup>52</sup> See, e.g., Scott, *supra* note 4 (quoting Acting Administrator of the Federal Centers for Medicare and Medicaid Services that, “[W]e have list prices, wholesale prices, average wholesale prices, rebates, supplemental rebates, mark-ups . . . [m]ost of that information is not available or well understood by the public” and University of Pittsburgh Professor Walid Gellad referring to pricing as a black hole and noting that “It’s impossible to understand what people are paying.”).

<sup>53</sup> See Neeraj Sood, Workshop Slides: *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics*, FED. TRADE COMM’N 101 (2017) [hereinafter FTC Workshop Slides], [https://www.ftc.gov/system/files/documents/public\\_events/1255653/understanding\\_competition\\_in\\_prescription\\_drug\\_markets\\_workshop\\_slides\\_11-8-17.pdf](https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf) [https://perma.cc/A9TE-GWCM]; see also MURRAY AITKEN ET AL., QUINTILES IMS HEALTH, MEDICINES USE AND SPENDING IN THE U.S. 2 (2017), [https://structurecms-staging-psyclone.netdna-ssl.com/client\\_assets/dwonk/media/attachments/590c6aa0/6970/2d2d/4182/0000/590c6aa069702d2d41820000.pdf](https://structurecms-staging-psyclone.netdna-ssl.com/client_assets/dwonk/media/attachments/590c6aa0/6970/2d2d/4182/0000/590c6aa069702d2d41820000.pdf) [https://perma.cc/L236-NQU3].

<sup>54</sup> See Scott, *supra* note 4.

<sup>55</sup> See *Current U.S. Inflation Rates: 2009 to 2020*, COINNEWS MEDIA GROUP LLC (2018), <http://www.usinflationcalculator.com/inflation/current-inflation-ra> [https://perma.cc/KS8P-B5PF].

<sup>56</sup> For an example of a plan requiring that the patient pay 100% of the costs of drugs up to a certain limit, see the Anthem insurance plan described at First Am. Consolidated Class Action Compl. at 7, *In re Express Scripts/Anthem ERISA Litig.*, 285 F. Supp. 3d 655 (S.D.N.Y. 2018) (No. 16-3399) [hereinafter Anthem Class Action Complaint]; see also CIGNA Insurance Plan Documents (2018) (showing patient pays for medication in full until \$2,500 family threshold) (on file with author).

their health care costs up to a defined amount.<sup>57</sup> Others require substantial deductibles or co-insurance, with studies showing dramatic reductions in coverage and shifts to percentage-based cost sharing for higher priced drugs across time.<sup>58</sup> Even when full Medicare coverage is in place, patients must pay part of the cost of medications, with gaps occurring that can force patients to pay the majority of costs.<sup>59</sup> These amounts are nearly always based on the list price and not the net price of the medication, thus depriving consumers of the benefit of the rebate price concessions.

In addition, although the number of people with health insurance increased substantially after passage of the Affordable Care Act in 2009,<sup>60</sup> 10% of those under 65 in the United States still had no insurance in 2017, and not all of those who had health insurance enjoyed prescription drug coverage.<sup>61</sup> Even with Medicare, 12% of beneficiaries are not enrolled in prescription drug coverage or covered by another prescription plan such as veteran's benefits.<sup>62</sup> Thus, cash-paying consumers who lack sufficient drug benefits also pay the exaggerated list price. As a result, the total out-of-pocket amount that U.S. consumers are spending on medication continues to rise sharply.<sup>63</sup>

Most important, rebates on the whole are not keeping pace with the rise in drug prices. Although the net price for an individual pharmaceutical purchase is a closely guarded secret, the Centers for Medicare and Medicaid Services collects and reports total rebate dollars percentages for all drug expenditures in these systems,<sup>64</sup> which can be used to calculate the average annual brand drug rebate. Between 2012 and 2015, total rebates on brand

<sup>57</sup> NAS REPORT, *supra* note 5, at 99–100.

<sup>58</sup> *Id.* at 98; Jalpa Doshi et al., *Specialty Tier-Level Cost Sharing & Bio. Agent Use in the Medicare Part D Initial Coverage Period Among Beneficiaries with Rheumatoid Arthritis*, *ARTHRITIS CARE & RES.* 1623–30 (2016); J.K. Jung, R. Feldman, C. Cheong, P. Du, & D. Leslie, *Coverage for Hepatitis C Drugs in Medicare Part D*, *AM. J. MANAGED CARE* 220–26 (2016); J.M. Polinski, P.E. Mohr & L. Johnson, *Impact of Medicare Part D on Access to and Cost Sharing for Specialty Biologic Medications for Beneficiaries with Rheumatoid Arthritis*, *ARTHRITIS CARE & RES.* 745, 745–54 (2009); J. Yazdany, R. A. Dudley, R. Chen, G.A. Lin & C.W. Tseng, *Coverage for High-Cost Specialty Drugs for Rheumatoid Arthritis in Medicare Part D*, *ARTHRITIS & RHEUMATOLOGY* 1474, 1474–80 (2015).

<sup>59</sup> MEDPAC 2017 REPORT, *supra* note 21, at 404.

<sup>60</sup> Patient Protection and Affordable Care Act., Pub. L. No. 111-148, 124 Stat. 119 (2010).

<sup>61</sup> NAS REPORT, *supra* note 5, at 98.

<sup>62</sup> *See id.*

<sup>63</sup> *See supra* notes 5–6 and accompanying text; cf. Robert Langreth, Blacki Migliozi & Ketaki Gokhale, *The U.S. Pays a Lot More for Top Drugs Than Other Countries*, *BLOOMBERG* (2015), <https://www.bloomberg.com/graphics/2015-drug-prices/> [<https://perma.cc/6Z3X-GS6X>] (concluding that those in the U.S. pay more for top drugs, even after accounting for discounts).

<sup>64</sup> *See* CTRS. FOR MEDICARE AND MEDICAID SERVS., 2019 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS 140 (2019).

drugs in the Medicare system rose from 16% to 24%.<sup>65</sup> During the same period, however, the price of brand drugs rose 42%.<sup>66</sup>

Consider these simplified numbers:<sup>67</sup> if a company raises prices from \$100 to \$142 dollars and gives back \$24, the buyer is still paying more. The \$118 net price is still above the original price of \$100. In short, rebates simply are not compensating for the increased costs, particularly as those costs continue to rise across time.

Against this backdrop, government budgets are struggling to cover pharmaceutical costs. For example, if the Defense Department were to have treated all VA patients infected with hepatitis C in 2015, using the first breakthrough Hepatitis C cure Sovaldi, the \$12 billion cost would have accounted for 20% of the department's annual budget—just for a single disease treatment.<sup>68</sup> With budgets in the home, patients report rationing or forgoing medications for lack of funding.<sup>69</sup> This is precisely the type of boundary that should create pressure to reduce pricing. And yet, puzzlingly, the rise persists. The following section describes the perverse incentives that relentlessly drive prices ever higher.

<sup>65</sup> See Robin Feldman, *The Devil in the Tiers* 76 (U.C. Hastings, Working Paper No. 379).

<sup>66</sup> See *supra* note 42 and accompanying text.

<sup>67</sup> One should note that the rebate amounts from the Centers for Medicare and Medicaid Services Trustees Report are average rebates, calculated across all drug expenditures. Individual drug transactions can vary widely.

<sup>68</sup> See Patricia Kime, *VA, DoD Spend More Than \$450M on Costly Hepatitis Drug*, USA TODAY (Jan. 8, 2015), <https://www.usatoday.com/story/news/politics/2015/01/08/government-hepatitis-drug-costs/21462363/> [<https://perma.cc/3FFQ-US9H>]; cf. Pauline Bartolone, *California Pays Insurers Millions More for Hepatitis C Drugs*, NPR (Jan. 28, 2016), <https://www.npr.org/sections/health-shots/2016/01/28/464708911/california-pays-insurers-millions-more-for-hepatitis-c-drugs> [<https://perma.cc/4F25-P6V6>] (noting that the state of California spent \$387 million to treat 3,624 patients with the new hepatitis C drugs).

<sup>69</sup> NAS REPORT, *supra* note 5, at 110 (explaining that patient “sticker shock” at the pharmacy leads them to forgo filling the prescription or extend their medication by reducing dosages); see also Robyn Tamblin, *The Incidence and Determinants of Primary Nonadherence with Prescribed Medication in Primary Care: A Cohort Study*, 160 ANNALS INTERN. MED. (2014) (showing that patients with higher copays, recent hospitalizations, other severe health problems, or combinations of these factors were less likely to fill their prescriptions); BARBARA K. RIMER ET AL., PRESIDENT'S CANCER PANEL, PROMOTING VALUE, AFFORDABILITY, AND INNOVATION IN CANCER DRUG TREATMENT A REPORT TO THE PRESIDENT OF THE UNITED STATES FROM THE PRESIDENT'S CANCER PANEL 17 (2018), [https://prescancerpanel.cancer.gov/report/drugvalue/pdf/PresCancerPanel\\_DrugValue\\_Mar2018.pdf](https://prescancerpanel.cancer.gov/report/drugvalue/pdf/PresCancerPanel_DrugValue_Mar2018.pdf) [<https://perma.cc/TH53-UL5J>] (detailing that higher out-of-pocket costs makes it less likely for patients to adhere to recommended treatment regimens or undergo financial hardship); NAT. CANCER INST., NAT. INSTS. OF HEALTH, FINANCIAL TOXICITY AND CANCER TREATMENT (PDQ)—HEALTH PROFESSIONAL VERSION, <https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-hp-pdq> [<https://perma.cc/6YUY-Z5EA>] (noting how high costs have resulted in cancer patients selling property and other assets, incurring medical debt, reducing spending on necessities, changing housing, and declaring bankruptcy).



B. *Rebates and Reimbursement: The Byzantine World of Drug Sales*

Most people in the U.S. have some form of health insurance that pays for prescription medication, either a public or private plan.<sup>70</sup> With each of these forms of insurance, a significant middle player negotiates between drug companies and those who pay the bills, whether the payors are insurance companies, self-funding employers, or Medicare/Medicaid systems. These middle players are known as Pharmacy Benefit Managers or PBMs.

PBMs started as simple claims processing services, helping health insurance plans manage the flow of patient claims for the reimbursement of drug purchases.<sup>71</sup> When claims processing became commoditized in the 1990s with the advent of digital processing, PBMs looked for ways to differentiate their services, eventually moving into the role of negotiating drug prices on behalf of their health plan clients.<sup>72</sup> The importance of this role,

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<sup>70</sup> Forms of health insurance include: 1) employer-sponsored health insurance and individually purchased plans, such as those offered by CIGNA, Anthem, Blue Cross, or Kaiser Permanente; 2) Medicare for those over 65; 3) Medicaid for those below a certain level of income; 4) government employee plans including Department of Defense Veterans Administration benefits and plans for federal, state, and local workers; 5) government insurance that provides health care to prisoners; and 6) state health insurance sold in established under the Affordable Care Act. Employer plans may be what are known as “self-insured” plans or a combination of a private plan and self-insurance, a route taken by some prominent companies such as Google and Walmart. Under self-insurance, an employer assumes all financial risk for all employee health care costs. Employee claims are paid directly from the company’s financial assets and are tax deductible by the employer. The employer is also responsible for any costs associated with administering the health plan. In one subset of self-insurance called Administration-services-only (ASO) arrangements, the employer buys only the claims administration function from a third-party company, often a PBM, as opposed to the insurance protection function itself. See JEFFREY D. MAMORSKY, HEALTH CARE BENEFITS LAW §3.04[3] 19–20 (2005). The federal government funds Medicaid and Medicare, but individual states administer the programs. See Jennifer Rae Fleming, *The Blurred Line Between Nursing Homes & Assisted Living Facilities: How Limited Medicaid Funding of Assisted Living Facilities Can Save Tax Dollars While Improving the Quality of Life of the Elderly*, 15 U. MIAMI BUS. L. REV. 245, 261 (2007) (“Each state administers its own Medicaid program while the federal Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration) in the United States Department of Health and Human Services monitors the state-run programs and establishes requirements for service delivery, quality, funding, and eligibility standards.”); see also BARBARA S. KLEES, CHRISTIAN J. WOLFE & CATHERINE A. CURTIS, CTRS. FOR MEDICARE & MEDICAID SERVS., DEPT OF HEALTH & HUMAN SERV., BRIEF SUMMARIES OF MEDICARE & MEDICAID: TITLE XVIII AND TITLE XIX OF THE SOCIAL SECURITY ACT AS OF NOVEMBER 17 (2009), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/downloads/MedicareMedicaidSummaries2009.pdf> [https://perma.cc/9PE2-PWKR] (“DHHS has the overall responsibility for administration of the Medicare program. Within DHHS, responsibility for administering Medicare rests with CMS.”); *id.* at 18 (“[E]ach State establishes its own eligibility standards; determines the type, amount, duration, and scope of services; sets the rate of payment for services; and administers its own program.”). In addition, insurance companies generally operate state and federal employee plans, such as those listed above—Cigna, Anthem, Blue Cross, Kaiser Permanente, etc.

<sup>71</sup> Gregory S. Kaupp & Scott B. Lynch, *To Regain Control of Drug Costs, Health Plans Must Understand the Road They’ve Traveled*, MEDSCAPE (Dec. 16, 2019), <https://www.medscape.com/viewarticle/432389> [https://perma.cc/ZFC6-YPBK].

<sup>72</sup> See *id.*

increased with implementation of the 2003 Medicare Modernization Act, which led to widespread drug coverage for Medicare patients.<sup>73</sup> Today, PBMs negotiate drug prices on behalf of their health plan clients for all types of plans.

PBMs leverage the volume demand from patients within an insurance program to negotiate price concessions from a drug company. In other words, the PBM is saying, “I will deliver a large volume of clients to you under this health insurance plan, if you will give a large rebate.”<sup>74</sup> In theory, PBMs use their negotiating leverage, along with their knowledge of things such as the post-rebate prices on similar drugs that drug companies have offered to their various clients in the past, to negotiate the lowest prices possible on behalf of their clients.

As benchmarks for these negotiations, the parties generally use the national Average Wholesale Price (AWP).<sup>75</sup> AWP refers to the average price reported by drug companies<sup>76</sup> as paid for drugs at the wholesale level, not including reductions for rebates or discounts. AWP is referred to as the list price, or more colloquially, “Ain’t What’s Paid.”<sup>77</sup> The figure also is not verified, and the U.S. Department of Health and Human Services has studied price disparities among these indexes. Finally, lawsuits have alleged collusion between the commercial publishers of AWP information and wholesal-

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<sup>73</sup> The 2003 Medicare Modernization Act provided senior citizens and other Medicare beneficiaries with voluntary prescription drug benefits beginning in 2006. PBMs manage the drug benefit systems for their clients using services such as assembling retail pharmacy networks, establishing drug formularies for the client, and using mail order pharmacy options. *See generally* FED. TRADE COMM’N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (2005) [hereinafter FED. TRADE COMM’N 2005 REPORT]; *see also* Jessica Wapner, *Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers*, NEWSWEEK (Mar. 17, 2017), <http://www.newsweek.com/big-pharma-villain-pbm-569980> [<https://perma.cc/PK3V-62JF>].

<sup>74</sup> *See* Morton & Boller, *supra* note 1, at 21–22 (rebates are percentage discounts used by manufacturers to gain market share from PBM enrollees).

<sup>75</sup> *See, e.g.*, Anthem Class Action Complaint, *supra* note 56, at 28; EXPRESS SCRIPTS, *Annual Report 2015*, EXPRESS SCRIPTS (2016), [http://www.annualreports.com/HostedData/AnnualReportArchive/e/NASDAQ\\_ESRX\\_2015.pdf](http://www.annualreports.com/HostedData/AnnualReportArchive/e/NASDAQ_ESRX_2015.pdf) [<https://perma.cc/ZR7S-QY52>]. Wholesale Acquisition Cost (“WAC”), is a similar benchmark used in these contracts and as a starting point in negotiations. *See id.* Wholesalers mark up the drug from the WAC by a certain percentage, which leads to the Average Wholesale Price (“AWP”). For example, if a drug has a WAC of \$250, its AWP across the nation might be \$250 + 20%, for a total of \$300. *See* Julie Appleby, *Tracking Who Makes Money on a Brand-Name Drug*, KAISER HEALTH NEWS (Oct. 6, 2016), <https://khn.org/news/tracking-who-makes-money-on-a-brand-name-drug/> [<https://perma.cc/H6M7-98A8>]; *see also* WellPoint, Inc. and Express Scripts, Inc., Pharmacy Benefit Mgmt. Services Agreement (EX-10.30) (Dec. 1, 2009) (specifying that the AWP refers to the average wholesale price of a prescription drug “as established and reported by the Pricing Source” and that a drug’s applied AWP will be the AWP for the actual 11-digit National Drug Code).

<sup>76</sup> Commercial publishers of AWP data include Truven Health Analytics, Red Book, Medi-Span, and First Data Ban National Drug Data File Plus. Drug companies report the average wholesale price to these third parties using indexes that include the National Drug Code (NDC), which is a universal drug product identifier for prescription and nonprescription drugs.

<sup>77</sup> Patrick Mullen, *The Arrival of Average Sale Price*, 4(3) BIOTECHNOLOGY HEALTHCARE 48, 48–53 (2007).

ers to artificially inflate AWP numbers, in order to increase the markup spreads for the wholesalers.<sup>78</sup>

A PBM's contract with a drug company can include complicated calculations of concessions and volume-based rebates. These will be measured periodically based on items such as the total volume of drugs purchased, the number of product prescriptions filled, or on maintaining or exceeding the prior year's percentage of an insurer's patients who filled their prescriptions in that drug class with that drug.<sup>79</sup> As detailed later in this Article, this rebate system significantly distorts the incentive structure of pharmaceutical pricing and reimbursement.

PBMs also manage the drug claims for each of their health plan clients and help each client establish formularies. Formularies are the lists of drugs for which a health plan will reimburse patients. Small group and individual health plans—including the Affordable Care Act's exchanges—are required to cover at least one drug in every class of medication.<sup>80</sup> A Medicare insurer typically is required to cover at least one drug in each class of medications, and to cover all drugs within the protected classes of antiretrovirals, antidepressants, antipsychotics, anticonvulsants, immunosuppressants, and antineoplastics.<sup>81</sup> In general, most insurance plans in both the public and private markets also require different levels of patient cost sharing for different drugs, managing these through what are known as formulary "tiers."<sup>82</sup> In

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<sup>78</sup> See Appleby, *supra* note 75 (describing the relationships between AWP and the markup fees that wholesalers receive). Concerns also have been raised about a practice known as repackaging, in which PBMs or their mail-order pharmacies repack a drug to obtain a new NDC code at a new and usually higher Average Wholesale Price. In the FTC's 2005 report, PBMs reported that repackaging rarely occurred. For example, one study participant reported repackaging in only 1 out of roughly every 1 million prescriptions filled. FED. TRADE COMM'N 2005 REPORT, *supra* note 73, at xiii. Recent anecdotal reports by community pharmacists and others suggest that this practice may be increasing. See FTC Workshop Slides, *supra* note 53.

<sup>79</sup> Provisions between drug companies and PBMs that condition rebates on maintaining or exceeding the prior year's percentage of an insurer's patients who filled their prescriptions in that drug class with that drug may operate as a method of helping larger pharmacies (and larger PBMs that own large pharmacies) avoid competition from smaller players. For details of this technique, and the manner in which it maintains the market position for both large drug companies and large pharmacies, see *infra* notes 168–71 and accompanying text.

<sup>80</sup> See 42 U.S.C. § 18022 (2018); 45 C.F.R. § 156.122(a)(1) (2020).

<sup>81</sup> See 42 U.S.C. § 1395w-104(b)(3)(G)(iv) (2018); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101, 117 Stat. 2066 (codified as amended in scattered sections of 26 U.S.C and 42 U.S.C.); CENTS. FOR MEDICARE & MEDICAID SERVS., MEDICARE MODERNIZATION ACT 2007 FINAL GUIDELINES – FORMULARIES, CMS STRATEGY FOR AFFORDABLE ACCESS TO COMPREHENSIVE DRUG COVERAGE (2007), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidance.pdf> [<https://perma.cc/BF3B-G8WV>]. See also Morton & Boller, *supra* note 1, at 19 (citing Mark Duggan & Fiona Scott Morton, *The Effect of Medicare Part D on Pharmaceutical Prices and Utilization*, 100 AM. ECON. REV. 590, 594 n.14, 603 (2010)).

<sup>82</sup> See EXPRESS SCRIPTS, *supra* note 35, at 11 ("Most clients choose formularies designed to be used with financial incentives, such as three-tier co-payments, which drive preferential selection of plan-preferred generics and branded drugs over their non-formulary alternatives."). See also Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 VAL. U.L. REV. 33, 34 (2007) ("A common structure is the three-tier plan. The first tier . . . typically provides for a copay of around \$10 for

one of the most significant aspects of the system, the PBM, together with the insurance plan, decides which drugs to include on which tier of the insurer's formulary. This includes establishing the incentives (and barriers to utilization) that will drive patients toward particular drug options.<sup>83</sup> Historically, health care economists and policy makers presumed that formularies would drive patients toward generic drugs and lower-cost competitors.<sup>84</sup> As will be discussed below, recent evidence suggests that is not the case.

As strange as it may seem, the insurance companies—the payors in this system—generally do not know the actual net price paid for individual drugs.<sup>85</sup> The PBM collects and delivers periodic reports along with rebates from drug companies apportioned to each plan according to the contract terms. Thus, although the health plan knows how much it reimburses a particular patient at the moment the patient buys the drug,<sup>86</sup> the health plan never knows the net price that the drug company receives.

In addition, as described below, the health plan may have difficulty teasing out the per unit price that the plan itself is paying for a particular drug across all purchases, let alone on a particular purchase. That information is tucked within the folds of complex data and contractual calculations,

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generic drugs. The middle tier, with a slightly higher copay, allows for the purchase of brand-name drugs that have been determined by the PBM to be the preferred brand drugs in the formulary for treating a particular disease or condition. The third tier, allows plan participants to purchase non-preferred brand drugs with the payment of the highest copay.”). In addition to requiring the highest copay, the third tier may include a lower percentage coverage. Modern formularies may have up to six tiers, including two levels of cost sharing each for generic, brands, and specialty drugs. The most restrictive specialty tier relies entirely on coinsurance (in which the patient pays a percentage of the cost or the full cost up to a specified amount), rather than a copay (in which the patient pays a fixed amount). Given the high price of specialty drugs, paying co-insurance is a particularly heavy burden for a patient to bear.

Tiering can have a significant effect on a patient. A 2017 survey of patients on private plans found that copays increased from \$11 for first-tier drugs to \$110 for fourth-tier drugs, average coinsurance rates rose from 17% per drug in the first tier to 38% in the third tier, and that in addition to copays and coinsurance, some health plans required additional deductibles for drugs, separate from the general annual deductible. GARY CLAXTON ET AL., KAISER FAMILY FOUND., EMPLOYER HEALTH BENEFITS 2017 ANNUAL SURVEY 150, 154, 159 (2017).

<sup>83</sup> See, e.g., GARY CLAXTON ET AL., KAISER FAMILY FOUND., EMPLOYER HEALTH BENEFITS 2017 ANNUAL SURVEY 150, 154, 159 (2017) (listing the PBM's services provided). See also NAS REPORT, *supra* note 5, at 52 (explaining that higher tiered drugs require greater copays from patients thereby discouraging use of the drug; narrowing indications for which a drug may be used also constrains volume; excluding the drug entirely from coverage is the most powerful leverage).

<sup>84</sup> In theory, formularies are divided into tiers with lower costing drugs on the lower tiers and higher, branded drugs on the higher tiers. Each tier corresponds to a certain copay with lower copays on lower tiers and higher copays on the higher tiers. This system is supposed to lead to consumers preferring lower cost generics to branded drugs. See Cole Werble, *Health Policy Brief: Formularies*, HEALTH AFFAIRS (Sep. 14, 2017), <https://www.healthaffairs.org/doi/10.1377/hpb20171409.000177/full/> [<https://perma.cc/5E5R-PJY8>].

<sup>85</sup> Mark Meador, *Squeezing the Middleman: Ending Underhanded Dealing in the Pharmaceutical Benefit Management Industry Through Regulation*, 20 ANNALS OF HEALTH LAW 77, 82 (2011) (noting PBMs are not required to share information about rebates with plan sponsors and so often remain silent and pocket some or all of the money saved through rebates).

<sup>86</sup> In health system lingo, this is referred to as the “point of sale.”

including rebates that may flow—in whole or in part—to the health plan later in the year.<sup>87</sup>

How is it possible that insurers like Blue Cross and companies like Walmart never know the net prices of the drugs they are paying for? Quite simply, that information is a fiercely guarded secret. The contracts between PBMs and drug manufacturers are claimed as trade secrets and staunchly protected, even from a PBM's own health insurance client.<sup>88</sup> In some cases, the contract between the health insurance plan and the PBM offers minimal audit rights. When audit rights are granted and the plan exercises those rights, the plan's auditors are likely to be denied full access to the PBM's drug company contracts, even for the limited purpose of confirming that the plan's own contracts are being carried out as negotiated.<sup>89</sup> One insurance industry consultant describes the situation as “buying blind.”<sup>90</sup>

The PBM industry is highly concentrated. Three PBMs—Express Scripts, CVS Health, and OptumRX—dominate 85% of the commercial insurance market.<sup>91</sup> In an indication of the power of the big three outside that market, the three major PBMs reportedly handled 50% of the prescription drug benefits for the Medicaid managed-care population in 2015, as well.<sup>92</sup> A number of PBMs also have acquired their own pharmacies. Patients may

<sup>87</sup> See FED. TRADE COMM'N 2005 REPORT, *supra* note 73, at 24 n.6 (stating that some PBM contracts with plan sponsors state the PBM has several MAC lists used for generic pricing and allowing the PBM to select which list it will use with a particular plan sponsor).

<sup>88</sup> See Hiltzik, *supra* note 9. One bright spot on the horizon is a recent decision from a California court, rejecting an attempt by pharmacists to claim First Amendment protection against efforts to force the revelation of certain pharmacy fees and pricing. See *Beeman v. Anthem Prescription Mgmt. Inc.*, 2007 U.S. Dist. LEXIS 103220 (C.D. Cal. Aug. 24, 2007). To the extent that drug companies challenge legislative attempts to mandate disclosure of this information on First Amendment grounds, the California decision may provide a useful analogy for the governmental position.

<sup>89</sup> Hiltzik, *supra* note 9 (noting that insurers “generally don’t have the right to audit PBMs’ rebate collections and distribution”); see Unions Report: *CVS Caremark: An Alarming Merger, Two Years Later*, CHANGE TO WIN 9 (2009) [hereinafter Unions Report]; *supra* note 10 and accompanying text.

<sup>90</sup> Hiltzik, *supra* note 9. Scott Gottlieb, Commissioner of the FDA recently referred to this system as “Kabuki drug-pricing constructs—constructs that obscure profit taking across the supply chain that dives up costs; that expose consumers to high out of pocket spending; and that actively discourage competition.” Scott Gottlieb, Commissioner of Food and Drug Administration, Remarks at America’s Health Insurance Plans’ National Health Policy Conference: Capturing the Benefits of Competition for Patients (Mar. 7, 2018). The voluminous number of claims combined with constantly fluctuating prices creates enormous data analytics challenges for those who might want to audit closely. The volume of data is one reason insurance companies hired PBMs to do might wonder whether the PBMs have simply become too big to audit.

<sup>91</sup> See Sood, Goldman & Van Nuys, *supra* note 1; see also FTC Workshop Slides, *supra* note 53, at 100. One can see the power of these three players, in particular, from the fact that in 2016, the California Public Employee Benefits System (CalPERS) had only three finalists in the bidding for contract to manage prescriptions for the nearly 500,000 members and their families enrolled in non-HMO health plans. Hiltzik, *supra* note 9. Only the big three can compete for the major prizes.

<sup>92</sup> Jon Roberts, CVS/Caremark Executive Vice President & President, *Gaining Lives with Our Unique PBM Capabilities* 27 (2014), [https://nanopdf.com/download/jon-roberts-presentation\\_pdf](https://nanopdf.com/download/jon-roberts-presentation_pdf) [https://perma.cc/FS95-ZV7S].

be offered preferred deals at those pharmacies or, in some cases, be required to purchase certain types of drugs from the PBM's own pharmacies. In the 1990s, some drug companies acquired PBMs, although the FTC eventually required the drug companies to effectively unwind some aspects of those acquisitions, citing competition concerns.<sup>93</sup>

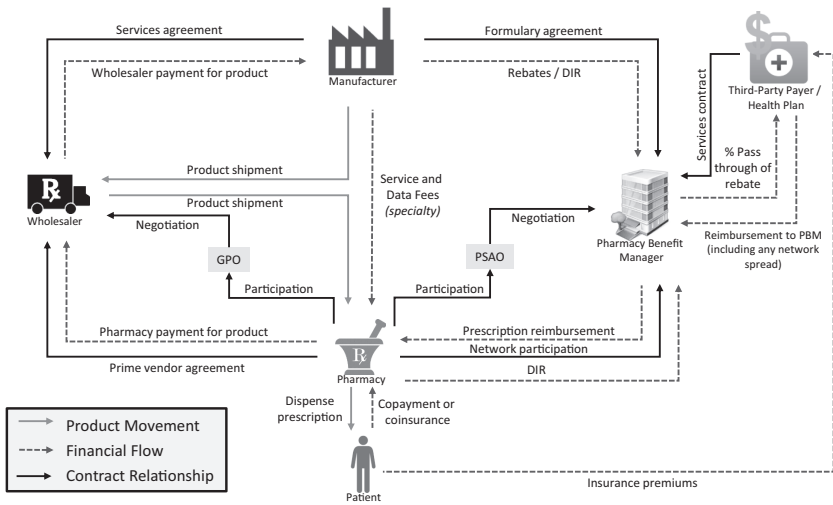
The following graphic shows the flow of payments throughout the drug supply chain, including pharmaceutical companies, wholesalers, PBMs, patients, and third-party insurance payors.

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<sup>93</sup> GENERAL ACCOUNTING OFFICE, *Pharmacy Benefit Managers: Early Results on Ventures with Drug Manufacturers*, 4–5 (1995), <https://www.gao.gov/assets/230/221921.pdf> [<https://perma.cc/2JY-9QRF>] (noting that following a slew of drug companies purchasing PBMs, the FTC finally intervened when Eli Lilly purchased PCS and established safeguards against potentially anticompetitive consequences). See also Merck & Co., Inc., et al., 127 F.T.C. 156 (1999) (requiring an “Open Formulary” along with other conditions in response to a complaint that Merck was receiving favorable treatment on Medco’s formulary); Eli Lilly & Co., 127 F.T.C. 577 (1999) (setting aside an order placing restrictions and obligations on Lilly’s use of its PBM after Lilly sold it to Rite Aid); Elizabeth L. Mitchell, *The Potential for Self-Interested Behavior by Pharmaceutical Manufacturers Through Vertical Integration with Pharmacy Benefit Managers: The Need for a New Regulatory Approach*, 54 FOOD DRUG L.J. 151, 152–53 n.16–17 (1999) (noting that SmithKline ultimately sold Diversified Pharmaceutical services for \$700 million after having originally paid \$2.3 billion for the PBM); Milt Freudenheim, *With Ties Lingerin, Medco Leaves Merck*, N.Y. TIMES (Aug. 20, 2003), <http://www.nytimes.com/2003/08/20/business/with-ties-lingering-medco-leaves-merck.html> [<https://perma.cc/SB7J-T7KQ>] (describing Medco’s spin-off from Merck); Merck & Co., Inc., *Letter to Shareholders: Important U.S. Federal Income Tax Information Concerning the Medco Health Solutions, Inc. Stock Distribution*, MERCK & CO., INC. (2003) (noting that shareholders “received 1206 shares of Medco Health common stock for each share of Merck common stock” owned); *FTC Gives Final Approval to Lilly Order; Pledges Continued Monitoring for Anticompetitive Practices*, FED. TRADE COMM’N (July 31, 1995), <https://www.ftc.gov/news-events/press-releases/1995/07/eli-lilly-and-company> [<https://perma.cc/NBQ2-L45R>] (noting SmithKline’s acquisition of Diversified Pharmaceutical Services in a press release also touching on concerns regarding the anticompetitive potential of similar acquisitions).

An even greater concern would be if a drug company purchased a health insurer or formed some form of joint venture alliance that provided pathways for disfavoring competitors. Consider the following competition risk of a drug company alliance with a health insurer. Suppose DrugCo with a 30% market share in a drug offers to underwrite capitation for a health insurer. In other words, DrugCo agrees to take on the burden of paying a group of doctors or health care providers a certain amount per enrolled patient, regardless of whether or how much the enrolled patient seeks care. In exchange, the health insurer would agree to give DrugCo a 40% market share. In this manner, DrugCo could purchase a greater market share. Although the industry flirted with that type of arrangement in the 1990s, nothing came to fruition, perhaps due to FTC scrutiny of competition in the industry. See FED. TRADE COMM’N, *supra* (noting that FTC approved SmithKline’s acquisition of Diversified Pharmaceutical Services while maintaining there are anticompetitive concerns which will be continually monitored). And if DrugCo purchased a health insurer, DrugCo would have more direct power for setting reimbursement and blocking competitors from access to patient markets. A new consolidation variant has arisen recently as insurance companies look to purchase PBMs, raising a different set of issues for competition authorities to contemplate. See Alex Kacik, *Cigna-Express Scripts Deal Unlikely to Benefit Consumers*, MODERN HEALTHCARE (Mar. 12, 2018), <https://www.modernhealthcare.com/article/20180312/NEWS/180319984/cigna-express-scripts-deal-unlikely-to-benefit-consumers> [<https://perma.cc/H7C9-ABAP>].

U.S. Distribution and Reimbursement System: Patient-Administered, Outpatient Drugs



GPO = Group Purchasing Organization; PSAO = Pharmacy Services Administrative Organization; DIR = Direct and indirect remuneration Source. *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (<https://drugch.ni/pharmacy/>). Chart illustrates flows for Patient-Administered, Outpatient Drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of product movement, financial flow, or contractual relationship in the marketplace.



*Picture 1.* Source: ADAM J. FEIN, DRUG CHANNELS INSTITUTE, THE 2019 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS (2019).

In theory, the system is designed so that at numerous points throughout the drug distribution system, the incentives align in favor of obtaining the lowest cost drug for the patient. The job of the PBM historically has been to provide valuable services to the plan sponsors by negotiating the lowest cost and highest quality drug benefit for each plan—whether public or private. Insurers should be able to use their volume buying power to obtain rebates that individual patients could never obtain on their own. Insurers also should be motivated to obtain good pricing structures and lower premiums in order to compete in the market for patient enrollees. Pharmacists, who know the prices of the drugs in their stock and see the patient’s cost sharing amounts at the cash register, should be able to give patients information on how to find the best deal and should be motivated to provide those deals so that patients can afford their medicines.

In addition, the norms of the medical profession obligate doctors to make decisions in the best interests of the patient.<sup>94</sup> Public interest groups should be motivated to step in and nudge the system in healthier directions. Finally, all of this occurs against the backdrop of a national policy to expedite and encourage vigorous competition through the rapid entry of

<sup>94</sup> NAS REPORT, *supra* note 5, at 111–12.

generic drugs as soon as patents expire.<sup>95</sup> Something, however, is not working in the system.

### III. HOW THE INCENTIVE STRUCTURES DRIVE PRICES HIGHER

As described in the prior section, in a competitive market, the incentive structures should operate to create competition and keep prices in check. The reality on the ground, however, is quite different. At numerous levels, the incentives operate to drive prices higher and reduce competition among therapeutically similar products—or what economists might call, substitute products. This includes incentives for PBMs, incentives for insurers (including Medicare and other government plans), incentives for some pharmacists, doctors, and patient advocacy groups, and, of course, incentives for drug companies themselves. Together, this alignment of incentives operates so that higher prices are a win-win for everyone—except for those who pay the price.

#### A. Why PBMs May Prefer Higher Prices

##### 1. PBM Pay Structure

The core of the incentive problem lies with the PBM system. These middle players, who establish the drug formularies and negotiate between drug companies and the insurance plans, have evolved in a manner that creates upward pressure on prices.<sup>96</sup> These players are uniquely situated with the bargaining power, drug information, and data to negotiate the most aggressive price concessions from drug companies, but have been distorted by reimbursement schemes that reward them most significantly when drug prices and drug spending increases.

The problem starts with a payment structure that, on the surface, would appear to be procompetitive, but in actuality minimizes the competitive pressures to reduce prices. Insurers pay their PBMs based on the extent of the discount that a PBM can negotiate with individual drug companies. In highly simplified form, a PBM is paid based on an amount off of the list price.<sup>97</sup>

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<sup>95</sup> See FELDMAN & FRONDORF, *supra* note 8, at 1 (describing the Hatch-Waxman system for rapid entry of generic drugs); cf. Jennifer L. Graber, Note, *Excessive Pricing of Off-Patent Pharmaceuticals: Hatch It or Ratchet?*, 92 N.Y.U. L. REV. 1146, 1162 (2017) (citing Anna Edney & Justin Sink, *Trump Calls Drug Pricing ‘Astronomical’ and Promises Changes*, BLOOMBERG POLITICS (Jan. 31, 2017), <https://www.bloomberg.com/news/articles/2017-01-31/trump-meets-with-drugmakers-as-industry-fears-price-controls> [<https://perma.cc/5T3P-EU4J>] (noting President Trump’s promise to find ways “to get new medicines to market faster”)).

<sup>96</sup> See EXPRESS SCRIPTS, *supra* note 35, at 13, 18, 62; see also Joana Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 NW. J.L. & SOC. POL’Y 1, 2 (2013) (noting that PBMs administer prescription drug benefits for health plan sponsors and also negotiate discounts from drug manufacturers in exchange for putting the manufacturers’ drugs on preferred medication lists).

<sup>97</sup> Some forms are modeled as price protections, others as anticipated rebate amounts.



The higher the list price, the greater the spread opportunity. In other words, the greater the distance between the list price and the final price, the more money a PBM makes.<sup>98</sup> In theory, this might encourage PBMs to drive prices down, given that their pay is directly tied to the level of discounts and rebates.<sup>99</sup> In reality, the incentives operate to drive prices higher. Drug companies compete with generics, or those who would offer lower-priced drugs within the same class, by raising the drug's list price, which allows them to offer what appears to be an even more attractive rebate deal to PBMs.

In this manner, the drug company can offer a sweeter deal to a PBM, without absorbing the full cost of that sweetener. The drug company collects the same final price for the drug, but the PBM can command a higher fee from the health plan in light of the greater discount. Moreover, the contract between the PBM and the insurance plan is based on the rebate level the parties think the PBM will be able to negotiate, while the insurance plan is never permitted to know the actual level of that rebate. If the rebate is more than the companies anticipated, the PBM pockets that difference as well.<sup>100</sup> Driving up prices is a win-win for PBMs and drug companies—drug companies can charge more for their products, while PBMs increase their slice of the pie.

One can think of the PBM role as analogous to that of a travel agent. In theory, both of them ought to be looking for the best price for the customer. However, a travel agent, who may be paid by the airline and hotel based on the cost of the vacation, has the incentive to sell you a nice Caribbean cruise, rather than a trip to a cheap motel at the beach town nearby. As long as the travel agent can get the trip for you at a price cheaper than other agents will charge, or than you could get on your own, the travel agent is in a good position. And if there are only three travel agents in the country, that is even better.

PBM contracts have been reported to last as long as seven years, while drug companies change their prices at least annually and sometimes more frequently.<sup>101</sup> On the one hand, this shifts risk to the PBM to ensure that it

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<sup>98</sup> See Meador, *supra* note 85, at 82 (noting that PBMs take advantage of the price range in various price lists for generic drugs, negotiating with manufacturers for a lower price and setting reimbursement rates with plan sponsors using a higher list price, in order to maximize the spread); cf. Morton & Boller, *supra* note 1, at 3 (noting that PBMs may use rebates to grow profits by keeping a share of the high prices paid by insurers for costly medication).

<sup>99</sup> See Morton & Boller, *supra* note 1, at 21–22 (noting that contracts between plan sponsors and the PBM are often based on list price without rebates in part because this incentivizes the PBM to bargain for larger rebates). Accounting methods for PBMs are also problematic. PBMs report their revenue based on the total value of drugs flowing through their contracts and their income as a percentage of that total revenue. Thus their earnings-per-share stock valuations increase as the total revenue increases, a figure that is, in part, a function of prices.

<sup>100</sup> For a more complete discussion of why insurers agree to this arrangement even without seeing the terms of PBMs contracts with drug manufacturers see *infra* notes 162–71 and accompanying text.

<sup>101</sup> For an example of a particularly powerful PBM-insurer contract, see Hiltzik, *supra* note 9 (reporting that in 2016, the California Public Employee Benefits System (CalPERS) awarded a five-year contract to OptumRx, one of the three major PBMs, to manage prescrip-

can constantly deliver at least the rebate for which it has contracted with its insurance client. On the other hand, drug companies and PBMs together use the system to increase both revenue to the drug firm and income to the PBM by raising list prices. One need not ascribe any motive on the part of drug companies to try to influence the design of the system. Drug companies have simply found a way to operate within the system to their own greatest advantage. Can one really expect anything different from profit-making enterprises?

In addition to rebates, drug companies offer payments in the form of administrative fees or data managing fees to PBMs.<sup>102</sup> These administrative fees do not have to be reported to the health insurance plans or included in any types of payments that flow through to the plan or to the patient. Increasingly, drug companies offer creative fees for “services,” such as providing research and information to the drug company.<sup>103</sup> These fees have the advantage of being invisible to the insurers, including Medicare and Medicaid systems. As a transfer of money from the drug company to the PBM, these payments reduce the drug company’s net income from sales of the drug and increase the PBM revenue related to a specific drug. Even when a drug company pays for services from a PBM, if the value of the service is substantially less than the payment made, the transaction is simply an indirect price concession. Once again, raising list prices can leave room for the drug company to offer these goodies, without reducing the company’s net income from sales of the drug. And of course, as described above, many people will be forced to pay the higher list prices.

As an outcome of this complex process of payments and inducements, the drug company’s product either may be placed in an advantageous position on the PBM formulary,<sup>104</sup> or the PBM may even entirely exclude a ge-

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tions for the nearly 500,000 CalPERS members and their families enrolled in non-HMO plans).

<sup>102</sup> Complaint at 6, *Boss et al. v. CVS Corp. et al.* (D.N.J. Mar. 17, 2017) (No. 17-01823) [hereinafter *Boss Compl.*] (arguing that payments other than rebates are provided under a variety of labels, including discounts, credits, concession fees, etc.); *see also* Cahn, *supra* note 9.

<sup>103</sup> *See, e.g.,* EXPRESS SCRIPTS, *supra* note 35, at 12 (describing its pharmaceutical services to include aligning its expertise and industry insight with the UBC consulting company, which, among other services, partners with drug companies to help prescribers with navigating prescription drug coverage and pharmacy options through patient access programs, including patient assistance programs, reimbursement, alternate funding and compliance services). Express Scripts acquired UBC in its purchase of another PBM (Medco), in 2012 and sold the subsidiary in 2017. Samantha Liss, *Express Scripts to Sell Subsidiary to Private-Equity Firm*, ST. LOUIS POST-DISPATCH (Nov. 27, 2017), [http://www.stltoday.com/business/local/express-scripts-to-sell-subsidiary-to-private-equity-firm/article\\_26514461-225a-5e81-8abb-09efe0ab005b.html](http://www.stltoday.com/business/local/express-scripts-to-sell-subsidiary-to-private-equity-firm/article_26514461-225a-5e81-8abb-09efe0ab005b.html) [https://perma.cc/GM8K-BEPQ].

<sup>104</sup> Rebate agreements may also ensure a form of most favored nation status, ensuring that competitors do not have better access in any way, presumably even if the competitor offers a lower price. *See, e.g.,* *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 400 (3d Cir. 2016) (contract clause preventing hospitals from giving competing drugs priority status).

neric or competing drug in the same class from being reimbursed at all.<sup>105</sup> Documents submitted to the U.S. Senate Committee on Finance show that in 2014, for example, Express Scripts PBM negotiated a significant rebate from Abbvie on its hepatitis C drug in exchange for giving that drug an exclusive position on its formulary and excluding the competing drugs Sovaldi and Harvoni.<sup>106</sup> Senate documents also note that some states followed suit awarding Abbvie's drug a preferred position on its formulary in light of the fact that "Abbvie submitted more aggressive rebates."<sup>107</sup>

## 2. *The Power of Volume*

The rebate, or the size of the rebate, may be conditioned on having a certain volume of the drug purchased by the PBM's client. All of the rebates, discounts, and other payments, which I refer to as "persuasion payments," can be structured as volume discounts, loyalty discounts, or market penetration rebates.

Regardless of the title of the rebate, the name of the game is volume. Volume rebates provide a significant advantage to entrenched market participants at the expense of lower-priced entrants. The more volume rebates a drug firm can offer the PBM, the better deal it can command to exclude its rivals. Similarly, the greater a drug's volume, the more the drug company

<sup>105</sup> See Complaint at 26, *Sanofi-Aventis U.S. v. Mylan GmbH*, No. 17-9105, 2019 U.S. Dist. Lexis 170790 (D.N.J. Oct. 24, 2017) (drug company Sanofi acknowledged that drug maker rebates in exchange for exclusive coverage "are not unheard of" but said that drug makers with monopolies "do not – and under U.S. antitrust law cannot – condition large rebates to block new rival drugs from key access to the market"). As described in this article, a drug company does not need to have full monopoly power in any particular drug to create blocking behavior, nor are the drugs that suffer necessarily new drugs. See *infra* notes 114–34 and accompanying text; see also Boss Compl., *supra* note 102, at 6 (arguing that however the rebates are named or described, they are a quid pro quo for formulary inclusion or placement).

<sup>106</sup> See Andrew Pollack, *Abbvie Deal Heralds Changed Landscape for Hepatitis Drugs*, N.Y. TIMES (Dec. 22, 2014), <https://www.nytimes.com/2014/12/22/business/pharmacy-deal-heralds-changed-landscape-for-hepatitis-drugs.html> [<https://perma.cc/U2KG-QLAN>]; Gail R. Wilensky, "Negotiating" Drug Prices for Medicare, 70 HEALTHCARE FIN. MGMT. MAG. 3, 32–33 (2016). Subsequently, CVS Health Corp. struck a deal to make Gilead's hepatitis C medicines the exclusive treatments for its customers following rebate negotiations. See Robert Langreth & Caroline Chen, *Gilead Makes Exclusive Deal With CVS for Hepatitis C Drugs*, BLOOMBERG (Jan. 5, 2015), <https://www.bloomberg.com/news/articles/2015-01-05/gilead-makes-exclusive-deal-with-cvs-for-hepatitis-c-medicine> [<https://perma.cc/8JWD-QNLP>]; STAFF OF S. COMM. ON FINANCE, 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM 114 (Comm. Print 2015) (citing an email from the Director, Federal Government Affairs at CVS Health Corp. stating "as new drugs came on to the market like Viekira Pak, we were able to negotiate discounts [with Gilead]"). In theory, when players equally situated compete to lower prices, the customer benefits. As noted below, however, problems may arise when the players are not equally situated, such as when one player has a large stable of drugs with which to bargain and the other does not. And as noted in prior sections, the entire rebate system pushes prices higher, prices that patients will frequently pay without the rebate and that create other burdens and economic distortions.

<sup>107</sup> STAFF OF S. COMM. ON FINANCE, 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM 88 (Comm. Print 2015).

can spread out any discount across each unit of the drug sold.<sup>108</sup> In other words, suppose DrugCo sells 100,000 bottles of LifeElixir at \$10 a piece to a particular PBM for total sales revenue of \$1 million. With rebates and other payments worth 20%, the drug company can offer the PBM a \$200,000 check, of which the PBM might keep a significant portion. In contrast, if a competitor sells only 10,000 bottles at the same \$10 price, the rebate and payment discount rate of 20% would provide only a \$20,000 check for the PBM. Thus, the same price and the same discount rate will be far less attractive to the PBM. And, of course, a new drug just coming on the market would lack the volume to match the total rebate dollars offered by the current market leader.

These rebate schemes do not necessarily aim for exclusivity in the market or even for massive increases in the market. If a drug company has a 50% market share, it may be tremendously expensive to extract too much additional market share. For example, if the competing drug is not a perfect substitute, some patients will simply refuse to switch, supported by laws that require a plan to allow patients to remain with their original drug under certain circumstances.<sup>109</sup> Other consumers may choose to pay for their original drug out of pocket, which could prevent the PBM from reaching the volume or other requirement for the payments. In those circumstances, the drug company would have to pay an enormous sum to the PBM to compensate. Thus, hypothetically, a PBM might simply aim to increase its market share by ten or fifteen percent. With drugs for which the molecule is really the same, for example insulin, a drug company might try to push its market share up far more aggressively. In many cases, however, the drug company may be bargaining for smaller market share increases, an approach that may be more difficult to measure in traditional federal antitrust terms, which may categorize behavior as inappropriate only when it rises to the level of attempts at market dominance, rather than smaller increases in market share.

The volume rebate barriers are particularly problematic in combination with the patent system and other aspects of the drug approval process that can create additional barriers to entry by competitors.<sup>110</sup> When a drug's patent or its other regulatory exclusivities expire, lower-priced generic competitors should be able to enter the market quickly and drive prices down.<sup>111</sup> The brand company, however, is likely to have enjoyed unfettered access to markets, so that when the patent expires, the company holds a majority of mar-

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<sup>108</sup> Michael E. Porter, *How Competitive Forces Shape Strategy*, 59 HARV. BUS. REV. 2, 137, 140 (1979) (noting how *buying* groups are more powerful if they purchase in large volumes).

<sup>109</sup> See generally *infra* note 175.

<sup>110</sup> FELDMAN & FRONDORF, *supra* note 8, at 49, 86, 136; Robin Feldman, *Empirical Evidence of Drug Pricing Games – A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 45 (2017); Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 54, 64 (2016) (describing the various bargaining chips utilized in negotiations between PBMs and manufacturers).

<sup>111</sup> See FELDMAN & FRONDORF, *supra* note 8, at 33.

ket share, if not total market dominance.<sup>112</sup> Given the advantages of volume in the PBM system, competitors may be unable to break through and gain more than limited market shares, despite their vastly lower prices.

Other contractual terms in the contracts between drug companies and PBMs can further entrench a market leader. An incumbent drug company with a PBM contract may be given a right of first refusal. This would allow the drug company to match any lower price that is bid by another company after new requests for bids have gone out. On the flip side, the drug company could promise that it will not offer a lower price to any other PBM or buying group.<sup>113</sup> Sometimes called most-favored-nation clauses, these agreements not only deter price competition in the PBM industry, they may also have the effect of setting uniform prices for drugs across the industry. Specifically, to the extent that state or federal reimbursements are based off of the lowest prices available or average sales price on a particular drug, promises not to give a better price help could help drug companies maintain price levels.

The circumstances described above relate to a company foreclosing competition using volume rebates related to a single drug. Courts have yet to address that issue squarely. However, dicta in older cases relating to foreclosure through volume rebates across multiple drugs suggest that single-drug behavior poses no threat to competition. The following section describes multi-drug foreclosure, and Part III.A.4 describes the older cases.

### 3. *Bundled Rebates*

When a drug company has a portfolio of drugs to offer, the opportunities for blocking competition increase. Consider a drug company that has three drugs, and imagine that two of the drugs are strongly buttressed against competition, perhaps protected by strong patents or regulatory exclusivities or by having no competitor on the horizon. The company's third drug is vulnerable to competition, either because its patents and exclusivities have expired or because the remaining patents are weak, secondary ones.<sup>114</sup> The

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<sup>112</sup> It is important to note that a patent is not a guarantee of a monopoly. It brings the right to exclude and the opportunity thereby to obtain a monopoly position. There may be substitutes in the market, however, such as ibuprofen and acetaminophen, or the market may have no interest in the drug. For a deeper discussion of these issues, see ROBIN FELDMAN, *RETHINKING PATENT LAW* 23 n.53 (2012) (citing Brief for Respondent at 24, *Ill. Tool Works Inc. v. Indep. Ink Inc.*, 547 U.S. 28 (2006) (No. 04-1329)).

<sup>113</sup> See, e.g., Complaint, *United States v. Blue Cross Blue Shield of Mich.*, 809 F. Supp. 2d 665 (E.D. Mich. 2011) (No. 2:10-cv-14155) (challenging Blue Cross Blue Shield of Michigan's use of MFNs); see also ROY LEVY, FEDERAL TRADE COMMISSION, *THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE* 54 (1999).

<sup>114</sup> Secondary patents cover various adjustments to a drug's timing, dosage, or delivery mechanism, rather than covering the main chemical formula or innovation. Secondary patents, sometimes called evergreen patents, may be added in an effort to extend the life of the drug's protection, and such patents can be more difficult to defend in court. For an explanation and empirical analysis of evergreening, see Feldman, *supra* note 8, at 596; Michael A. Carrier,

company can bargain so that the weaker drug receives an exclusive or preferred position on the formulary.

The strategy is known as packaged, bundled, or loyalty rebates<sup>115</sup> With such an approach, a DrugCo tells a PBM that in order to get the best rebate, the PBM's client must accumulate a certain volume, not just across one drug, but across all of the drugs. Under those terms, a competitor with only one drug could be completely unable to offer a comparable deal.

The strategy may be particularly powerful when one drug of the drugs that are part of the bundle enjoys significant market share, perhaps due to a strong patent position. In that case, the brand company could offer a break on the price of the patented product—for which there is strong protection against competition—in exchange for a preferred position for drugs in which there is strong competition. The competitor would not be in a position to offer a comparable deal.

*a. Allergan Pharmaceuticals's Drug Restasis.* For example, in October of 2017, Shire Pharmaceuticals sued Allergan Pharmaceuticals, alleging that Allergan used bundled rebates to block competition and preserve its dominant market share in the blockbuster dry-eye medication, Restasis.<sup>116</sup> Shire's complaint alleged that this scheme does not save patients money as the "clinically inferior" Restasis is "not an innovative product" and has a greater incidence of adverse reactions.<sup>117</sup> According to the complaint, the brand drug enjoyed a complete monopoly on the preferred tier of Medicare formularies from 2002 until the FDA approved the competing brand drug Xiidra, and Allergan developed the scheme to shore up its monopoly position as the competing drug emerged.<sup>118</sup> The complaint alleges further that the scheme has made it impossible for the new drug to gain reasonable formulary access, and that according to one Medicare plan administrator, given Allergan's bundling scheme, Shire could give the new drug away for free and the numbers still wouldn't work.<sup>119</sup> This striking statement demonstrates the power that market share combined with bundled rebates can wield in blocking newer competition.

*b. Johnson & Johnson's Drug Remicade.* In a similar vein, a case filed in late 2017 alleges that Johnson & Johnson attempted to suppress competi-

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Nicole L. Levidow & Aaron S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECH. L.J. 1379, 1405 (2016); and Stacy L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 687 (2009).

<sup>115</sup> See Robin Cooper Feldman, *Defensive Leveraging in Antitrust*, 87 GEO. L.J. 2079, 2103–05 (1999); see also Phillip E. Areeda & Herbert Hovenkamp, *Package or Bundled Discounts*, in ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION 556 (3d ed. 2011).

<sup>116</sup> See Complaint at 6, 21–23, *Shire U.S., Inc. v. Allergan, Inc.*, No. 17-7716 (D.N.J. 2017) (implying specifically that Allergan's product portfolio, including many popular Glaucoma drugs, provides them the "financial wherewithal to give . . . rebates that far exceed anything that Shire could offer on Xiidra").

<sup>117</sup> *Id.* at 2, 3, 18–19.

<sup>118</sup> *Id.* at 4–5.

<sup>119</sup> *Id.* at 6–7.

tion following expiration of the patent protection on the company's inflammation drug Remicade.<sup>120</sup> Johnson & Johnson's drug dominated the market from 1998 through 2016, when Pfizer introduced the biosimilar version, Inflectra.<sup>121</sup> According to the complaint, just weeks after the biosimilar's introduction, Johnson & Johnson began its "Biosimilar Readiness Plan" which included anticompetitive bundling, coercive rebates, and exclusionary contracts.<sup>122</sup> The complaint contends that Johnson & Johnson induced insurers to enter contracts that required an explicit commitment to exclude the biosimilar completely from formularies or to provide reimbursement only in the rarest of circumstances."<sup>123</sup>

Tactics cited in the complaint include threatening to withhold rebates on Remicade prescriptions—both from existing and new patients—unless insurers agree to exclusivity<sup>124</sup> and bundling the rebates across multiple products so insurers that refuse to grant Remicade exclusivity will suffer rebate losses across their drug portfolios.<sup>125</sup> The deals apply not only to insurers but to providers such as hospitals, who purportedly declined to stock the biosimilar, even though it was covered by government programs, effectively forcing the government to continue reimbursing providers for the more expensive Remicade.<sup>126</sup> The Remicade lawsuit suggests the power of bundled rebates in the market for drugs delivered in the hospital setting, as well as drugs purchased from retail pharmacies.

c. *AstraZeneca's Drug Nexium*. In 2015, AstraZeneca entered into a small settlement with the U.S. Department of Justice regarding its drug Nexium.<sup>127</sup> The case alleged that AstraZeneca provided rebates to a PBM in exchange for giving Nexium sole and exclusive status on formularies.<sup>128</sup> The case also alleged that, as part of the deal, the drug company gave price concessions on other drugs, including Prilosec, Toprol SL, and Plendil.<sup>129</sup> At the time, the drug company was already engaged in shifting the market from Prilosec to Nexium, such that price concessions for Prilosec would not hurt

<sup>120</sup> Complaint at 1, Pfizer, Inc., v. Johnson & Johnson and Janssen Biotech, Inc., 2018 U.S. Dist. LEXIS 31690 (E.D. Pa. 2018) (No. 17-4180).

<sup>121</sup> *Id.*

<sup>122</sup> *Id.* at 2.

<sup>123</sup> *Id.* at 3. If insurers are allowed to reimburse for the biosimilar when Remicade has failed, the complaint alleges that the effects of the contract are still exclusionary because physicians are unlikely to turn to the biosimilar if the original drug failed. *See id.* at 3–4.

<sup>124</sup> *Id.* at 5.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> Dep't of Justice, Office of Public Affairs, AstraZeneca to Pay \$7.9 Million to Resolve Kickback Allegations, Press Release (Feb. 11, 2015), <https://www.justice.gov/opa/pr/medco-pay-79-million-resolve-kickback-allegations> [<https://perma.cc/4E97-X6MV>].

<sup>128</sup> Complaint for Damages and Other Relief under the *Qui Tam* Provisions of the Federal False Claims Act and Similar State Provisions at 2, United States of America et al. v. AstraZeneca LP et al., No. 10-00910 (D. Del. 2010).

<sup>129</sup> *Id.* at 17.

the company and would provide little benefit to the PBM's insurance clients.<sup>130</sup>

*d. Other Health Care Markets: Vaccine and Medical Devices.* Bundling rebate schemes appear in other sectors of the pharmaceutical market as well. In the vaccine market, as opposed to medications, Sanofi paid to settle an antitrust bundling suit.<sup>131</sup> The suit alleged that when a competing company planned to enter the market to compete against Sanofi's pediatric meningitis vaccine menactra, Sanofi charged up to 34.5% higher prices for the vaccine, unless buyers agreed to purchase all of Sanofi's vaccines exclusively.<sup>132</sup> Sanofi paid \$61.5 million in October of 2017 to settle the case, which was pending in a federal district court in New Jersey.<sup>133</sup>

In the medical device market, a competitor sued Tyco for engaging in anticompetitive conduct related to discounts for its oximity meter product, a non-invasive device that clips onto the end of patient's finger and measures pulse and blood oxygen saturation. Tyco provided loyalty discounts to hospitals that agreed to purchase a certain percentage of their requirements from the company, sole-source discount agreements, and bundled rebate agreements.<sup>134</sup> In an unpublished, non-precedential opinion, the trial court upheld the jury's findings of anticompetitive conduct related to all three types of agreements—an opinion that will be discussed further in Part III.A.4 below.

*e. Does Negotiating on a Drug-by-Drug Basis Eliminate Bundling?* In the modern context, PBMs and drug companies could argue that bundled behavior is not possible, asserting that they negotiate rebates with a drug company on a drug-by-drug basis. Even to the extent that is accurate, other fees flowing from drug companies to PBMs need not be based on a single drug. Moreover, the complexity of the contracts can camouflage the bundling aspects. For example, DrugCo's bid on drug X can stipulate that if the plan provides a favored position for another one of the company's drugs Y, then the rebate on drug X will increase by an additional amount. In that way, DrugCo can reference other drugs in its bid for a single drug.

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<sup>130</sup> FELDMAN & FRONDORF, *supra* note 8, at 71.

<sup>131</sup> See generally Order Granting Final Approval of Class Action Settlement, Approving Plan of Distribution, and Final Judgment and Order of Dismissal, *Castro, M.D., P.A. v. Sanofi Pasteur, Inc.*, 2012 U.S. Dist. LEXIS 96001 (D.N.J. 2012) (No. 11-7178) [hereinafter *Sanofi Settlement Final Approval*]; Order Granting Preliminary Approval of the Proposed Settlement, Approval of the Proposed Manner and Form of Notice, and Appointment of Escrow Agent and Settlement Administrator at 2, *Castro, M.D., P.A. v. Sanofi Pasteur, Inc.*, 2012 U.S. Dist. LEXIS 96001 (D.N.J. 2012) (No. 11-7178) [hereinafter *Sanofi Settlement Preliminary Approval*].

<sup>132</sup> Class Action Complaint at 3, *Castro, M.D., P.A. v. Sanofi Pasteur Inc.*, LEXIS 96001 (D.N.J. 2012) (No. 11-7178).

<sup>133</sup> See generally *Sanofi Settlement Final Approval*, *supra* note 131; *Sanofi Settlement Preliminary Approval*, *supra* note 131, at 2.

<sup>134</sup> *Masimo Corp. v. Tyco Health Care Group, LP.*, No. 02-cv-4770(MRP), 2006 U.S. Dist. LEXIS 29977, at \*3 (C.D. Cal. Mar. 22, 2006) (unpublished case with no precedential value).



Finally, although price is important to a PBM in awarding a contract to a drug company, it is not the only factor. PBMs could also consider stability of source and supply, which means that the company with more drugs and greater resources is in a better position. PBMs may also favor dealing with fewer manufacturers, to reduce transaction costs, once again favoring the company with more drugs in a way that can provide more room for bundling-type effects.

#### 4. *Scattered Decisions on Volume Discounts in the Health Care Industry*

Bundled rebates did not originate with the emergence of the PBM middle-player system. This author wrote about bundled pharmaceutical rebates roughly twenty years ago, in relation to efforts to block generic competitors out of the market who might try to gain a foothold against entrenched monopolists by splintering off sections of the market and gaining a foothold.<sup>135</sup> That case sets the stage for the modern antitrust battles that may unfold as rebates are challenged in the courts. Specifically, Eli Lilly had a monopoly over the cephalosporin market for almost a decade when competitor SmithKline introduced two new types of cephalosporin.<sup>136</sup> Lilly responded with a rebate plan providing optimum prices only when hospitals purchased a certain amount of at least three of Lilly's five cephalosporin options.<sup>137</sup>

SmithKline brought an antitrust action against Eli Lilly alleging that Lilly's marketing scheme was "an unlawful tying device," and that Lilly had committed "monopolization in violation of section two of the Sherman Act."<sup>138</sup> The district court declined to find illegal tying given that buyers had the freedom to purchase the products individually, even if the terms were economically unfavorable.<sup>139</sup>

The district court agreed with the plaintiff, however, that Lilly's rebate scheme constituted "the willful maintenance of monopolistic power."<sup>140</sup> The court explained that it is impermissible for Lilly to use pricing to link monopolistic products with another competitive product to deter a competitor from entering or effectively competing in the market.<sup>141</sup> In dicta, however, the court suggested that Lilly was free to take efforts to maximize profits when competing "*product versus product*."<sup>142</sup> This 1976 language may com-

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<sup>135</sup> See Feldman, *supra* note 115, at 2091, 2104 (citing *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1976)).

<sup>136</sup> *SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089, 1093 (E.D. Pa. 1976).

<sup>137</sup> *Id.* at 1091–92.

<sup>138</sup> *Id.* at 1091.

<sup>139</sup> *Id.* at 1112–14.

<sup>140</sup> *Id.* at 1120–21.

<sup>141</sup> *Id.* at 1128. *But see Masimo Corp.*, 2006 U.S. Dist. LEXIS 29977, at \*34–37 (unpublished case with no precedential value criticizing the reasoning in *SmithKline*).

<sup>142</sup> *SmithKline Corp.*, 427 F. Supp. at 1128.

pligate modern efforts to rein in volume discount behavior, outside the explicit bundling context.

In a separate section of the decision, the *Eli Lilly* court declined to find tying in the case because the buyer was free to buy the two drugs separately, despite any financial burden. The court noted that although “[t]he economics of the market place precluded that freedom of choice for most hospitals; such a freedom of choice . . . is enough to circumvent the tie-in prohibitions of the relevant antitrust laws.”<sup>143</sup>

The definition of “choice” embodied in the court’s analysis leaves much to be desired. At some point, the notion of what constitutes a choice is so extreme as to become absurd. For example, suppose I say, “I’m not forcing you to buy both products. You could certainly buy them separately. I will just take your first-born child as payment, if you do.” Would we really say this is a choice? And when it comes to profits—the beloved child of free enterprise—is it really a choice when the economic effects are so drastic?

In addition to the 1976 *Eli Lilly* case, a more modern case addresses health care rebates, although in the context of medical devices, rather than drugs. As noted above,<sup>144</sup> *Masimo v. Tyco* concerned various discount programs related to Tyco’s oximity meter. These included a single-product discount to hospitals that agreed to purchase a certain percentage of their requirements from the company (market share discount), a sole source agreement, and bundled discounting.<sup>145</sup> In an unpublished, non-precedential opinion, the trial court upheld various jury verdicts finding anticompetitive conduct for each of these forms of agreement. The court found that the market share discounts in relation to single-drug activity constituted exclusive dealing arrangements in practical effect, foreclosing more than twenty-four percent of the market, thereby violating Section 1 of the Sherman Act and Section 3 of the Clayton Act, as well as violating Sherman Act Section 2’s prohibition on attempted monopolization.<sup>146</sup> The court found that the sole source agreement violated the same provisions.

The bundled discount portion of the decision also resulted in a decision at odds with *Eli Lilly*, which was handed down in a different circuit. Explicitly disagreeing with the logic of the *Eli Lilly* opinion, the trial court in *Masimo* declined to find that bundled discounts constituted a tying arrangement.<sup>147</sup> Rather, the court held that as a general matter, bundled discounts do

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<sup>143</sup> See *id.* at 1114 (citing *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 6 n.4 (1958) (“Of course where the buyer is free to take either produce by itself there is no tying problem even though the seller may also offer the two items at a single price”)).

<sup>144</sup> See *supra* text accompanying note 134.

<sup>145</sup> *Masimo Corp.*, 2006 U.S. Dist. LEXIS 29977, at \*3.

<sup>146</sup> See *id.* at \*16, \*19, \*33.

<sup>147</sup> See *id.* at \*37 (unpublished opinion from the Central District of California disagreeing with the Third Circuit opinion of *Eli Lilly & Co. v. SmithKline* and another Third Circuit decision related to discounts outside the health care context, *LePage’s Inc. v. 3M*, 324 F.3d 141, (3d Cir. 2003), *cert. denied*, 124 S. Ct. 2932 (June 30, 2004)).

not constitute monopolization without evidence of predatory pricing—that is, pricing below cost—or tying.

Thus, antitrust decisions on single-drug and bundled discounts in the health care industry are few and far between, with much of that language unpublished or in dicta from forty years ago. Even if the language were precedential, the pharmaceutical industry distribution system forty years ago was a pale shadow of the world we live in today. In the modern context, volume discounts in both bundled and single-drug settings are being deployed on a vastly more sophisticated and dangerous scale, given the incentive structures and information asymmetries in the PBM market.

### 5. *The Effects of Bundled Rebates*

The system certainly provides strange results, some of which are beginning to leak into public view. For example, a 2017 article in the *New York Times* reported on insurance plans that punished patients for filling prescriptions with the generic version, rather than the brand.<sup>148</sup> One patient learned that using the generic version of Adderall would cost her family \$50 more per month; another found that his plan would not cover the generic version of Adderall at all, with the result that he had to pay \$90 a month in co-payments when he normally paid \$10 or less a month for his generic medications. Tactics such as these have helped Adderall keep twenty-nine percent of the market share, when the average market share for brands after one year of generic competition is far less.<sup>149</sup> Similarly, pharmacists were informed at the end of 2017 that some Medicare prescription drug plans (with formularies designed by the CVS Caremark PBM) would cover only brand-name versions of twelve drugs, some of which have generic competitors on the market.<sup>150</sup> These reimbursement decisions led one physician to describe the pattern as “Alice-in-Wonderland time in the drug world.”<sup>151</sup>

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<sup>148</sup> Charles Ornstein & Katie Thomas, *Take the Generic, Patients are Told. Until They Are Not.*, N.Y. TIMES (Aug. 6, 2017), <https://www.nytimes.com/2017/08/06/health/prescription-drugs-brand-name-generic.html?mtrref=undefined> [https://perma.cc/U4JU-4P3X].

<sup>149</sup> See *id.* Henry Grabowski, Genia Long & Richard Mortimer, *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. MED. ECON. 1, 6, 7 (2013); Andreas J. Dirnagl & Myrvet A. Cocoli, *Global Generic Pharmaceutical Industry Review: Corporate Research*, BANK OF TOKYO-MITSUBISHI 11 (2016), <https://www.krungsri.com/bank/getmedia/a5599675-701b-49d8-a857-33d247c773a0/BTMU-Research-201602-29.aspx> [https://perma.cc/VT6Z-PYBS]; ASS'N FOR ACCESSIBLE MED., *Generic Drug Access & Savings in the U.S.*, ASS'N FOR ACCESSIBLE MED. 16 (2017) <https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf> [https://perma.cc/87WZ-WPLG].

<sup>150</sup> Ornstein and Thomas, *supra* note 148.

<sup>151</sup> *Id.* In an example from medical care, rather than medicines, the FTC entered into a consent agreement in 2017 with a group of ophthalmologists in Puerto Rico. The complaint alleged that collusion by the physician group had forced a health plan and network administrator to abandon plans for a new lower-cost network. See *generally*, Cooperativa de Médicos Oftalmólogos de Puerto Rico, No. C-4603 F.T.C. (2017), [https://www.ftc.gov/system/files/documents/cases/170303c4603\\_cooperativa\\_order.pdf](https://www.ftc.gov/system/files/documents/cases/170303c4603_cooperativa_order.pdf) [https://perma.cc/2XQR-6ECW]; Press Release, Fed. Trade Comm'n, Puerto Rico Ophthalmologist Group Settles FTC Charges that Members Agreed to An Illegal Boycott of Health Plan (Jan. 19, 2017), <https://www.ftc.gov/>

Moreover, an empirical study by this author documented widespread formulary discrepancies that disadvantage generic drugs in favor of brand drugs.<sup>152</sup> For example, from 2010–2017, the percentage of generic drugs on the most-preferred tier dropped from seventy-three percent to twenty-eight percent.<sup>153</sup> This harms patients, given that a patient’s generic copay triples when moving from the most-preferred tier to the next tier, even though the health plan’s cost for generic drugs on the two tiers remains the same.<sup>154</sup> During the same period, the percentage of drugs placed on inappropriate tiers in relation to drugs with the same active ingredient increased from forty-seven percent to seventy-four percent.<sup>155</sup>

In the same vein, a pair of class action lawsuits filed in 2017 against Walgreens and CVS alleged that the pharmacies charged patients more for purchasing certain generic drugs than they would have had to pay without insurance or if paying cash.<sup>156</sup> The cases alleged violations of Racketeering Influence and Corrupt Organizations Act, fraud, violations of state unfair competition and consumer protection laws, breach of fiduciary duty, and violation of provisions of the patients’ health care plans.<sup>157</sup>

The rebate system for brand drugs can have spillover effects on prices for generic drugs. For example, the pharmaceutical company Valeant drew public fury when it raised the price of its drug Syprine from \$652 in 2010 to \$21,267 in 2015.<sup>158</sup> In February of 2018 the generic company Teva an-

news-events/press-releases/2017/01/puerto-rico-ophthalmologist-group-settles-ftc-charges-  
members [https://perma.cc/KH6H-6NA4].

<sup>152</sup> See Feldman, *supra* note 65.

<sup>153</sup> *Id.* at 30–31.

<sup>154</sup> *Id.* at 31–32; see also 2017 EMPLOYER HEALTH BENEFIT SURVEY, KAISER FAMILY FOUNDATION, (Sept. 19, 2017), <https://www.kff.org/report-section/ehbs-2017-section-9-prescription-drug-benefits/> [https://perma.cc/T87V-EBK5] (documenting average copay on various tiers).

<sup>155</sup> *Id.* at 25.

<sup>156</sup> See Complaint at 2, *Schultz v. CVS Health*, No. 17-00359 (D.R.I., Aug. 07, 2017), ECF No. 1; Complaint at 2, *Grabstald v. Walgreens Boots Alliance, Inc.*, No. 17-05789, (N.D. Ill., Aug. 09, 2017), ECF No.1 (alleging that plaintiffs would have paid less for generic drugs had they paid with cash instead of insurance). These complaints were voluntarily dismissed. Notice of Voluntary Dismissal, *Schultz v. CVS Health*, No. 17-00359 (D.R.I. Aug. 23, 2017), ECF No. 8; Notice of Voluntary Dismissal, *Grabstald v. Walgreens Boots Alliance, Inc.*, No. 17-05789 (N.D. Ill. Sept. 27, 2017), ECF No. 25 (providing notice of plaintiffs’ voluntary dismissals of their cases).

<sup>157</sup> See Press Release, Dep’t of Justice, CVS Caremark Corp. to Pay \$36.7 Million to U.S., 23 States, and D.C. to Settle Medicaid Prescription Drug Fraud Allegations (Mar. 18, 2008), [https://www.justice.gov/archive/usaof/iln/chicago/2008/pr0318\\_01.pdf](https://www.justice.gov/archive/usaof/iln/chicago/2008/pr0318_01.pdf) [https://perma.cc/F6MJ-BSKJ] (announcing that CVS Caremark agreed to pay \$36.7 million to the U.S. government, twenty-three states, and the District of Columbia to settle claims that the company improperly switched patients from the tablet version of the ulcer and stomach acid prescription drug Ranitidine to a more expensive capsule version, in order to increase Medicare reimbursements).

<sup>158</sup> Katie Thomas, *Patients Eagerly Awaited a Generic Drug. Then They Saw the Price.*, N.Y. TIMES (Feb. 23, 2018), [https://www.nytimes.com/2018/02/23/health/valeant-drug-price-syprine.html?emc=edit\\_th\\_180224&nl=todaysheadlines&nid=497896550224](https://www.nytimes.com/2018/02/23/health/valeant-drug-price-syprine.html?emc=edit_th_180224&nl=todaysheadlines&nid=497896550224) [https://perma.cc/D9ZP-KD6K].

nounced that it would sell a generic version of the drug.<sup>159</sup> The joy and optimism that greeted the announcement was dampened, however, when the price for the generic emerged. At \$18,375 for a bottle of 100 pills, the generic is hardly a bargain, and certainly not for a drug that cost \$652 in 2010.<sup>160</sup> The Syprine example shows the way in which the systemic structures that push brand prices higher can create opportunities for soaring generic prices, as well. In other words, the system creates an umbrella effect, sheltering the generics from having to reduce prices too quickly or too steeply.

Some insurers have begun requiring that the PBMs pass through<sup>161</sup> part or all of the rebates they receive from drug companies. While a noble effort, rebate pass through provisions have little power when insurers do not have the right to see the contracts between the drug companies and PBMs. Most important, rebate pass through attempts miss the point. For example, one industry consultant notes even when PBM contracts specify that all or most of rebates must be passed through to the health insurer, the language defines the term “rebate” as amounts attributable to utilization of pharmaceuticals by the health plan, which may be defined to exclude price concessions paid on mail-order and specialty pharmacies, bundled rebates or loyalty payments, and fees not designated as rebates. In short, drug companies can simply shift that money to other types of side payments that the PBM can hold onto.<sup>162</sup> The incentives continue unabated.<sup>163</sup>

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<sup>159</sup> *Teva Announces Launch of Generic Version of Syprine in the United States*, BUS. WIRE (Feb. 9, 2018), <https://www.businesswire.com/news/home/20180209005252/en/> [<https://perma.cc/7TPB-H6CB>].

<sup>160</sup> Thomas, *supra* note 158.

<sup>161</sup> With pass through, the PBM must transmit all of the rebates from drug companies to the health plan, rather than keeping part of the spread. See Ge Bai, Mariana P. Social & Gerard F. Anderson, *Policy Options to Help Self-Insured Employers Improve PBM Contracting Efficiency*, HEALTH AFF. BLOG (May 29, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190529.43197/full/> [<https://perma.cc/K5ST-7K35>]. For an explanation of the current system in contrast, see *supra* text accompanying notes 99–102.

<sup>162</sup> See *infra* note 182 and accompanying text; see also *supra* note 161 (noting that when PBM contracts agree to pass through all or most of the rebates to their clients, the contracts may define rebates to exclude rebates paid with respect to utilization of specialty drugs).

<sup>163</sup> Concerned about the role PBMs may be playing in rising drug spending, a few states recently have tried to absorb the PBM functions themselves. For example, in July of 2017, West Virginia’s Medicaid agency took over for the PBMs, and the state’s Department of Health and Human Resources reports that it saved roughly \$30 million in the first six months. See Ivan Zhykhariev, *Health Care Policy: PBMs’ Medicaid Role Under Attack in Some States*, 6 CAPITOL F. 1, 1–2 (2018), [https://www.ohiopharmacists.org/aws/OPA/pt/sd/news\\_article/152158/\\_PARENT/layout\\_interior\\_details/false](https://www.ohiopharmacists.org/aws/OPA/pt/sd/news_article/152158/_PARENT/layout_interior_details/false) [<https://perma.cc/9L28-Z7NS>]. It would be difficult for states to remove PBMs from their Medicare and Medicaid services entirely, given the myriad of services that PBMs provide at so many levels. Most important, our history casts doubt on the notion that government programs are likely to run more smoothly and efficiently than free-market programs. The challenge involves fixing the perverse incentives and competitive barriers that are distorting the current market system.

## 6. *Why Insurers Allow the PBM Rebate System*

One might ask why insurers would ever agree to such a system. Consider a highly sophisticated and economically powerful private health insurer or self-insured employer. A player with that level of sophistication and buying power, in theory, could demand a different deal from its PBM, including pass through of all rebates and comprehensive files on all claims and rebate checks.

*a. Insurance Company Interest in Maintaining the Status Quo.* However, it may not be in the health plan's immediate economic interests to bargain for these terms.<sup>164</sup> Recent exchanges between the PBM Express Scripts and the U.S. Securities and Exchange Commission demonstrate that PBMs charge a health insurer more if the insurer receives a rebate pass through. In addition, one cannot overestimate the data analysis challenges and the enormous time and resources necessary for health insurers to fully interpret what is happening. Moreover, as described above, volume agreements work so that those who are already in the market and have a higher volume can offer deals that cheaper entrants cannot match. Thus, to the PBM and to the plan, the price may actually be cheaper.

PBMs are also already well ahead of the game when it comes to offering attractive deals to health insurers. A more recent innovation in PBM contraction does not involve rebates at all. Known as "price protection," the PBM promises the insurer that overall prices will rise between two and four percent a year and no more, for example. This approach completely obscures the rebates and other payments from drug companies to the PBMs, allowing these deals to flourish unchecked while appealing to the health insurer's bottom-line interests.

Even if the health insurer had sufficient size and economic power to exert its muscle, it might still be entirely rational to go with the flow. Any individual insurer that tried to buck the system would bear all the burdens of trying to ensure competition in the drug industry, meaning that no one would be willing to move alone. And of course, antitrust law frowns deeply on the collusion among insurance competitors that might produce joint action. Companies could rationally conclude that responding to the clear, short-term benefit is a better opportunity.

*b. Long- and Short-Term Costs.* The long-term versus short-term problem is magnified by the pressures created for a public company of satisfying annual and quarterly expectations for shareholders and market analysts.<sup>165</sup> For both public and private companies, year-end or quarterly bonuses, designed to incentivize performance, may create pressure on con-

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<sup>164</sup> See Eric R. Slusser, Exec. Vice President and Chief Fin. Officer to Sec. & Exch. Comm'n (June 26, 2017) (on file with author) (noting PBM Express Scripts finds that some clients prefer to keep a greater percentage of rebates).

<sup>165</sup> See Nitzan Shilon, *Putting Directors' Money Where Their Mouths Are: A New Approach to Improving Corporate Takeover Dynamics*, 2017 COLUM. BUS. L. REV. 511, 584.

tracting departments and company executives to favor short-term over long-term interests, in order to secure their bonus payments.<sup>166</sup> Next year or next quarter, someone else could have replaced them in the job or the bonus structure could have changed. Thus, the value of collecting a bonus today increases. The burden of the long-term cost is diffused, given that they will be borne by competitors unable to enter and compete. Any remaining long-term cost is difficult to perceive, measure, and respond to in the short term. The pressures of the short term, combined with the diffusion of the long-term costs, drown out any long-term considerations.

*c. PBM Market Concentration and Insurance Companies.* Concentration in the PBM market also makes it difficult for insurance companies to push back. When the PBM big three offer some of the same key terms—including refusing to give auditors access to drug company contracts—a health insurance company’s options are limited. Insurers may even inadvertently support the system, by sending letters to patients warning them that the drug they are on is not covered or not preferred. From the insurer’s perspective, that is perfectly reasonable information to share with the patient,<sup>167</sup> even if the preferred drug has a lower cash price or if the effects of the insurer’s formulary will be to reduce competition in a supplier’s industry.

Some larger employers and insurers are beginning to push back by forming their own, internal PBMs. These include employers such as Berkshire Hathaway and J.P. Morgan and insurers such as Anthem and the Kaiser HMO system. To the extent this route proves effective across time, however, the approach of forming one’s own PBM would be available only for large players. In addition, if large players form their own PBM, the incentives still might continue unabated. Drug companies could shift from sharing monopoly rents with PBM middle players to sharing those rents with health insurers. The true competition that brings down prices and benefits patients would continue to languish.

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<sup>166</sup> Martin D. Mobley, *Compensation Committee Reports Post-Sarbanes-Oxley: Unimproved Disclosure of Executive Compensation Policies and Practices*, 2005 COLUM. BUS. L. REV. 111, 150, 171–74; cf. Julie Wokaty, *Investors Say Executive Pay Packages at Pharma May Incentivize Drug Pricing Risks*, INTERFAITH CTR. ON CORPORATE RESP. BLOG (Dec. 13, 2017) <http://www.iccr.org/investors-say-executive-pay-packages-pharma-may-incentivize-drug-pricing-risks-0> [https://perma.cc/N5UR-B5HV] (explaining post-shareholder resolution on drug pricing and access with quote from United Auto Workers Retiree Medical Benefits Trust representative that “misaligned incentive pay may encourage executives to sacrifice long-term, organic growth from drug discovery for short-term, ‘quick fix’ strategies that may pose business risks”).

<sup>167</sup> In some cases, written notice of certain formulary changes is mandated by state law. See, e.g., TEX. INS. CODE ANN. § 1369.0541(a)(3) (2011); N.M. STAT. ANN. § 59A-22-49.4 (2019) (Texas and New Mexico state laws mandating that insurers provide to affected parties sixty-days’ advance written notice if a drug is removed or loses preferred classification on a formulary).

### 7. Summary of the PBM Rebate System

As described above, rising prices are largely cost free to the drug company.<sup>168</sup> The drug company can return the extra amount collected with the price increase to the PBMs in the form of side payments and rebates, while maintaining or increasing the same drug sales revenue.<sup>169</sup> As my mother always told me, however, if it looks too good to be true, it is too good to be true. Thus, if price increases are cost free for a drug company, then who is paying the bill? At the head of the line are the employers. Insurance companies pass the increased price of medications to the employers in the form of more expensive health insurance. Next in line are the individual patients. As described above,<sup>170</sup> many people pay the full list price at some point, and some patients pay the full list price all the time. Individual patients also pay in the form of higher rates for purchasing the insurance in the first place, as portions of the increased costs are passed down to them. Government programs, and the citizens whose taxes provide the funding for those programs, also pay in terms of the need to provide social and charitable programs when individuals become impoverished by medical costs. Society's greatest cost, however, is the reduction of competition among drug substitutes. Rising prices help drug companies secure advantageous positions on the formularies and block generic and new entrants from gaining much of a foothold. The system also reinforces the dominant position of larger drug companies and larger PBMs. The overall reduction in competition redounds to the great detriment of a society that depends on open and vigorous competition.

In short, it is the perfect lose-lose for patients. Manufacturers raise the price, the consumer pays the higher price, the extra goes to the PBM, and in exchange, the PBM creates competition-free zones for the drug company's drug.<sup>171</sup> In the short term, the patient pays more in the form of higher prices; in the long term, the patient pays more in the form of fewer competitors to offer lower-priced drugs.

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<sup>168</sup> Price rises may impose costs on the drug company in terms of reputation, and drug companies are certainly taking a beating in the press for high prices. In addition, a health insurance plan does have to pay the reimbursement at the time of the sale, before any rebate might be gained. In reaction, the plan could push its PBM to put the drug on a less desirable tier, thereby affecting utilization.

<sup>169</sup> In other words, the drug company maintains the same revenue from the PBM and increases revenue overall by pulling in higher prices from those who are paying without a rebate, such as patients who have not reached their deductibles, cannot obtain insurance coverage for the medication, or have no drug coverage at all.

<sup>170</sup> See *supra* notes 56–59.

<sup>171</sup> Cf. FELDMAN & FRONDORF, *supra* note 8, at 35–36 (describing how pay-for-delay deals between brand and generic hopefuls allow drug companies to use regulatory incentives for first-filing generic companies to extend competition-free zones, with consumers paying the price).



## B. *Why Pharmacies May Prefer Higher Prices*

Pharmacies also play a key role in the drug supply chain, as the point-of-sale contact for patients. The pharmacist collects the insurance reimbursement payment and the patient's copay or co-insurance amount,<sup>172</sup> and this may be the first time patients see how much they must contribute to a particular drug's cost.

### 1. *Pharmacies and Drug Companies*

However, large pharmacies, such as substantial retail pharmacy chains, may also receive side payments from drug companies.<sup>173</sup> These can include payments for monitoring data or providing other information to the drug company. If those payments are based on a percentage of total revenue or unit volume flow, these can provide incentives for the pharmacy to prefer a drug company with greater market share or with the most expensive drug. To the extent any of these payments are ever based on drug price, that would also create a bias towards higher prices.

In addition, higher-volume drug companies, who sell to more patients, drive more patients to a pharmacy—patients who may buy non-prescription items offered at the pharmacy.<sup>174</sup> Once again, the pharmacy's interests may lie in arrangements favorable to the large-volume drug companies that hold greater market share, and unfavorable to newer players, such as generics entering the market.

### 2. *How Laws Incentivize Higher Pharmacy Prices*

In theory, pharmacists should inform patients about lower-priced alternatives. This is particularly important when the calculations for co-insurance or copayments are complex, and a patient might be better off paying for the drug on a cash basis, rather than paying a high copay out of pocket. Unfortunately, both contract law and state dispensing laws get in the way of providing information to the patient. Until recently, some PBM contracts with pharmacies contained gag rules that prevented pharmacists from volunteering or even providing the cash price to the patient.<sup>175</sup> Although Congress

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<sup>172</sup> As described below, the patient's contribution may be reduced by coupons or cards supplied by the drug company to the patient.

<sup>173</sup> See Milt Freudenheim, *And You Thought a Prescription Was Private*, N.Y. TIMES (Aug. 8, 2009), <https://www.nytimes.com/2009/08/09/business/09privacy.html> [<https://perma.cc/P669-YQEX>] (showing that pharmacies selling patient data to drug manufacturers is legal even in the face of recently enacted privacy laws).

<sup>174</sup> See *supra* note 22 and accompanying text. In theory, a patient's ability to buy other items in the household budget basket would be constrained when costs increase for medicine. Although that concept is not entirely irrelevant in health care, health care markets do not behave in a manner analogous to ordinary markets.

<sup>175</sup> See RICHARD CAUCHI, NAT'L CONF. OF STATE LEGISLATURES, PROHIBITING PBM "GAG CLAUSES" THAT RESTRICT PHARMACISTS FROM DISCLOSING PRICE OPTIONS: RECENT STATE

passed an anti-gag-clause provision that was signed into law in 2018,<sup>176</sup> pharmacists still can provide information only if they have it and are motivated to share it with the patient.

In addition, many dispensing laws allow pharmacists to substitute the precise generic for the brand, but they do not allow substitution within the same class of drugs—that is, the laws do not allow substitution among drugs that treat the same disease and provide similar results but are not specified as the FDA-approved generic for that precise version of the brand.<sup>177</sup> Nor do they allow pharmacists to substitute a generic unless that generic is related to the brand drug for which the prescription is written. Thus, drug companies can develop a new version of the drug, with a different timing, dosage, or delivery system. The new version will be protected by new patents, such that the generic may have to wait more than a decade before offering the new version. In that case, the pharmacist cannot suggest that the patient go with the older generic version, even though the price may be much lower for something that is essentially the same.<sup>178</sup>

### 3. Specialty Pharmacies

Specialty pharmacies are those that generally deal only with costly or complex treatments.<sup>179</sup> For specialty pharmacies, the incentives for higher prices may be even stronger. Some specialty pharmacies handle only a single drug. In that case, the pharmacists would never have the incentive, or

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LEGISLATION 2016-2018, (2018) (describing these rules as “restrictions that mean a pharmacist is prohibited by a contract with a PBM from *informing consumers* that the drug they want to buy . . . could be purchased at a lower cost if the consumers paid out of pocket rather than purchasing through their insurance plan.”) (emphasis added); Robert Pear, *Why Your Pharmacist Can't Tell You That \$20 Prescription Could Only Cost \$8*, N.Y. TIMES (Feb. 24, 2018), <https://www.nytimes.com/2018/02/24/us/politics/pharmacy-benefit-managers-gag-clauses.html> [<https://perma.cc/X9BL-82FY>] (quoting Thomas E. Menighan, the chief executive of the American Pharmacist Association: “the pharmacist cannot volunteer the fact that a medicine is less expensive if you pay the cash price and we don’t run it through your health plan”); *see also id.* (describing how multiple states enacted laws to “make sure pharmacists can inform patients about less costly ways to obtain their medicines”); Paige Pelton, *Some Pharmacists Barred from Helping Patients Save Money*, ACTION NEWS JAX (Feb. 22, 2018), <https://www.actionnewsjax.com/news/local/some-pharmacists-barred-from-helping-patients-save-money/705277162/> [<https://perma.cc/RTX8-4727>] (describing that contracts may prohibit pharmacies from telling patients about savings when paying in cash).

<sup>176</sup> *See Patient Right to Know Drug Prices Act*, Pub. L. No. 115–263, 132 Stat. 3672 (2018).

<sup>177</sup> *See* FELDMAN & FRONDORF, *supra* note 8 (discussing technique of filing for patents on minor modifications in dosage or delivery system of a drug and encouraging doctors to prescribe the new formula so that pharmacists cannot substitute the generic, which will have been approved only for the prior dosage or delivery system).

<sup>178</sup> *See* FELDMAN & FRONDORF, *supra* note 8, at 69–71 (describing product hopping); *see also* Feldman, *supra* note 8, at 597 (showing an empirical study concluding that on average seventy-eight percent of drugs associated with new patents in the FDA’s records were for existing drugs as opposed to new ones).

<sup>179</sup> *See* FELDMAN & FRONDORF, *supra* note 8, at 86; *see also* Jennifer Hagerman et al., *Specialty Pharmacy: A Unique and Growing Industry*, 2013 PHARMACY TODAY 39, 39.

even the opportunity, to substitute a generic version.<sup>180</sup> Specialty pharmacies also have been used by drug companies as part of strategies to prevent generic hopefuls from getting the samples necessary to gain FDA approval. In this strategy, the brand company supplies its drug only through specialty pharmacies and declines permission to sell to potential generic competitors.<sup>181</sup>

Finally, specialty pharmacies can provide easy opportunities for drug companies to provide additional side payments, in a manner that can help buttress the drug's market position. For example, in 2015, Novartis paid \$390 million to settle a case with the U.S. Attorney in the Southern District of New York related to its drugs Exjade and Myfortic, drugs related to side effects from blood transfusions and organ transplants, respectively.<sup>182</sup> The case alleged that Novartis gave rebate deals to specialty pharmacies in return for recommending the two drugs, as well as creating incentives and pressure on doctors to prescribe Exjade. The case alleged violation of anti-kickback statutes and the False Claims Act.<sup>183</sup> Such drug company payments to a pharmacy can distort the pharmacy's incentives, leading to undesirable results for consumers.

Other opportunities exist for drug companies to provide payments directly to specialty pharmacies. In particular, the FDA has been increasingly approving drugs on the condition that the company provide additional information about safety and efficacy over time.<sup>184</sup> These approvals are in re-

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<sup>180</sup> Carrier, Levidow & Kesselheim, *supra* note 114, at 1381 (noting that Daraprim was sold to a network of specialty pharmacies through an exclusive deal with Walgreens); Andrew Pollack, *Drug Makers Sidestep Barriers on Pricing*, N.Y. TIMES (Oct. 19, 2015), <https://www.nytimes.com/2015/10/20/business/drug-makers-sidestep-barriers-on-pricing.html> [<https://perma.cc/BP9B-6PWA>] (reporting that some patients were directed by doctors to specialty pharmacies carrying Horizon-manufactured Duexis, a combination of Motrin and Pepcid costing about \$1,500 a month).

<sup>181</sup> See FELDMAN & FRONDORF, *supra* note 8, at 85–86.

<sup>182</sup> See Press Release, Dep't of Justice U.S. Attorney's Office, Manhattan U.S. Attorney Announces \$370 Million Civil Fraud Settlement Against Novartis Pharmaceuticals for Kickback Scheme Involving High-Priced Prescription Drugs, Along with \$20 Million Forfeiture of Proceeds from the Scheme (Nov. 20, 2015), <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis> [<https://perma.cc/M7ZG-3GJQ>].

<sup>183</sup> See *id.*; see also John George, *AmerisourceBergen-owned Specialty Pharmacy to Pay \$13.4M to Settle Kickback Allegations*, PHILA. BUS. J. (Aug. 24, 2017), <https://www.bizjournals.com/philadelphia/news/2017/08/24/amerisourcebergen-pharmacy-bioservices-exjade.html> [<https://perma.cc/U35K-YL4H>] (noting that the specialty pharmacy involved paid \$13.4 million in the settlement).

<sup>184</sup> See, e.g., Food and Drug Association Safety and Innovation Act of 2012, Pub. L. No. 112-144, 126 Stat. 993 (allowing the FDA to base accelerated approvals for certain drugs on markers that indicate the drug is "reasonably likely to predict clinical benefit"); John Carroll, *FDA floats new rules for testing Alzheimer's drugs*, SCIENCE (Feb. 16, 2018), <http://www.sciencemag.org/news/2018/02/fda-floats-new-rules-testing-alzheimers-drugs> [<https://perma.cc/WRH3-T5GX>] (remarking that the FDA's draft guidelines effectively suggest an accelerated approval pathway for Alzheimer's drugs if they can indicate the drug is working); see also Caroline Chen and James Paton, *The FDA is Approving Drugs at a Staggering Pace*, BLOOMBERG (Oct. 6, 2017), <https://www.bloomberg.com/news/articles/2017-10-06/flurry-of-drug-approvals-has-wall-street-eyeing-pharma-profits> [<https://perma.cc/T6Q2-NFXX>] (noting how

sponse to pressure on the FDA to get drugs out to market more quickly. These FDA requirements provide an incentive for the company to track its drugs closely, which in turn provides an avenue for conferring tracking payments to any type of pharmacy. It may also allow drug companies to limit the distribution networks, even when such limited distribution is not required by the FDA. If such payments are volume-based or not in proportion to the pharmacy's services, the structure again reinforces market position and erects barriers to entry.

#### 4. *Concerns of PBMs Merging with Pharmacies*

The greatest concerns, however, exist when PBMs purchase or run their own pharmacies, which magnifies the anticompetitive opportunities. First, a PBM has much greater power to direct patient buying practices than pharmacies, given that the PBM designs the formulary, which dictates how much a patient will have to pay for a given drug. The PBM's power to direct patients can combine with incentive distortions in the pharmacy space. These distortions are especially problematic when the PBM also owns a specialty pharmacy that shares monopoly rents with a drug company, particularly a current market leader or large-volume drug company.<sup>185</sup> In addition, when formularies require that patients purchase their specialty medicines from the PBM's own pharmacy, the PBM's incentives and control systems are perfectly aligned in favor of the drug company that can offer the highest level of persuasion payments. One interest group report asserted that certain PBMs write their contracts so that specialty drugs must be filled at their own pharmacies and then reclassify drugs as specialty to drive traffic there.<sup>186</sup> Given the lack of a consistent definition of specialty drugs, such a tactic certainly would be possible.

Consider the May 2016 class action filed in the wake of a contract dispute between the health insurance company Anthem and the PBM Express Scripts. In 2009, the PBM purchased a smaller PBM that was owned by Anthem. Details of the complex deal, which involved a 10-year agreement for the PBM to administer Anthem's prescriptions, emerged when the

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the FDA's recent high rates of drug approvals are tied to 2012 legislation widening the use of accelerated approvals).

<sup>185</sup> See *supra* notes 114–34 (describing incentives for PBMs to favor a company's drug, particularly with market leaders and large volume drug companies); see also EXPRESS SCRIPTS, *supra* note 35, at 13 (explaining that with their specialty pharmacies, they purchase directly from the pharmaceutical companies and wholesalers).

<sup>186</sup> Unions Report, *supra* note 89, at 6. The report also cites a pharmacists' advocate explaining that pharmacists observed the Caremark PBM referring to refrigerated injectable medications as specialty drugs so that they would have to be filled exclusively by the PBM's pharmacy, despite the fact that all state pharmacies are required to have refrigeration, and classified high-cost oral oncology drugs as specialty medication, although they do not require special care of administration. In contrast, the PBM does not classify inexpensive drugs such as the Coumadin blood thinner as specialty, although the drug requires monitoring. See *id.* at 7.

parties entered litigation over the terms of the contract in March 2016.<sup>187</sup> The class action alleges that the companies breached their fiduciary duties to patients by negotiating that the Express Scripts PBM would pay less to purchase the smaller PBM company in exchange for getting to charge patients above competitive market price for prescription drugs.<sup>188</sup> In other words, Anthem got more money out of the sale, while patients would have to pay more over time.

The PBM also could give preference to its own retail pharmacy, restricting patients' access to drugs and preventing independent drugstores from competing for new customers. One Caremark plan, for example, restricts patients from getting 90-day supplies of a drug from any pharmacy other than Caremark's own CVS pharmacies.<sup>189</sup> If a PBM uses its formulary power to drive patients towards its own retail pharmacies, the group can also benefit in the form of ancillary purchases, such as tissues, soap, or over-the-counter medications, that the patient may make once in the store.<sup>190</sup> As one commentator noted, regardless of whether the dominant company in the combined pair is the PBM or the pharmacy, the combination provides incentives for the PBM to steer patients to its own pharmacies, rather than contracting with as many pharmacies as possible to provide maximum location, convenience and care for its patients, tying its products together to some degree.<sup>191</sup>

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<sup>187</sup> Anthem, Inc. v. Express Scripts, Inc., No. 16-CV-02048, 2017 WL 1134765 (S.D.N.Y. Mar. 23, 2016).

<sup>188</sup> See Second Amended Complaint ¶ 26, *In re Express Scripts/Anthem ERISA Litig.*, 285 F. Supp. 3d 665 (S.D.N.Y. 2018) (No. 16-3399).

<sup>189</sup> See *Prescription Benefits FAQ*, CVS CAREMARK CORP., <https://www.nhsd.org/cms/lib/PA01001961/Centricity/Domain/65/Prescription%20FAQs%204.1.2016.pdf> [<https://perma.cc/8B9E-YL9D>] (“CVS Pharmacy is the only retail pharmacy that can provide . . . a 90-day supply” of a prescription for Caremark plan members in the Maintenance Choice program).

<sup>190</sup> See Unions Report, *supra* note 89, at 2–3; CVS CAREMARK CORP., 2008 ANALYST/INVESTOR MEETING TRANSCRIPT, STATEMENT OF HELENA FOULKES 7 (2008) (on file with author) (CVS Caremark executive discussing how CVS Caremark planned to issue 10 million ExtraCare promotional benefits cards to patients enrolled in prescription benefits plans); see also *The CVS Caremark ExtraCare Health Card*, CVS CAREMARK CORP. (2008), [https://www.caremark.com/portal/asset/fsa\\_thp.pdf](https://www.caremark.com/portal/asset/fsa_thp.pdf) [<https://perma.cc/EZJ7-TRZS>] (CVS Caremark providing discounts on certain CVS-brand items such as allergy and cold remedies, first aid materials, and oral hygiene products for holders of their ExtraCare Health card); Press Release, CVS/Pharmacy Expands ExtraCare Program with New Pharmacy and Health Rewards (Feb. 4, 2013), <https://cvshhealth.com/newsroom/press-releases/cvspharmacy-expands-extracare-program-new-pharmacy-health-rewards> [<https://perma.cc/XSJ8-C736>] (announcing a program wherein customers can earn “free CVS money” for in-store items as a reward for filling a certain number of prescriptions at CVS/Pharmacy).

<sup>191</sup> See *FTC Closes Antitrust and Unfair Competition Investigation of CVS Caremark Post-merger Marketing Practices*, AKIN GUMP STRAUSS HAUER & FELD LLP (Jan. 19, 2012), <https://www.akingump.com/en/news-insights/ftc-closes-antitrust-and-unfair-competition-investigation-of-cvs-caremark-post-merger.html> [<https://perma.cc/M8T7-B255>] (noting that under some PBM contracts, members are automatically enrolled in CVS Caremark's ExtraCare loyalty program, which may serve the purpose of driving consumers to CVS pharmacies instead of others).

Finally, the information that a PBM can gain from owning a general or specialty pharmacy—particularly about patient usage and patient behaviors—increases the information asymmetries that put their insurance clients at a disadvantage.<sup>192</sup> In short, when PBMs own pharmacies, the originally intended structure, in which the PBM is responsible for negotiating the best bargain on drug prices, becomes so tilted that patients' interests are bound to suffer.

Consider the example of one PBM and the drug Zyprexa, which is prescribed for psychiatric conditions including schizophrenia and bipolar disorder. Documents unsealed in a lawsuit filed by health insurance plans show that CVS Caremark, a combined PBM and pharmacy, offered to send a letter to 120,000 doctors touting the benefits of Zyprexa.<sup>193</sup> One might imagine that the claims information would allow the PBM to target physicians who had prescribed Zyprexa or any competing drugs. The text of the proposed letter appears in court documents, along with internal documents from the maker of Zyprexa, noting "the first wave of results from the most recent [PBM] physician mailings."<sup>194</sup>

The letter has the feel of being designed to dance right up to the edge of legality without stepping over, although the later court complaint suggests the letter may have tripped past the line anyway. The language is carefully worded to appear to be simply providing useful information as a health plan intermediary, noting that "Caremark manages the prescription drug benefit plan for one or more of your patients," and "we are pleased to provide you the enclosed information . . . to review at your convenience."<sup>195</sup> The letter goes on to tout the benefits of Zyprexa and to downplay recent reports of side effects.<sup>196</sup>

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<sup>192</sup> See, e.g., EXPRESS SCRIPTS, *supra* note 35, at 10–11 (touting its information flow and explaining that "[o]ur claims processing system also generates a database of drug utilization information that can be accessed at the time a prescription is dispensed, on a retrospective basis to analyze utilization trends and prescribing patterns for more intensive management of the drug benefit, and on a prospective basis to help support pharmacists in drug therapy management decisions").

<sup>193</sup> Complaint at 23–39, *Sergeant Benevolent Assoc. Health & Welfare Fund v. Eli Lilly Co.*, No. 06-CV-06322 (E.D.N.Y. 2006). One press report, using quotations that could not be confirmed with the nonredacted court material, contained alleged quotes from internal documents that the letter would target doctors based on "the most recent . . . claims data," and the campaign was "designed to influence key prescribers" to assist in a "tactical plan for Zyprexa." FirstWord Pharma, *CVS Unit Played Both Sides, \$6.8 Billion Lilly Lawsuit Reveals*, FIRSTWORD PHARMA (June 12, 2009), <http://www.firstwordpharma.com/node/367134?tsid=17#axzz59SxEvJjt> [<https://perma.cc/TU6J-5HF2>]; see also Unions Report, *supra* note 89, at 4; cf. EXPRESS SCRIPTS, *supra* note 35, at 9 (noting that "[o]ur physician connectivity program facilitates well-informed prescribing by delivering benefit and formulary evaluations and medication history, both electronically and in real-time, as physicians write prescriptions).

<sup>194</sup> See Complaint at 23–39, *Sergeant Benevolent Assoc.*

<sup>195</sup> See *id.*

<sup>196</sup> See *id.*

The tone of the letter is one of gentle, subtle persuasion rather than heavy-handed argument.<sup>197</sup> At the end of the day, however, the PBM's combination with one of the largest pharmacies in the country gave it the ability to mine data to push a particular drug over competitors.<sup>198</sup> The potential power of such arrangements gives drug companies the opportunities to advance their sales agendas in a manner that will appeal to the PBM's incentive structures and harm competition. Such arrangements also highlight the dangers of PBM mergers with pharmaceutical companies, particularly in highly concentrated PBM and pharmacy markets.<sup>199</sup>

In 2005, shortly after the rise of the PBM industry, Congress directed the FTC to investigate whether conflicts of interest or "self-dealing" might arise if PBMs owned mail-order pharmacies. Concerns included that such integration might lead to a failure to substitute and dispense generics or the possibility of replacing generics with more expensive drugs.<sup>200</sup> The FTC's report, however, concluded that these allegations were without merit, examining the potential anticompetitive effects of PBMs owning mail-order pharmacies.<sup>201</sup> Despite the report's conclusions, the increased vertical and horizontal concentration in the PBM industry over the last fifteen years and anecdotal evidence suggest that an updated analysis of this and other aspects of the industry would be warranted.

Thus, perverse incentives can lead pharmacies to prefer brand drugs over generics, regardless of the higher brand prices. The problems can increase when retail or specialty pharmacies combine with PBMs, given that the entities negotiating drug price and volume are also selling to individual customers and advising on which drug to choose.

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<sup>197</sup> See John Russell, *Lilly Pays CVS Caremark to Try to Get Doctors to Prescribe Cymbalta*, INDIANAPOLIS STAR (Oct. 18, 2009) <https://indystar.newspapers.com/image/126786606/?terms=22lilly%2Bpays%2Bcvs%22> [<https://perma.cc/P5XX-RLYF>] (describing letters mailed by CVS to physicians promoting Eli Lilly's antidepressant Cymbalta and designed to look like international mailings).

<sup>198</sup> The case also alleged that the maker of Zyprexa pushed the drug for off-label uses for the treatment of dementia, when the company's internal research showed that the drug did not counteract dementia. See Second Amended Complaint ¶¶ 54–57, *In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488 (E.D.N.Y. 2006); Noel Brinkerhoff, *Eli Lilly Pushed Useless Drug for Dementia*, ALLGOV (June 15, 2009), <http://www.allgov.com/news/controversies/eli-lilly-pushed-useless-drug-for-dementia?news=839025> [<https://perma.cc/Z2C4-HPG7>]. Doctors are permitted to prescribe off-label uses for drugs, and recent court cases have affirmed that drug companies have the right to advertise those uses. See *United States v. Caronia*, 703 F.3d 149, 168 (2d Cir. 2012); Robin Feldman & Connie Wang, *May Your Drug Price Be Ever Green* 60 (UC Hastings Research Paper No. 256, Oct. 29, 2017).

<sup>199</sup> See, e.g., Complaint at 48–50, *Boss v. CVS Health Corp.*, No. 3:17-cv-01823 (D.N.J. 2017) (alleging that Sanofi, Norvo Nordisk, and Eli Lilly engaged in an insulin price fixing scheme); see also Jacklyn Wille, *Sanofi, CVS, Others Accused of Insulin Price Fixing*, BLOOMBERG LAW (Mar. 20, 2017, 5:48 PM), <https://news.bloomberglaw.com/corporate-law/sanofi-cvs-health-others-accused-of-insulin-price-fixing> [<https://perma.cc/A2LA-5KST>] (describing collusion between drug manufacturers and PBMs that led to *Boss v. CVS*).

<sup>200</sup> See FED. TRADE COMM'N 2005 REPORT, *supra* note 73, at vi.

<sup>201</sup> See *id.*

### C. Why Insurers May be Pushed Towards Higher-Priced Drugs

In theory, insurers should not prefer higher prices. Although there are a limited number of major players in the health insurance market, the market is less concentrated than the PBM market, with the top ten companies controlling just over half of the market.<sup>202</sup> Higher prices can translate into higher premiums, which makes it more difficult to attract patient enrollees. Counterintuitively, insurers, in some cases, do prefer higher prices for drugs because of certain aspects of the health care market incentive structure.

Odd aspects of this structure do dilute the effects of price increases, as well as create some circumstances in which it is actually better for the health insurance company when prices are higher. For example, consider the strange case of the Medicare system. Medicare health insurance plans may have incentives in certain circumstances for higher drug prices for two reasons, both stemming from provisions in the Affordable Care Act.<sup>203</sup> First, once a Medicare patient reaches the out-of-pocket threshold, the government picks up 80% of the remaining cost through its reinsurance, rather than the health plan paying the full, remaining cost.<sup>204</sup> Thus, higher drug prices push Medicare patients more quickly into the territory in which the government picks up a greater portion of the tab and the health insurance company administering the plan pays less.

Second, Medicare makes the health insurance company allocate the rebate dollars they receive from pharmaceutical companies back to the government's reinsurance plan. However, the formulas operate in a way that when most of the rebates are for higher-priced drugs, the health insurer actually pays less, the government's reinsurance obligations rise, and the patient pays more.<sup>205</sup> As one government report noted, a Medicare health insurance plan's decision to place higher priced drugs on its formulary rather than lower priced ones, "may be a rational response to the incentives they face."<sup>206</sup>

In short, in some cases, patients will be able to move past the uncovered gap more quickly, and the health insurance plan will have more dollars that could be spent on lowering premiums for all patients, when the Medicare patient utilizes a higher priced, non-generic drug. The problem, of course, is the long-term risk to competition from generics. As with other incentive structures discussed throughout this Article, this is counterproductive.

Finally, health insurers do have a path of least resistance. Although it may not be optimal, the insurance company can always choose to shift costs to the patients, by increasing copays and co-insurance. That has, indeed,

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<sup>202</sup> Sood, Goldman & Van Nuys, *supra* note 1, at 32.

<sup>203</sup> Adam J. Barnhart & Jason Gomberg, *The AIDS Institute: Financial Incentives in Medicare Part D*, MILLIMAN 1, 6 (2016).

<sup>204</sup> MEDPAC 2017 REPORT, *supra* note 21, at 404.

<sup>205</sup> *Id.*

<sup>206</sup> *Id.*



happened in recent years.<sup>207</sup> Thus, perverse incentives can push against a health insurer's motivation to drive patients into cheaper drugs.

#### D. Doctors, Hospitals, and Other Medical Practitioners

For some doctors, hospitals, and other medical practitioners, the incentive structures may be similar to those for PBMs. Medical practitioners or organizations that provide medications directly to patients may be open to a variation of the persuasion payments given to PBMs. For example, doctors may be offered payments in the form of what are called "key opinion leader" payments or lesser forms of benefits such as wining and dining. For some hospitals, drug companies can offer medication rebates.<sup>208</sup> In turn, the treatment facility charges patients the list price, or even some rebate off the list price, and pockets the spread. In this way, drug companies can raise the list price of the drug and offer a larger rebate, thereby maintaining revenue while offering enticing payments. A drug company may condition the rebates on volume or exclusivity in that setting in the same manner as with PBMs. A hospital may even believe that it is getting a good deal for its patients, obtaining a rebate for them by guaranteeing volume across the full patient load. As described with the PBM payments above,<sup>209</sup> however, the patient pays in the form of reduced competition in the long run, as well as higher prices when the facility does not pass the rebate through. These opportunities can occur when hospitals and medical practitioners provide in-house infusions or other treatments, particularly for certain forms of cancer, as well as for medications during surgery or hospitalization.

The courts, however, have not necessarily been sympathetic to competitors complaining about these types of activities under antitrust law. In 2016, the Third Circuit affirmed dismissal of a case against Sanofi, regarding rebates to hospitals for its anticoagulant drug Lovenox.<sup>210</sup> The plaintiff alleged that the threat of not obtaining these rebates effectively "handcuffed" hospitals, forcing them to choose Lovenox over the competitor's product, which had different but overlapping indications.<sup>211</sup> The circuit court, however, saw only a reasonable marketing effort and ruled that "[t]o the extent that Sanofi's conduct caused damage to its competitors, that is not a harm for which Congress has prescribed a remedy." Ultimately, however, the court found there was "no evidence that Sanofi's actions caused broad harm to the competitive nature" of the market.<sup>212</sup> Thus, the decision sends a signal to firms and regulators, providing a tacit blessing to continue the behaviors.

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<sup>207</sup> See *supra* notes 205–06 and accompanying text.

<sup>208</sup> See the previous section's description of how Novartis created incentives and pressures for doctors to prescribe Exjade. See *supra* note 183 and accompanying text.

<sup>209</sup> See *supra* notes 136–59 and accompanying text.

<sup>210</sup> See *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 400 (3d Cir. 2016).

<sup>211</sup> *Id.* at 407.

<sup>212</sup> *Id.* at 399, 407.

A particularly troubling issue arises with what are known as 340B hospitals. Section 340B of the federal Public Health Service Act (PHSA) provides that certain nonprofit hospitals that serve the nation's most vulnerable patients receive large rebates on drugs used in outpatient treatment, which are thought to be used for indigent care.<sup>213</sup> Drug companies provide these rebates up front, as discounts off the list price, and the rebates may amount to as much as a 50% deduction off list price.<sup>214</sup> Medicare then reimburses these physician-administered drugs at a much higher rate,<sup>215</sup> 6% above the average list prices. The relevant hospitals receive those rebates even for those patients who have private insurance. Private plans generally reimburse for those drugs at rates even higher than Medicare, further increasing the spread.

In theory, the amounts are intended to help those hospitals in their work for low-income or vulnerable patients, but the law does not require any showing that the funds are actually used in that manner. Some government sources and commentators have questioned whether the spread simply increases hospitals' bottom lines and market shares.<sup>216</sup> More than 42,000 entities participate in the 340B program.<sup>217</sup> Whenever spread exists, the economics create incentives for rising prices and agreements that entrench large drug companies and disfavor lower-cost or newer entrants.

### *E. Patients and Patient Advocacy Groups*

Looking first at patients, drug manufacturers increasingly provide coupons or coupon cards to patients, in order to encourage them to purchase what might otherwise be an expensive drug. In this manner, drug companies can appeal directly to the patient's wallet. With a coupon or coupon cards, the brand company agrees to pay all or a significant portion of the patient's out-of-pocket costs. While lower out-of-pocket costs sound appealing, they actually drive demand down for lower-priced alternatives, reinforcing the

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<sup>213</sup> See Public Health Service Act § 340B, 42 U.S.C. § 256 (2018); NAS REPORT, *supra* note 5, at 105–06.

<sup>214</sup> See Lynn Kennedy & Helen Gao, *Inside Rx: Discounts Available for Insulin and Other Diabetes Medications*, DIATRIBE (May 16, 2017), <https://diatribe.org/inside-rx-discounts-available-insulin-and-other-diabetes-medications> [https://perma.cc/SP7F-XZE6]. Drug companies are not required by the Act to provide these price concessions up front, but it has become the practice to do so.

<sup>215</sup> These are physician-administered drugs, which are covered under Medicare Part B.

<sup>216</sup> See Casey Ross, *Trump takes on hospitals: the facts behind fight over 340B drug discounts*, STAT (2017), <https://www.statnews.com/2017/11/06/340b-drug-discounts-fight/> [https://perma.cc/W3M8-BLW5].

<sup>217</sup> See H. ENERGY & COMMERCE COMM., REVIEW OF THE 340B DRUG PRICING PROGRAM 13 (2018), [https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review\\_of\\_the\\_340B\\_Drug\\_Pricing\\_Program.pdf](https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf) [https://perma.cc/99A4-M2JC]; see generally Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities*, 33 HEALTH AFF. 1786 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4591849/> [https://perma.cc/B793-K3MN].

incentives for more expensive drugs, which, in turn, drives costs higher throughout the system.

Red flags for the behavior include that the copayment offsets are almost always offered by brand drugs—primarily when competition exists from generics or other brands—and that the benefits are normally directed at patients who have prescription drug insurance plans.<sup>218</sup> Beyond blocking lower-cost competition, this practice distorts the economic effects as well. For example, the cost of reimbursing the patient's copay is much less than the full cost difference between the branded drug and the generic. Thus, although the patient pays little, the insurance company bears a far higher cost.<sup>219</sup> In addition, when the patient's cost goes to zero, drug companies can encourage over-consumption of the drug,<sup>220</sup> for example when patients stockpile drugs that they do not need, allow automatic refills for drugs they may not be using, or have less incentive to ask doctors if the drugs are still necessary.

Coupons are increasing as a common feature of the drug landscape. Between 2007 and 2010, spending on brand drugs that offer coupons grew from 30% to over 50% as a percentage of spending on all brand drugs,<sup>221</sup> and the strategy seems to have conferred considerable benefit on drug companies. Studies suggest that copay coupons increase brand drug sales by 60%, mostly by reducing sales to generic competitors, as well as by increasing drug costs for all enrollees in prescription drug plans.<sup>222</sup> The blockbuster arena of cholesterol-lowering drugs provides an example of the coupon practice. In 2012, only three medications made up more than 75% of the statin market, with the two brand drug companies widely distributing copay coupons.<sup>223</sup> When the first generic competitor entered the market, the maker of the brand drug Lipitor engaged in an aggressive coupon strategy to maintain market share, until additional generics were finally able to enter the market.<sup>224</sup> Presumably, the strategy helped preserve market share and revenue as long as possible, until the presence of multiple generics made the strategy too expensive and difficult to maintain.

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<sup>218</sup> NAS REPORT, *supra* note 5, at 93–94. One should note that coupons are not available for government insurance because they would be considered a form of kick-back.

<sup>219</sup> See Morton & Boller, *supra* note 1, at 27.

<sup>220</sup> See *id.* at 26.

<sup>221</sup> Leemore Dafny, Christopher Ody & Matthew Schmitt, *When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization*, 9 AM. ECON. J. ECON. POLICY 91, 94 fig. 1 (2017) (noting that this measure does not capture actual coupon use, given that not all buyers use or are eligible to use coupons).

<sup>222</sup> *Id.*; see also Joseph S. Ross & Aaron S. Kesselheim, *Prescription Drug-Coupons – No Such Thing as a Free Lunch*, 369 N. ENG. J. MED. 1188, 1188–89 (2013).

<sup>223</sup> David Grande, *The Cost of Drug Coupons*, 307 JAMA 2375, 2375 (2012); see also Dafny, Ody & Schmitt, *supra* note 221, at 120 n.41 (noting that “copay coupons for Lipitor may have resulted in loss of share for generic statins”).

<sup>224</sup> FELDMAN & FRONDORF, *supra* note 8, at 22 (describing Hatch-Waxman's so-called “Paragraph IV” provision in which the first generic in some circumstances receives a six-month period in which no other generics may enter the market, as an incentive to do battle with the branded drug).

Although the goal in many circumstances is to find the least costly alternative for the patient, strategies like this can encourage the highest-priced drug, driving demand away from lower-cost drug substitutes. In the process, companies can purchase brand loyalty, along with the volume that provides a platform for the PBM strategies described above.

Beyond coupons, drug companies have provided meals, gifts, or other payments to patients so that the patients will advocate for the use of a particular brand with other patients. For example, the *New York Times* reported that hemophilia drug manufacturers and specialty pharmacies, whose products cost between \$30,000 to a few hundred thousand dollars annually per patient, have taken to courting patients and their relatives with free meals and hiring opportunities to gain inside access in selling their drugs. The companies' attempts to attract the business of individuals with costly treatments by hiring them have blurred the lines between patient and drug salesperson, creating ethical dilemmas in the community.<sup>225</sup> The practice has a happy side effect as well. If patients begin to complain too loudly, the drug company can pay them off in a manner that reduces public relations friction, while shifting the costs to insurers.<sup>226</sup> And, as always, the long-term burdens fall on society in the form of reduced competition and higher health care costs overall.

Patient advocacy groups are another way in which drug companies can influence market behavior. Ostensibly, these groups are formed by patients who have a particular disease in order to advocate for policies and practices in the interests of those patients. These organizations are not required to disclose their funding sources, however, and research shows that the majority of patient advocacy groups receive significant support from drug and device companies.<sup>227</sup> In order to maintain their funding levels, such groups may directly or indirectly advocate for policies that push drug prices higher.

Funding patient assistance programs and patient advocacy groups have additional financial advantages, including tax credits for the drug company. In particular, drug companies can donate their drugs to their own foundation or to independent charitable organizations that support the purchase of the company's drugs, earning charitable deductions in the process.<sup>228</sup> In fact,

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<sup>225</sup> See Andrew Pollack, *Hemophilia Patient or Drug Seller? Dual Role Creates Ethical Quandary*, N.Y. TIMES (Jan. 13, 2016), <https://www.nytimes.com/2016/01/14/business/hemophilia-patient-or-drug-seller-dual-role-creates-ethical-quandary.html> [<https://perma.cc/NN53-ZAGU>]; see also Philip Kucab, Katelyn Dow Stepanyan & Adriane Fugh-Berman, *Direct-to-Consumer Marketing to People with Hemophilia*, 13 PUB. LIBR. OF SCI. MED. 1 (2016); Morton & Boller, *supra* note 1, at 3 (noting that brands may offer kickbacks in the form of coupons, financial assistance, free meals, patient care and other benefits to avoid moving demand to lower-priced alternatives).

<sup>226</sup> See Thomas, *supra* note 158.

<sup>227</sup> NAS REPORT, *supra* note 5, at 94 (citing Matthew S. McCoy et al., *Conflicts of Interest for Patient-Advocacy Organizations*, 376 NEW ENG. J. MED. 880–85 (2017)).

<sup>228</sup> See Austin Frerick, *The Cloak of Social Responsibility: Pharmaceutical Corporate Charity*, 153 TAX NOTES 1151, 1151–64 (2016); see also Morton & Boller, *supra* note 1, at 27–28 (discussing the implications of the Frerick paper).

such patient assistance programs constituted ten of the fifteen largest charitable foundations in the United States as of 2014.<sup>229</sup>

Donations such as these are particularly valuable deductions because under a tax code provision, the company gets a deduction above the cost of the drug.<sup>230</sup> Brand drugs are generally inexpensive to make, with the bulk of expenditures coming from the research and development and the approval processes.<sup>231</sup> A special enhanced-deduction provision allows drug companies to deduct not simply the cost basis of the inventory they donate, but the basis *plus* half the difference between that and the fair market value, up to twice the basis.<sup>232</sup> In other words, the provision gives the company an enhanced deduction for the appreciation in the value of the product. This tax provision makes the donations unusually valuable, and the higher the list price, the greater the benefit to the company—at least until the company reaches the cap.

#### F. The Full Landscape

In short, despite a health care system that relies on competition to ensure the quality of care and reduce prices, the system contains precisely the opposite incentives. Nearly all of the parties along the drug supply chain—including PBMs as well as certain types of pharmacies, insurers, doctors, hospitals, and public interest patient groups—do better when prices rise.<sup>233</sup> In particular, woven throughout all the Article's sections above are the incentives for the drug companies themselves. The system allows drug companies to use some of their monopoly rents to entrench their market shares and to share those rents with each segment along the drug distribution continuum.

With consumer spending on the rise and frustration mounting, everyone points fingers at others in the system.<sup>234</sup> And as one commentator noted

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<sup>229</sup> Morton & Boller, *supra* note 1, at 29 (citing Frerick, *supra* note 228).

<sup>230</sup> See 26 U.S.C. § 170(e)(3) (2018); 26 C.F.R. § 1.170A-1 (2019) (tax provisions detailing the enhanced deduction, where a deduction on donated drug inventory will equal the cost of the drug plus half of the difference between the list price and the cost); see also Morton & Boller, *supra* note 1, at 29 (describing the history of the enhanced deduction, including that Congress first restricted corporate deductions of “income property” to the donor’s cost and then eased that restriction as a means of incentivizing the donation of medical supplies rather than disposing of them); ROGER COLINVAUX, ENFORCING THE ENHANCED CHARITABLE DEDUCTION, URBAN INST. CTR. ON NONPROFITS AND PHILANTHROPY AT URBAN-BROOKINGS TAX POLICY CTR. 1 (2012), <https://www.urban.org/sites/default/files/publication/23211/412727-Enforcing-the-Enhanced-Charitable-Deduction-Improved-Reporting-on-the-Form-.PDF> [<https://perma.cc/UTY5-FDN5>].

<sup>231</sup> Morton & Boller, *supra* note 1, at 29 (noting that pharmaceuticals have a low marginal cost).

<sup>232</sup> See *id.*

<sup>233</sup> These groups are not necessarily monolithic, nor do they all benefit. For example, smaller and rural pharmacies may not benefit, and the same may be true of employers who self-insure.

<sup>234</sup> See, e.g., Robert Langreth & Rebecca Spalding, *Gilead Executive Says Pharmacy Benefit Managers Keep Prices High*, BLOOMBERG (Mar. 3, 2017, 4:13 PM), <https://www.bloomberg.com/news/articles/2017-03-03/gilead-executive-says-pharmacy-benefit-managers-keep->

dryly, insurers, drug companies, and PBMs would do better for investors if they “just kept quiet to preserve their very profitable relationship.”<sup>235</sup>

To some extent, they are all correct, although greater blame may lie with some players than others. In particular, although much anger is focused on PBMs, they are merely responding to the rent-sharing opportunities placed in front of them. The core problem lies with the distorted incentive structures. If society fails to fix this, we can add ourselves to the list of those to blame.

#### IV. ALIGNING INCENTIVES

##### A. *What Won't Work*

Interestingly, some of the pharmaceutical industry's pledges and fixes may be of limited value, and in some cases counterproductive. Consider the controversial pledge some drug companies have entered into regarding keeping the rise in list prices below 10%. On the one hand, that is certainly better than an increase above 10%. On the other hand, it provides cover for increasing prices to that level, and discourages anything below it. Unfortunately, companies get absolutely no benefit from increasing only 7–8%, for example, and they could get hammered by shareholders and capital markets for going much lower than 10%. Thus, 10% helps to set a floor for price increases in addition to a ceiling.

Another proposal for taming drug prices that is gaining popularity from drug companies and some commentators is called value-based pricing or a version of that called outcomes-based pricing. For example, in discussing the industry's support for value-based pricing, the executive vice president of the pharmaceutical industry association made the following comments about when new breakthrough drugs will come to market:

[W]ill it have a big price tag? It might. If we really are moving toward a value-based health care system, then medicines that truly represent value should merit a larger price, and we're comfortable with saying that should be the case.<sup>236</sup>

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prices-high [https://perma.cc/JX3F-8PY9] (Gilead executive pointing to PBMs and saying “[i]f we just lowered the cost of Sovaldi from \$85,000 to \$50,000, every payer would rip up our contract”); see also Eric Sagonowsky, *Lilly CEO: With Pharma Friends in High Places, It's 'Time for Action' to Ease Drug Costs*, FIERCEPHARMA (Jan. 10, 2018, 7:33 AM), <https://www.fiercepharma.com/pharma/lilly-ceo-says-pharma-hasn-t-done-enough-pricing-but-now-time> [https://perma.cc/26WX-J3VR].

<sup>235</sup> Charley Grant, *The Blame Game on Drug Prices is Getting Dangerous*, WALL STREET J. (Apr. 9, 2017, 1:27 PM) <https://www.wsj.com/articles/the-blame-game-on-drug-prices-is-getting-dangerous-1491758834> [https://perma.cc/AN2F-N5N2].

<sup>236</sup> Dylan Scott, *Drug Makers and Insurers, Longtime Rivals, Eye an Alliance on Prices*, STAT (2015), <https://www.statnews.com/2015/11/24/drug-prices-health-insurers/> [https://perma.cc/WNE3-88RY]; see also Sagonowsky, *supra* note 234.

The basic notion of value-based pricing is that drug companies should be compensated based on the value that they provide with their drug treatments. A key problem, as the National Academies of Science concluded, lies with the question of how to determine when and the extent to which intervention with a particular drug has been of value.<sup>237</sup> This is particularly true given that the scientific field lacks a straightforward method of even determining what would count as evidence of value.<sup>238</sup>

A version of value-based pricing would look at outcomes. In this particular strain, drug companies would provide a drug, and the payer would receive a rebate if the drug failed to save a patient's life, provide a cure, or work as expected.<sup>239</sup> For example, Novartis is testing this approach with an

<sup>237</sup> See NAS REPORT, *supra* note 5, at 53–54, 57; see also INST. OF MED., FINDING WHAT WORKS IN HEALTH CARE: STANDARDS FOR SYSTEMATIC REVIEWS 17–18 (Jill Eden et al. eds., 2011) (observing how it is often difficult to assess the quality of systematic research reviews documenting the potential harms and benefits of medical interventions); Matthew J. Page et al., *Bias due to selective inclusion and reporting of outcomes and analyses in systematic reviews of randomized trials of healthcare interventions*, COCHRANE DATABASE SYSTEMIC REV. (2014) (exploring how the choice of which outcomes to report in systematic reviews of health care interventions may result in biased or inaccurate value assessments); INST. OF MED., SHARING CLINICAL TRIAL DATA: MAXIMIZING BENEFITS, MINIMIZING RISKS 17 (2015) (discussing challenges to determining intervention efficacy from clinical trials research, including “lengthy time frame, high cost, and often limited relevance of the research it produces”).

<sup>238</sup> See NAS REPORT, *supra* note 5, at 56–57 (describing how different health organizations determine value or what would constitute evidence of value); see also Jeffrey L. Anderson et al., *ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines*, CIRCULATION 2329–45 (2014) (noting that the ACC-AHA uses a cost-effectiveness framework that measures the treatment's dollar value per quality-adjusted life-year, while factoring in the quality of evidence that treatment is beneficial); Lowell E. Schnipper, *American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options*, 33 J. CLINICAL ONCOLOGY 2563 (2015) (noting that ASCO uses a point-based framework that considers clinical benefit, toxicity, palliation, and increased time off all treatment, but the framework does not integrate the drug's score with cost); INST. FOR CLINICAL & ECON. REVIEW, OVERVIEW OF THE ICER VALUE ASSESSMENT FRAMEWORK AND UPDATE FOR 2017-2019 (2017) (explaining that ICER value framework considers cost-effectiveness, clinical effectiveness, various contextual considerations like ethical/legal issues, and overall budget impact on GDP); Memorial Sloan Kettering Cancer Center, *Drug-Abacus Methods*, <https://drugpricinglab.org/tools/drug-abacus/methods/> [<https://perma.cc/L25H-ZP3W>] (explaining that value framework considers survival, toxicity, novelty, R&D cost, rarity of the treated disease, and the burden of the disease on the U.S. population); Nat'l Comprehensive Cancer Network, *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) with NCCN Evidence Blocks*, <https://www.nccn.org/evidenceblocks/> [<https://perma.cc/2S2J-BPCQ>] (explaining that stakeholders judge value based on overall impression of the following factors: efficacy, safety, evidence quality and consistency, and affordability are taken into account).

<sup>239</sup> See NAS REPORT, *supra* note 5, at 59; see also Jeanne S. Mandelblatt et al., *Evaluating Frameworks that Provide Value Measures for Health Care Interventions*, 20 VALUE IN HEALTH 186, 189–90 (2017) (proposing and applying criteria for evaluation of value frameworks to assess health care treatments); Stephen Barlas, *Health Plans and Drug Companies Dip their Toes into Value-based Pricing: The Pressure is On P&T Committees to Monitor Utilization*, 41 PHARM. & THERAPEUTICS 39, 39–41, 53 (2016) (describing that Amgen agreed to provide two “pay for performance” rebates if its drugs failed to obtain certain results and citing performance-based agreements between drug manufacturers and insurers); Alan M. Garber & Mark B.

expensive drug for treatment of pediatric patients with Acute Lymphoblastic Leukemia.<sup>240</sup> The company will charge for the drug only if patients respond to treatment after one month of therapy.

The pricing and patient care data would be key for monitoring these value-based contracts. Imagine a vertically integrated PBM-Insurer-Pharmacy, which already has an incentive to share data with its rebate-conferring drug company partners. These will be the only entities controlling this essential information, which is necessary for evaluating the drug company's value claims. Such information and data analytic asymmetries will only expand and grow more problematic, making it nearly impossible for payors and government entities to engage in independent auditing.

In addition, putting aside the sticky issue of determining the extent to which a drug "provides value," outcome-based pricing could present serious moral hazards. In simplified form, drug companies are saying in essence, "I will give you my expensive drug. If the patient dies, you either get a rebate or don't pay in the first place." This could create an uncomfortable incentive structure, in which insurers, PBMs, hospitals, and doctors get paid more if the patient dies. Why would one want a system in which the provider does better financially if the patient dies? That is particularly of concern if the drug company's payments are arriving in the form of rebates, rather than in the form of not charging in the first place. Rebates given to a hospital at key times of the year could be distributed to executives and staff or used to improve a hospital's books at the end of a reporting period. Moreover, some of the risks associated with complex diseases, for which many of these outcome-based models are proposed, are not solely attributable to the drug treatment and the structure could have an impact on incentives to provide complimentary care that may be costly or burdensome on a hospital.

The entire notion of valuing medicines based on improvements in people's lives, rather than the cost of making the medication, is out of focus if not downright irrational. As noted above, my own life and comfort may be of incalculable value to me, even when the likelihood of success is low or the additional lifespan provided is minimal. As one commentator explained,

The key question is not: What's it worth to save a child's life. . . If that was the question, the polio (vaccine) they gave me when I was 6 years old would have cost a million dollars. The right question

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McClellan, *Satisfaction Guaranteed — "Payment by Results" for Biologic Agents*, 357 *NEW ENG. J. OF MED.* 1575, 1575–76 (2007) (noting an extreme instance in which Johnson and Johnson offered to waive charges for consumers who did not obtain desired results for one of its drugs).

<sup>240</sup> See Press Release, Novartis, Novartis Receives First Ever FDA Approval for a CAR-T Cell Therapy, Kymriah(TM) (CTL019), for Children and Young Adults with B-Cell ALL that is Refractory or Has Relapsed At Least Twice (Aug. 30, 2017), <https://www.novartis.com/news/media-releases/novartis-receives-first-ever-fda-approval-car-t-cell-therapy-kymriahctl019-children-and-young-adults-b-cell-all-refractory-or-has-relapsed-least-twice> [<https://perma.cc/87LX-HJGG>].



is: What is the price that will maximize accessibility and affordability, while maintaining a robust R&D pipeline.<sup>241</sup>

Of the current methods for aligning incentives for market actors with those of consumers and creating a more rational system, neither price pledges nor value-based pricing do a sufficient job. Pledges effectively create a floor for drug manufacturers to increase prices, while value-based pricing ignores overall constraints on personal and governmental health care. Moreover, neither of these approaches grapples with the root of the incentive problem.

## *B. What Will Work?*

### *1. Market Information*

Markets, like gardens, grow best in the sun. And they wither without information. Thus, when an industry's pricing information and rebate relationships are secret, deeply hidden, or obscured even from payors, one should not be surprised to see significant competitive distortions and suboptimal outcomes. Quite simply, entrants and prospective entrants power the economic engines of competition, and information provides the fuel for those engines.

To begin restoring sanity to pharmaceutical markets, information must flow. That includes transparency about pricing information. All aspects of the deals, including rebates and financial benefits in any form, at a minimum, should be visible to the payers and the government. Governments, however, have limited resources and face numerous demands. In light of these limitations, in the best of all circumstances, the full range of information would be visible to competitors and to the public. In particular, in an open and democratic society, we would be foolish to bypass the power of the press and individual citizens in their ability to ferret out objectionable behavior, especially in the modern age of crowdsourcing and social media. One can understand why industry would not wish to see this, but why would society put shackles around its great twin powers: the free market and an informed citizenry? These are among the core values upon which the United States rests, although certainly not the only ones.

*a. Changes at the Federal Level.* The best opportunities for shining light into the deep, dark crevices of pharmaceutical pricing lie at federal legislative and regulatory levels. Any number of federal laws could be amended to mandate information transparency. This could be done through amendments to the Food & Drug Act, which regulates the manufacture and marketing of all prescription and nonprescription medication. Current FDA marketing authority relates only to providing improper marketing or adver-

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<sup>241</sup> Kelton, *supra* note 31.

tising regarding risks and side effects.<sup>242</sup> That statutory authority could be amended to mandate that the FDA collect and release accurate information on pricing and rebates. Historically, the FDA has been reluctant to engage in competition issues, hewing more closely to their mandate for monitoring safety and efficacy.<sup>243</sup> Thus, Congress might be well-served to specify authority for the FTC<sup>244</sup> to act under its consumer protection powers if companies fail to provide adequate price transparency.<sup>245</sup>

A different approach to transparency could utilize the Employee Retirement Income Security Act (ERISA), which sets standards for pensions and health plans in private industry. Congress could amend ERISA to require transparency within plans.<sup>246</sup> The agencies that administer Medicare and Medicaid could similarly mandate transparency within these programs.<sup>247</sup>

More indirectly, transparency could be accomplished through regulations from the federal agencies that fund pharmaceutical research. Many of the drugs that end up in our medicine cabinets began with federal funding of academic research by agencies such as the National Institutes of Health (NIH). NIH regulations could mandate that those who receive funding must include transparency stipulations for those who license or purchase their in-

<sup>242</sup> See generally *Prescription Drug Advertising: Questions and Answers*, U.S. FOOD AND DRUG ADMINISTRATION, [https://www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers#non\\_requirements](https://www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers#non_requirements) [<https://perma.cc/4PQW-F4RV>].

<sup>243</sup> See, e.g., Robin Feldman, Evan Frondorf, Andrew K. Cordova, & Connie Wang, *Empirical Evidence of Drug Pricing Games—A Citizen’s Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39 (2017) (showing that despite the FDA having “the power to summarily deny any petition it believes was filed with the ‘primary purpose’ of delaying generic approval if the petition also does not ‘on its face raise valid scientific or regulatory issues’” and evidence that a significant number of citizen petitions are filed by drug companies in a last-ditch effort to delay competition, and the fact that the vast majority of citizen petitions are denied, the FDA has yet to summarily dismiss a single citizen petition); see also Michael Carrier, *Five Actions to Stop Citizen Petition Abuse*, 118 COLUM. L. REV. ONLINE 81 (2018); Michael Carrier, *Food and Drug Admin. Comment Letter Addressing Abusive Citizen Petition*, FDA REQUEST FOR COMMENTS ON CITIZEN PETITIONS (Oct. 18, 2018).

<sup>244</sup> Federal Trade Commission Act, 15 U.S.C. § 45(a)(2) (2006) (prohibiting deceptive advertising practices affecting commerce generally); *id.* § 52 (giving the FTC the power to prohibit false advertising regarding over the counter drugs).

<sup>245</sup> See Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1907) (which regulates the manufacture and marketing of all prescription medication); see generally *Prescription Drug Advertising: Questions and Answers*, *supra* note 242 (Congress granted the power to regulate advertising and prohibit false advertising regarding over-the-counter drugs to the FTC, but the power to regulate advertising for prescription drugs to the FDA.).

<sup>246</sup> Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (1974) (setting standards for pensions and health plans in private industry); see also *Gobeille v. Liberty Mutual Ins. Co.*, 136 S. Ct. 936, 943–45 (2016) (outlining the extensive ways in which ERISA can mandate oversights and standards).

<sup>247</sup> See 42 U.S.C. § 1302 (1987) (noting that the Secretary can “make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he or she] is charged”); see also Social Security Act, 42 U.S.C. § 1395hh (2003) (authorizing the Secretary to promulgate “regulations as may be necessary to carry out the administration of the insurance programs”); Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency, 84 Fed. Reg. 20,732 (May 10, 2019) (to be codified at 42 C.F.R. pt. 403).

ventions.<sup>248</sup> Thus, either directly or indirectly, Congress could pave the way for transparency.

*b. Changes at the State Level.* States also have the power to mandate transparency, certainly when the state is an employer, administrator of a program, or other payor, and likely for all health insurance activity within its borders.<sup>249</sup> States also may have the power to mandate particular aspects of information openness through state pharmacy substitution laws, related to substituting generic prescriptions for brands, and other state regulatory processes. In fact, states continue to be at the forefront of battling these difficult issues. States have passed or proposed 178 bills (enacting 44 of them) relating to price transparency, clawbacks, price gouging, gag rules (which keep pharmacists from pointing customers toward the cheapest alternatives), and PBM regulation.<sup>250</sup>

The proposals range from bold to timid, and the pharmaceutical industry is expected to mount fierce opposition to these laws, including filing suit under the basis of trade secret laws, the First Amendment, and various other U.S. Constitutional provisions.<sup>251</sup> Such challenges already have been filed in California, Nevada, Maryland, and North Dakota.<sup>252</sup>

<sup>248</sup> See Robin Feldman et al., *Viral Licensing: Ensuring the Public Interest When Taxpayers Fund Pharmaceutical Research*, 59 SANTA CLARA L. REV. 641, 648 (2020).

<sup>249</sup> Although a discussion of federalism and a state's power is well beyond the scope of this article, for an analysis of these issues in the context of state drug legislation, see generally ROBIN FELDMAN ET AL. NATIONAL ACADEMY FOR STATE HEALTH POLICY, STATES' RIGHTS: A PATENT LAW ANALYSIS OF NASHP RATE-SETTING MODEL ACT 1-10 (2018), <https://nashp.org/wp-content/uploads/2018/03/White-Paper-2018.pdf> [<https://perma.cc/7D2S-M4EE>].

<sup>250</sup> *State Legislative Action to Lower Pharmaceutical Costs*, NAT'L ACAD. FOR STATE HEALTH POLY (Oct. 9, 2018), <https://nashp.org/wp-content/uploads/2018/01/Copy-of-Tracker-Update-All-Legislation-10.9.2018.pdf> [<https://perma.cc/AJW7-4SPR>]; see also Richard Cauchi, *State Remedies for Costly Prescription Drugs*, NAT'L CONF. OF STATE LEGISLATURES (Aug. 2018), [www.ncsl.org/research/health/state-remedies-for-costly-prescription-drugs.aspx](http://www.ncsl.org/research/health/state-remedies-for-costly-prescription-drugs.aspx) [<https://perma.cc/98QG-Z6RF>].

<sup>251</sup> EXPRESS SCRIPTS, *supra* note 35, at 30–31 (listing courts that have turned down their First Amendment requests); Jay Hancock & Shefali Luthra, *As States Target High Drug Prices, Pharma Targets State Lawmakers*, KAISER HEALTH NEWS (Feb. 1, 2018), <https://khn.org/news/as-states-target-high-drug-prices-pharma-targets-state-lawmakers/> [<https://perma.cc/G8BU-G6VV>]; see also EXPRESS SCRIPTS, *supra* note 35, at 31–32 (citing *Jerry Beeman & Pharm. v. Caremark Inc.*, 322 F. Supp. 3d 1027, 1031 (C.D. Cal. 2018)) (noting that upon remand, district courts denied defendants' motion to dismiss the case on first amendment constitutionality grounds of a California law requiring the disclosure of retail drug prices to clients). *But see* 1-800 Contacts, Inc., 2017 WL 1345289 F.T.C. 9372 (2017) (denying defense to horizontal antitrust agreements that the parties were merely protecting their intellectual property).

<sup>252</sup> See *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018) (federal suit in which the Association for Accessible Medicines sued the state of Maryland over a law that would allow the attorney general to monitor drug price changes and seek orders to reverse increases or issue fines); *Pharm. Res. & Mfrs. of Am. v. Brown*, No. 2:17-CV-02573-MCE-KJN, 2018 U.S. Dist. LEXIS 148499 (E.D. Cal. Aug. 28, 2018) (federal suit in which the Pharmaceutical Research and Manufacturers of America sued the state of California over a law requiring pharmaceutical companies to alert insurers of price increases above a certain threshold and of reasoning for the increase at least 60 days before the planned increase); *Pharm. Res. & Mfrs. of Am. v. Sandoval*, No. 2:17-CV-2315-JCM-CWH, 2017 U.S. Dist. LEXIS 149468 (D. Nev. Sep. 14, 2017) (federal suit in which the Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization sued the state of Nevada over an insu-

Some respected academics and government reports also have argued that drug pricing information should be kept secret, on the notion that if drug companies know the true prices their competitors are offering for drugs, the companies will collude to keep prices high.<sup>253</sup> Although well-meaning, those analyses are misguided. To begin with, some of these perspectives are based on a study from the 1990s of bidding in the cement industry in Denmark.<sup>254</sup> It is a limited data point from an industry that has struggled with collusion.<sup>255</sup> Normally, for empirical evidence to support a broad policy, one would want to see broad-based evidence from the industry in question or alternatively, from an extensive range of reasonably comparable industries, and certainly evidence of a more recent vintage.

In general, it is quite odd to suggest that keeping price information secret is good for competition. Rather, when things are secret, any collusion that exists will be extremely difficult to uncover. Moreover, the notion that price information is a recipe for collusion, defies the experience of the nation's free market economy, in which pricing information normally is not hidden from consumers, government entities, and auditors.

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lin pricing transparency law on basis of trade-secret protection); *Pharm. Care Mgmt. Ass'n v. Tuft*, 297 F. Supp. 3d 964 (D.N.D. 2017) (federal suit in which the Pharmaceutical Care Management Association sued the state of North Dakota over a law that would ban gag orders on the basis of trade-secret protection).

<sup>253</sup> See Lao, Feinstein & Lafontaine, Comment Letter, *supra* note 29 (suggesting that requirements for public health plans to publicly disclose pricing and cost information may facilitate collusion); U.S. DEPT OF JUSTICE & FED. TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE 49–51 (1996) (describing an antitrust “safety zone” and stating that without adequate safeguards, an exchange of price or cost data among health care providers can lead to collusion and increased prices); Morton & Boller, *supra* note 1, at 22–23; Leemore Dafny, Northwestern Univ. Professor, Competitive Effects of Price Transparency at 6 (on file with author); Joanna Shepherd, *Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market*, 99 CORNELL L. REV. ONLINE 1, 1–2, 18–20 (2013) (stating that if pharmaceutical manufacturers know details of their competitors' rebate arrangements or price discounts, “tacit collusion among them becomes possible”); NAS REPORT, *supra* note 5, at 63–65 (advocating for true transparency in pricing information and citing arguments in opposition to transparency).

<sup>254</sup> See Shepherd, *supra* note 253, at 19 n.96; Dafny, *supra* note 253, at 7 (citing Svend Albaek, Peter Møllgaard & Per B. Overgaard, *Government-Assisted Oligopoly Coordination? A Concrete Case*, 45 J. OF INDUSTRIAL ECON. 429 (1997)). *But see* David Besanko, David Dranove & Craig Garthwaite, *Insurance and the High Prices of Pharmaceuticals* (Nat'l Bureau of Econ Res., Working Paper No. 22353, 2016), <http://www.nber.org/papers/w22353.pdf> [<https://perma.cc/495E-NEVL>] (economic demand model provides rationale for drug companies setting prices above value and suggesting that problems are worse with smaller drug firms than larger ones, which cannot externalize as many of the costs).

<sup>255</sup> See Ania Thiemann, *Serial Offenders: Why Some Industries Seem Prone to Endemic Collusion*, ORG. FOR ECON. COOPERATION & DEV. 11, 30–31, 53 (2015) (stating that the cement and concrete industry has been frequently investigated for collusive behavior, with some serial offenders having been investigated or sanctioned more than ten times each); *see also* Joseph E. Harrington Jr. et al., *The Discontent Cartel Member and Cartel Collapse: The German Cement Cartel 7–8* (Ctr. for Eur. Econ. Res., Discussion Paper No. 14-084, 2014) (noting that cartel formation in cement markets is common due to economic and market factors that make collusive agreements profitable and stable, in addition to describing a German cartel among six large cement companies in 1991 that lasted several years).

If price information truly is such a dangerous recipe for collusion, the current system is certainly no panacea. As described above, there are numerous ways in which the secrecy helps entrenched players insulate themselves from competition. In addition, drug companies are increasingly including most-favored-nation clauses, in which the PBMs agree to protect the drug companies by guaranteeing them the highest price anyone is willing to pay. Market leaders in a drug and those who offer a range of drug products can offer the volume needed to obtain most-favored-nation clauses provisions, insulating themselves from price competition. This circumstance is enhanced by the secrecy of the deals and that further insulates entrenched players from market competition. Price secrecy may also help maintain the position of dominant players. A subset of large players will be able to discover the prices, with the result that the collusion behavior will be impossible to detect, along with other improper behavior that is occurring. In the end, the players we worry most about may be able to obtain the information, while midsize competitors who are best suited to inject true competition are left in the cold. Finally, if we are truly convinced that drug companies will collude in their bidding with PBMs, one could always mandate that whatever agency oversees release of the information must observe a delayed release. This would alleviate collusion concerns without insisting that information must never see the light of day.

Legislative and regulatory efforts to mandate transparency are likely to run into the claim that price information and pricing terms constitute a trade secret. Pharmaceutical companies and PBMs continue to advance this argument in cases and commentary.<sup>256</sup> The issue has yet to be squarely addressed in the courts, however, and scholars have cast serious doubt on whether such information constitutes a trade secret under either federal or state trade secret law.<sup>257</sup>

*c. The Al Capone Approach.* With bar owners as our image, perhaps we should return to the era of Prohibition and borrow a strategy effective in relation to that era's famous gangster, Al Capone. The Federal Bureau of Investigation (FBI) finally was able to jail Capone not for his many crimes related to bootlegging alcohol, murder, and mayhem, but for tax evasion.<sup>258</sup> In other words, sometimes the indirect approach can be effective when the direct approach may be difficult to accomplish.

For example, mandating transparency certainly is one approach, but other mechanisms might work as well. Consider a recent exchange between Express Scripts (one of the big three PBMs) and the Securities and Ex-

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<sup>256</sup> See Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 YALE J.L. & TECH. 61, 74–79 (2020).

<sup>257</sup> See *id.*; see also Annemarie Bridy, *Trade Secret Prices and High-Tech Devices: How Medical Device Manufacturers are Seeking to Sustain Profits by Propertizing Prices*, 17 TEXAS INTELL. PROP. L.J. 187, 192 (2009).

<sup>258</sup> Fed. Bureau of Inv., *History: Al Capone*, FED. BUREAU OF INVESTIGATION (2018), [www.fbi.gov/history/famous-cases/al-capone](https://perma.cc/A5YU-CNZ8) [https://perma.cc/A5YU-CNZ8].

change Commission (SEC).<sup>259</sup> The series of letters involves the PBM's accounting treatment of various items and the disclosure involved in that treatment. In the exchange, the SEC objects to the fact that Express Scripts does not separately disclose the rebates and other payments it receives from pharmaceutical companies, as well as other detailed information.

Express Scripts may be making a good faith effort to comply with accounting standards, given the unusual timing and funding flows of the industry. Nevertheless, the exchange is a poignant reminder of the SEC's power. If accounting regulations designed and applied to the PBM industry were to require a different level of disclosure, the shadowy world of pricing might find itself in the sunlight.

In its comments to Express Scripts, the SEC conveys surprise that the PBM seems to be treating the money flow from drug companies as though the drug companies were the PBM's customers—when in fact, the health plans are the customers. Here is the SEC's language: "It is unclear why you believe accounts receivable from pharmaceutical manufacturers are a component of customer receivables considering that pharmaceutical manufacturers do not appear to be your customer."<sup>260</sup>

The choice to lump the revenue flow from pharmaceutical companies in with the revenue flow from health plans may simply be sloppy accounting, and Express Scripts readily agrees to separate out the two figures going forward.<sup>261</sup> Nevertheless, Dr. Freud might suggest that there are no accidents: It would be quite easy for a PBM to begin thinking of drug companies as its clients, rather than keeping the interests of health plans and patients in mind.<sup>262</sup>

In particular, financial disclosures such as these highlight the extent to which *nonrebate* revenue from drug companies may constitute a significant part of a PBM's business. In the case of Express Scripts, its 2017 annual

<sup>259</sup> Letter from Eric R. Slusser, Exec. VP & CFO, Express Scripts Holding Co., to U.S. Sec. & Exch. Comm'n, Div. of Corp. Fin. (June 26, 2017) (on file with author); Letter from Joel Parker, Senior Assistant Chief Accountant, Office of Beverages, Apparel & Mining, U.S. Sec. & Exch. Comm'n, Div. of Corp. Fin., to Eric R. Slusser, Exec. VP & CFO, Express Scripts Holding Co. (Aug. 2, 2017) (on file with author); Letter from Bradley Phillips, VP, Controller & Chief Accounting Officer, Express Scripts Holding Co., to U.S. Sec. & Exch. Comm'n, Div. of Corp. Fin. (Aug. 30, 2017) (on file with author); Letter from Joel Parker, Senior Assistant Chief Accountant, Office of Beverages, Apparel & Mining, U.S. Sec. & Exch. Comm'n, to Eric R. Slusser, Exec. VP & CFO, Express Scripts Holding Co. (Sept. 29, 2017) (on file with author); Letter from Bradley Phillips, VP, Controller & Chief Accounting Officer, Express Scripts Holding Co., to U.S. Sec. & Exch. Comm'n, Div. of Corp. Fin. (Oct. 12, 2017) (on file with author).

<sup>260</sup> Letter from Joel Parker, *supra* note 259.

<sup>261</sup> Letter from Bradley Phillips, *supra* note 259.

<sup>262</sup> See Linette Lopez, *The Feds Just Asked a Huge Healthcare Company Who Their Real Clients Are and the Answer Is Totally Unsatisfying*, BUS. INSIDER (Dec. 7, 2017, 4:09 PM), [http://www.akleg.gov/basis/get\\_documents.asp?session=30&docid=42823](http://www.akleg.gov/basis/get_documents.asp?session=30&docid=42823) [https://perma.cc/F82D-TZBM] (citing accounting professor Ed Ketz's comment that "at 40% [of receivables] we can start thinking of the pharmaceutical companies as customers. They're not just bystanders in this equation").

report suggests that nonrebate revenue from drug companies could be up to \$1.4 billion—a significant figure in comparison to Express Script’s \$5.4 billion in operating income.<sup>263</sup>

From society’s perspective, one might hope that the law would channel a PBM into thinking of the good of the patients served by the formularies it is crafting. Attempts to claim that PBMs have a duty to patients have fallen flat, however, running up against issues related to ERISA, the mammoth federal law that governs most health plans and pensions.<sup>264</sup> A different understanding of the role of ERISA could shift the landscape considerably, opening the door to claims that the PBMs are breaching their fiduciary duty to patients.

As an additional alternative to mandating that PBMs and drug companies make their pricing information public, governments might be able to achieve similar results by acting in their capacity as buyers. In this case, the government entities would be borrowing a page from the federal procurement book. For example, companies selling to federal defense agencies must disclose a host of information on pricing in sole bidding circumstances. Until 2013, the statute was known by the memorable acronym TINA (the Truth in Negotiations Act), but it is now saddled with a far less memorable title, the Truthful Cost or Pricing Data Act.<sup>265</sup> Commercial items such as drugs, however, are exempt from this statute.<sup>266</sup>

A state or federal government agency could promulgate a regulation that, in the agency’s capacity as a buyer of health insurance products, requires full pricing information to be provided. Although such an approach would mandate disclosure only when the government is a buyer, the government is indeed a buyer in a wide swath of purchases. In this manner, governments would not have to mandate that drug company-PBM interactions be revealed in all circumstances, yet a wealth of critical information would be revealed. Thus, rather than flatly mandating transparency, the government

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<sup>263</sup> Express Scripts, Annual Report (Form 10-K) (Feb. 27, 2017) (especially no. 13, “Segment information”). That line item would also include management fees that Express Scripts received for administering networks that are reported on a net revenue basis. See Letter from Bradley Phillips, *supra* note 259.

<sup>264</sup> See, e.g., *Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3d 463, 477 (7th Cir. 2007); *In re Express Scripts, Inc., Pharmacy Benefits Mgmt. Litig.*, No. 1672, 2006 U.S. Dist. LEXIS 65168, at \*18 (E.D. Mo., Sept. 13, 2006); *Mulder v. PCS Health Sys., Inc.*, 432 F. Supp. 2d 450, 456–59 (D.N.J. 2006); N.Y. State Teamsters Council Health & Hosp. Fund v. Centrus Pharmacy Solutions, 235 F. Supp. 2d 123, 128 (N.D.N.Y. 2002). For a discussion of these cases, along with the perspective that PBMs should *not* be held to a fiduciary duty under ERISA, see Thomas P. O’Donnell & Mark K. Fendler, *Prescription or Proscription? The General Failure of Attempts to Litigate and Legislate Against PBMs as “Fiduciaries,” and the Role of Market Forces Allowing PBMs to Contain Private-Sector Prescription Drug Prices*, 40 J. HEALTH L. 2 (2007). For a general description of ERISA, see U.S. Dep’t of Labor, *Health Plans and Benefits: ERISA*, <https://www.dol.gov/general/topic/health-plans/erisa> [<https://perma.cc/N7GE-FKR4>].

<sup>265</sup> See 41 U.S.C. §§ 3501–09 (2018); Federal Acquisition Circular 2005–73, 79 Fed. Reg. 24191 (May 29, 2014).

<sup>266</sup> 41 U.S.C. § 3503.

could accomplish much of the same result simply by virtue of its rights as “little old buyer, me.”

In short, when the direct route is not feasible, there are times when an indirect route might get you there as well. In other words, governments might follow the Al Capone example.

## 2. Reduce Concentration and Rethink Markets

*a. The Shape of Markets.* Rising prices and competition concerns raise questions about the level of concentration in various levels of the drug delivery chain. The PBM markets are dominated by three players who hold up to eighty-five percent of the market with commercial insurers; PBMs have merged with large pharmacy chains, along with purchasing specialty pharmacies; and concentration has increased among generic drug manufacturers, in insurance markets, wholesalers, and in local hospital markets, although not to the severe extent seen in the PBM market.<sup>267</sup> In light of these concerns, federal and state competition agencies should tread carefully when it comes to approving merger and purchase requests from major players, either at the same level of the distribution chain horizontally or between players at different levels of the distribution chain vertically.

*b. Market Power and Multiplicity Effects.* In examining the markets themselves, competition agencies would do well to focus on the potential anticompetitive effects possible through the PBM contracting and incentive structures described throughout this article. One does not need market domination in a particular drug to create these effects, and federal market penetration measures may fail to properly capture the effects of those behaviors.<sup>268</sup>

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<sup>267</sup> See *supra* note 91 and accompanying text; see also E.R. Berndt et al., *The Generic Drug User Fee Amendments: An Economic Perspective*, 5 J.L. & BIOSCIENCES 103, 103–41 (2017); see generally M. Aitken et al., *Has the Era of Slow Growth for Prescription Drug Spending Ended?*, 35 HEALTH AFF. 1595 (2016); E.R. Berndt et al., *The Landscape of US Generic Prescription Drug Markets*, NAT'L BUREAU OF ECON. RESEARCH (2017); Mark Dugan et al., *Providing Prescription Drug Coverage to the Elderly: America's Experiment with Medicare Part D*, 22 J. ECON. PERSP. 69 (2011); John Norton, *Media Scrutiny of PBM Corporations Ratchets Up – Part Two*, NCPA'S BLOG – THE DOSE (Apr. 7, 2016), <https://www.ncpanet.org/newsroom/ncpa's-blog—the-dose/2016/04/07/media-scrutiny-of-pbm-corporations-ratchets-up-part-two> [<https://perma.cc/4PG9-UNUB>] (noting that CVS pharmacy owns Caremark PBM; that Rite Aid pharmacy, which Walgreens announced a purchase of in 2016, owns the PBM EnvisionRx; and that Express Scripts PBM owns specialty pharmacies; and several PBMs own smaller pharmacies); Thomas L. Greaney, *Coping with Concentration*, 36 HEALTH AFF. 1564, 1565 (2017); Lisa Ellis, *Snapshot of the American Pharmaceutical Industry*, HARV. SCH. OF PUB. HEALTH (July 14, 2016), <https://www.hsph.harvard.edu/ecpe/snapshot-of-the-american-pharmaceutical-industry/> [<https://perma.cc/H8DG-T2JD>] (noting that a few companies hold the majority of market share in the drug wholesale market in the US).

<sup>268</sup> On the practice of anticompetitive tying, compare *Suburban Mobile Homes v. AMFAC Communities*, 161 Cal. Rptr. 811, 817 (Ct. App. 1980) (“[W]e emphasize that the power over the tying product (here, home sites) can be sufficient even though the power falls short of dominance and even though the power exists only with respect to some buyers in the market.”), with *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 27 (1984) (holding that an entity controlling 30 percent of a market does “not generate the kind of market power that justifies condemnation of tying”).



This is particularly true in the context of deals that exploit volume across multiple drugs. If competition measures focus only on the market power of each individual drug in a company's stable, the power of overall volumes and the multiplicity effects will be overlooked.

The varying ways of exerting power in pharmaceutical markets described in the sections above should be a wake-up call to state and federal regulatory agencies, whose definitions of market power should be updated to take into account multiplicity effects. One can think of multiplicity effects as the combined effects of different tactics or of the same tactic across a range of products. For the purposes of antitrust actions, antitrust authorities will consider actions that create or maintain the power to raise price or restrict supply in a relevant market.<sup>269</sup> From that perspective, the definition of relevant market is key.

During the 1990s era of federal government action against Microsoft, the notion of relevant markets expanded to include the notion of nascent markets.<sup>270</sup> Specifically, antitrust authorities recognized that an existing company might exert power, not just to threaten competitors in a current market, but to prevent the creation of new markets that might threaten its dominance.<sup>271</sup> In other words, measuring only existing markets allows actions that can strangle the baby in its cradle, before a new technological or splinter market ever struggles to its feet. Those are tremendously important advances, but in light of modern multiplicity effects, they are not enough.

This is not the first time that multiplicity effects in markets have stymied antitrust concerns. In the context of patent trolling, courts and antitrust authorities do not have the tools for combatting the potential to affect prices in one market by targeting companies across that market with a large portfolio of patents that will be too expensive to fight off, even if most of the patents are unrelated to that market and many of them are weak.

In a similar vein, one cannot fully measure the potential competitive impact of agreements related to a particular drug and its substitutes without looking at the full range of drugs and markets that might be leveraged through that activity. In short, modern markets require development of mul-

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<sup>269</sup> See Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) (“[I]n defining relevant market to be used in determining whether monopolization is present, Commission is not bound to follow antitrust standards as strictly as courts must under Sherman and Clayton Acts; ultimate objective of any criteria used is to delineate markets which conform to areas of effective competition and to realities of competitive practice.”)

<sup>270</sup> See *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (stating anticompetitive conduct may be inferred when exclusionary conduct is aimed at producers of both nascent and established competitive technologies).

<sup>271</sup> See *id.* (“[I]t would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will—particularly in industries marked by rapid technological advance and frequent paradigm shifts.”); see also Findings of Fact, *United States v. Microsoft Corp.*, No. 98-1232, 97 F. Supp. 2d 59 (D.D.C. 2000) at ¶ 60 (noting that Microsoft recognizes nascent paradigms that could oust its position as a primary platform for applications development and user interface, especially in a market characterized by rapid and dynamic shifts).

tiplicity analyses that allow antitrust authorities to understand and measure ripple effects, along with the complex effects of volume and bundling.

Competition agencies may also need to be sensitive to the potential for hub-and-spokes structures, which can be understood, in general, as the following. Market competitors may not get together on price or other terms. In a hub-and-spokes arrangement, middle parties can create the mechanism for collusion among the competitors, enforcing agreements that have the effect of maintaining price controls or blocking other, lower-priced competitors from access that would harm the market power of the group. The middle player is the hub, which connects all of the competitors arrayed around it on spokes.

A cutting-edge area of concern within the consultant sphere is the potential for collusion established through artificial intelligence (AI) programs. Without AI, human analysts are likely to reach differing conclusions about the precise behavior that would lead to optimal results—at least if there is no collusion. Suppose, however, that AI programs have the ability to cycle through the behavioral options in a complex, layered manner that consistently reaches approximately the same results. Different entities could have perfectly coordinated efforts, while pointing to the AI to say, “The computer made me do it.” How would one prove collusive intent in a circumstance like that? The challenges of AI for planning behavior will require creative rethinking of antitrust doctrines.

Finally, from a competition standpoint, the most interesting change on the horizon may be arising within the market itself. Amazon, Berkshire Hathaway, and J.P. Morgan have formed a new venture to disrupt the PBM and pharmaceutical distribution system. Using their own businesses as a lab, the trio hopes to develop ways of delivering health care to the more than one million employees of their companies in a way that reduces the high prices, administrative costs, and waste of the current system. When giants walk, the earth trembles. The Amazon/Berkshire Hathaway/J.P. Morgan venture is a market solution that has fascinating potential, assuming that the government regulations favoring entrenched players do not get in the way.

Such horizontal collusion is at the core of forbidden behavior under antitrust laws. Although that may not be the case with the drug industry, when prices are rising dramatically and middle players hold significant sway, one would want to observe carefully.

c. *The Federal Trade Commission’s Expanded Investigative Authority Under Section 6(b)*. The powerful investigative authority under Federal Trade Commission Act Section 6(b) could aid the design of any regulatory or legislative change and help clarify changing market conditions.<sup>272</sup> The FTC has longstanding authority to conduct broad economic studies and to

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<sup>272</sup> See Morton & Boller, *supra* note 1, at 38.

issue reports and legislative recommendations based on findings.<sup>273</sup> A particularly valuable component of this authority is provided in § 6(b) of the FTC Act, which allows the commission to demand reports and other information from entities “whose business affects commerce.”<sup>274</sup> This section provides additional weight to the FTC’s investigative powers, allowing the agency to compel the disclosure of reports and other information under oath.<sup>275</sup> The FTC has exercised this clout with varying frequency, and the expansive breadth of this authority has been repeatedly confirmed by courts.<sup>276</sup>

Considering the current circumstances of the drug pricing scheme, where pharmaceutical manufacturers and PBMs negotiate private deals shrouded in secrecy, the commission’s authority to compel the production of valuable reports, accurate market data, and information is particularly advantageous.<sup>277</sup> Specifically, the language of § 6(b) grants the FTC a mandate to extract “answers in writing to specific questions, furnishing to the commission such information as it may require”—this creates room for access to secret negotiations potentially so confidential that they were never formally recorded.<sup>278</sup> As evidenced by historic examples described below, there is a substantial amount of progress that can be achieved through these investigations.

<sup>273</sup> See OFFICE OF POLICY PLANNING, FED. TRADE COMM’N, HISTORY OF SECTION 6 REPORT – WRITING AT THE FEDERAL TRADE COMMISSION, 6 (Apr. 1981) [hereinafter FTC HISTORY OF SECTION 6 REPORT], <https://www.ftc.gov/sites/default/files/documents/reports/history-section-6-report-writing-federal-trade-commission/231984.pdf> [<https://perma.cc/C3N5-DD2Z>] (describing the FTC’s “investigatory and publicity powers” dating back to its establishment in 1914); see also Robin Feldman, *Intellectual Property Wrongs*, 18 STAN. J.L. BUS. & FIN. 250, 313 (2013).

<sup>274</sup> 15 U.S.C. § 46(b) (2018). While Congress also has investigative authority and has examined pharmaceutical pricing in the past, the FTC may be better suited for the task both because of internal competition expertise and because of its relative insulation to the effects of lobbying. See Michael D. Bopp & Delisa Lay, *The Availability of Common Law Privileges for Witnesses in Congressional Investigations*, 35 HARV. J.L. & PUB. POL’Y 897, 905 (2012) (noting “Congress’s broad investigative authority”); see also STAFF OF S. COMM. ON FINANCE, 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM, 106–10 (Comm. Print 2015) (investigating the dramatic increase in prices for the commonly used Hepatitis C drug, Sovaldi).

<sup>275</sup> 15 U.S.C. § 46(b).

<sup>276</sup> See, e.g., *United States v. Morton Salt Co.*, 338 U.S. 632, 651 (1950) (recognizing “the authority of the Commission under § 6 to require special reports of corporations”); *Appeal of FTC Line of Business Report Litigation*, *Deering Milliken, Inc. v. Fed. Trade Comm’n*, 595 F.2d 685, 703 (D.C. Cir. 1978) (offering a broad interpretation of the “relevance” element of an FTC request for information); *F.T.C. v. Texaco, Inc.*, 555 F.2d 862, 883 (D.C. Cir. 1977) (describing the FTC’s authority to “compel production of evidence ‘from any place in the United States, at any designated place of hearing’” and removing an “unwarranted” travel and expense burden on the Commission).

<sup>277</sup> See *supra* note 269 and accompanying text; 15 U.S.C. § 46(b) (noting the FTC’s authority to “require” that entities “whose business affects commerce” provide “to the commission such information as it may require”). Regarding the question of whether such information might be protected by trade secret, see text accompanying note 257 (explaining that academics have cast doubt whether price and price term information constitute trade secrets under state and federal law).

<sup>278</sup> 15 U.S.C. § 46(b) (2018).

Although rare, past FTC studies and reports resulting from § 6(b) investigations have not only increased transparency but have also prompted new legislation.<sup>279</sup> An early FTC Task Force even remarked that the agency's investigations were likely to have had "the most substantial impact and enduring value" of all its endeavors.<sup>280</sup> For example, in 1977, the FTC used data obtained directly from drug manufacturers to begin an impactful investigation of prescription drugs because "public source material was inadequate."<sup>281</sup> The commission also concluded that trademarked brand names created the basis for monopoly power and had the potential to extend market power beyond the life of an existing patent's protections.<sup>282</sup> In addition, the FTC determined that state laws prohibiting the substitution of pharmaceutical products for prescribed trademarked products were barriers to competition.<sup>283</sup> The FTC's resulting report was used to comment on draft legislation in the pharmaceutical industry<sup>284</sup> and provided support for a model law that would help generate savings to consumers of a maximum range of \$400 million to \$500 million annually in favorable market conditions, and that was adopted almost verbatim in Maryland.<sup>285</sup> Finally, the FTC's study indirectly contributed to the Supreme Court decision that overturned a state statute's limits against revealing and advertising retail drug prices.<sup>286</sup>

The FTC voted to initiate another extensive § 6(b) investigation into the economic activities of approximately 25 non-practicing entities (NPEs) in 2013.<sup>287</sup> NPEs are entities whose primary activity and business model entails licensing and litigating patents as opposed to creating products.<sup>288</sup> Growing prevalence of this lucrative business model brought increased public attention to the practice of patent trolling and consequently prompted responses on the federal and state levels as well as in legislative, regulatory, and common law arenas.<sup>289</sup> The FTC's § 6(b) action served as one of several regulatory actions, along with White House-issued report and executive orders on

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<sup>279</sup> See FTC HISTORY OF SECTION 6 REPORT, *supra* note 273, at 2–7.

<sup>280</sup> See *id.* at 2 (citing Stanley E. Boyle, *Economic Reports and the Federal Trade Comm'n: 50 Years' Experience*, 24 FED. BAR J. 489, 493 (1964) (quoting FEDERAL TRADE COMM'N, TASK FORCE REPORT ON REGULATORY COMM'N, app. N, at 127 (1949))).

<sup>281</sup> See *id.* at 63.

<sup>282</sup> See *id.*

<sup>283</sup> See *id.* at 64.

<sup>284</sup> See *id.* (citing the FDA Drug Regulation and Reform Act as an example).

<sup>285</sup> See *id.* at 64 n.189.

<sup>286</sup> See *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 758–62, 770–72 (1976).

<sup>287</sup> See *FTC Seeks to Examine Patent Assertion Entities and Their Impact on Innovation, Competition*, FED. TRADE COMM'N (Sept. 27, 2013), <https://www.ftc.gov/news-events/press-releases/2013/09/ftc-seeks-examine-patent-assertion-entities-their-impact> [<https://perma.cc/EH5Z-FJ6Z>].

<sup>288</sup> Robin Feldman, *The Pace of Change: Non-practicing Entities and the Shifting Legal Landscape*, 18 CHAP. L. REV. 635, 636 (2015).

<sup>289</sup> See *id.* at 637, 642–43 (citing Robin Feldman, Tom Ewing & Sara Jeruss, *The AIA 500 Expanded: The Effects of Patent Monetization Entities*, UCLA J.L. & TECH. 1, 58 (Fall 2013)) (noting that "of the top ten most frequent filers of patent litigation, all ten were non-practicing entities).

patent assertion, the U.S. Patent and Trademark Office's response to the executive orders,<sup>290</sup> and a workshop hosted by the FTC and the Department of Justice examining the antitrust implications of NPEs in December 2012.<sup>291</sup> Furthermore, § 6(b) authority was used as a tool to collect more complete information for a potential policy response to patent assertion activities at a critical moment: when cost-benefit analysis of the NPE business model was limited at best and suspicion about its potentially adverse impacts on consumers was steadily increasing.<sup>292</sup> The FTC was able to use this information to propose recommendations for legislative and judicial reform to maximize productive business behavior and minimize the effects of nuisance infringement litigation.<sup>293</sup>

These examples suggest the great influence that FTC investigations can have on future legislation.<sup>294</sup> Beyond this potential, there are other upsides to an FTC investigation—most notably increased transparency. An FTC investigation into these secret transactions would increase the amount of information available for players besides Congress; academics, payors, and even consumers would benefit greatly from accessibility to this information.<sup>295</sup> Other scholars supported FTC efforts imposing this authority to scrutinize the pharmaceutical industry in an effort to mitigate skyrocketing drug prices.<sup>296</sup>

*d. Ruthless Simplification.* For those who like complexity, the system of intellectual property rights for pharmaceuticals is a garden of delights. From the Hatch-Waxman legislation through the Biologics Price Competition and Innovation Act of 2009 (the Biosimilars Act), to the maze of regulatory exclusivities and beyond, the judicial and regulatory processes

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<sup>290</sup> See *id.* at 642.

<sup>291</sup> See Robin Feldman & W. Nicholson Price II, *Patent Trolling: Why Bio & Pharmaceuticals Are at Risk*, 17 STAN. TECH. L. REV. 773 (2014) (citing Press Release, Dep't of Justice, Federal Trade Commission to Hold Workshop on Patent Assertion Entity Activities (Nov. 19, 2012), [http://www.justice.gov/atr/public/press\\_releases/2012/289873.htm](http://www.justice.gov/atr/public/press_releases/2012/289873.htm) [<https://perma.cc/KL5Y-V9T8>]).

<sup>292</sup> Edith Ramirez, Chairwoman, Fed. Trade Comm'n, Opening Remarks at Computer & Communications Industry Association and American Antitrust Institute Program (June 20, 2013), [https://www.ftc.gov/sites/default/files/documents/public\\_statements/competition-law-patent-assertion-entities-what-antitrust-enforcers-can-do/130620paespeech.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/competition-law-patent-assertion-entities-what-antitrust-enforcers-can-do/130620paespeech.pdf) [<https://perma.cc/T3JJ-G9YC>].

<sup>293</sup> FED. TRADE COMM'N, PATENT ASSERTION ENTITY ACTIVITY: AN FTC STUDY, 8–13 (2016), [https://www.ftc.gov/system/files/documents/reports/patent-assertion-entity-activity-ftc-study/p131203\\_patent\\_assertion\\_entity\\_activity\\_an\\_ftc\\_study\\_0.pdf](https://www.ftc.gov/system/files/documents/reports/patent-assertion-entity-activity-ftc-study/p131203_patent_assertion_entity_activity_an_ftc_study_0.pdf) [<https://perma.cc/85ML-VYWL>].

<sup>294</sup> See *supra* notes 279–293 and accompanying text.

<sup>295</sup> See *id.*

<sup>296</sup> See, e.g., Hemphill, *supra* note 8, at 643 (noting that the FTC is “well positioned” to address game playing in the pharmaceutical industry as the agency “has general authority to require firms to divulge confidential information”); see also William E. Kovacic, *The Importance of History to the Design of Competition Policy Strategy: The Federal Trade Commission and Intellectual Property*, 30 SEATTLE U.L. REV. 319, 327–28 (2007) (describing FTC efforts to use § 6(b) authority in the pharmaceutical industry).

surrounding intellectual property rights for drugs are among the most complex corners of our legal system.

Of course, some complexity in pharmaceuticals is inevitable. The intellectual property rights systems for drugs must, of necessity, interact with approval processes, and those approval processes must operate with exquisite awareness of public health and safety. These are heady responsibilities. Nevertheless, the system has become so complex and convoluted that it threatens to collapse in on itself.

And, of course, complexity breeds endless opportunities.<sup>297</sup> It ensures that the legislators and regulators will always be at least a step behind in an endless game of cat and mouse. Year after year, government actors must attempt to block strategic behaviors that have developed even as the industry develops new ones.<sup>298</sup> In such a process, it is clear that our incentives structure is badly misaligned with societal goals.

Putting the system back on track will require ruthless simplification. It means stripping away the intricate details that are so appealing to those who must forge compromises among interest groups, compromises that sow the seeds of current and future strategic behavior. In short, what has become business as usual for the pharmaceutical industry must become a thing of the past.

The 180-day period of exclusivity for first-filing generics is a classic example of a complexity that provides game-playing opportunities, one that is ripe for simplification. It is an extremely complicated and intricate piece of legislation. Unfortunately, the system has provided a method for generics and branded pharmaceutical companies to form anticompetitive agreements within which the generic agrees to stay off the market in exchange for some form of payment.

A simplified approach, in which the six-month period of exclusivity attaches only if the patent is actually invalidated, could reduce the game-playing. Along the same lines, one scholar has suggested that governments should reduce complexity by viewing any transfer of contemporaneous value conferral as a payment.<sup>299</sup> Frankly—and although it is akin to heresy to suggest this—one could argue that the entire first-filer exclusivity period should be eliminated. There may be sufficient market opportunities for generics without that incentive—particularly given the high price of branded

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<sup>297</sup> See ROBIN FELDMAN, *RETHINKING PATENT LAW* 165 (2012).

<sup>298</sup> See, e.g., *supra* note 16 (describing the Paragraph IV first-filer exclusivity that encourages generic companies to enter the market swiftly to challenge brand name drugs); see also FELDMAN, *supra* note 297, at 143 (noting that the brand name companies cannot receive more than one 30-month stay period on potential generic competitors); *id.* at 65 (noting that new legislation “requires that citizen petitions with the potential to affect generic approval . . . be considered within 150 days”); *id.* at 49–65 (describing examples of the complex second generation of pay-for-delay settlements, taking place even after courts try to shut down pay-for-delay settlements of the first generation).

<sup>299</sup> See Hemphill, *supra* note 8, at 686–88 (advancing the proposal and arguing that the law should require firms to actually earn their exclusivity).

pharmaceuticals—and the game-playing it has spawned may outweigh the benefits of having such a system.

A broader tactic for simplification would involve taking a standards-based approach instead of, or in addition to, a rules-based approach. The goal with a standards-based approach would be look at the overall effect of a behavior in an effort to thwart those who follow the letter of the law, but manage to arrive at a destination that the law intends to forbid. Such an approach can be useful when those being governed may be able to find loopholes to defeat governmental intent. The tax code's "step transaction" doctrine provides a classic example of a standards approach, allowing tax authorities to collapse all steps of a transaction if the steps are part of an overall plan to avoid taxation.<sup>300</sup>

Of course, a legal restriction packs a powerful punch only if authorities are willing to wield that restriction. Consider citizen petitions filed at the FDA for the purpose of delaying competitive entry. In an effort to limit the impact of that type of behavior, Congress passed legislation providing that the FDA must rule on a citizen petition within 150 days.<sup>301</sup> This is an example of a rules-based solution to a problem.<sup>302</sup> In the same legislation, Congress granted the FDA the ability to summarily deny a citizen petition if the petition has "the primary purpose of delaying the approval of an application."<sup>303</sup> An example of a standards-based approach, the summary denial provision suffers from two problems.<sup>304</sup> First, the petition is toothless. At worst, the sham tactic fails more quickly, and the company trying the tactic moves onto another approach. Second, the FDA has yet to summarily deny a single petition—and this despite empirical evidence that the majority of petitions are filed as a last-ditch effort to hold off competition<sup>305</sup> and that almost all petitions are denied.<sup>306</sup> A standard is useless if no one is willing to apply it and if the results of its application are meaningless.

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<sup>300</sup> See FELDMAN & FRONDORF, *supra* note 8, at 144 (describing the step-transaction doctrine to advocate for more liberal use of standards-based approaches in the pharmaceutical field).

<sup>301</sup> Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012) (codified at 21 U.S.C. § 355(q)(1)(F) (2018)).

<sup>302</sup> See FELDMAN & FRONDORF, *supra* note 8, at 144.

<sup>303</sup> 21 U.S.C. § 355(q)(1)(E).

<sup>304</sup> See FELDMAN & FRONDORF, *supra* note 8, at 144 (noting that proving "purpose," as required in the citizen petition context, is a tricky affair; any time intent is involved, the government stands at a disadvantage; the accused party can always counter that it had a perfectly legitimate idea in mind; thus, concepts such as "primary effect" could be more useful).

<sup>305</sup> See Robin Feldman et al., *Empirical Evidence of Drug Pricing Games: A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 44 (2017).

<sup>306</sup> See Michael Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 332–33, tab. 4 (2016) (finding that ninety-two percent of citizen petitions filed by competitors against drug companies between 2011 and 2015 were denied by the FDA); Michael Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 249 (2012) (noting that eighty-one percent of citizen petitions filed by competitors against drug companies between 2001 and 2010 were denied by the FDA).

Although one tends to think of penalties in terms of dollars assessed to a company, that need not be the case. Pharmaceutical companies can pay hundreds of millions of dollars in fines and still find a tactic to have been worth the cost. In 2015, pharmaceutical company Teva paid \$1.2 billion in FTC fines and class-action settlements regarding its pay-for-delay tactics to block generic competitors of its narcolepsy drug Provigil.<sup>307</sup> Despite this hefty bill, the company still profited from the delay to the tune of roughly \$2 billion.<sup>308</sup>

In addition to, or in the place of, fines, Congress or a regulatory agency could provide that a misbehaving company will lose certain regulatory privileges. The government also could impose penalties on the lawyers involved in behaviors that violate the standards. For example, under the SEC's system to deter fraudulent filings, the Enforcement Division can impose punishment on the company making the filing, and the Litigation Division can suspend the attorney from practice before the commission.<sup>309</sup> This could provide a model for responding to bad behavior in the drug industry and could be applied at either the state or federal level, depending on the level at which the bad behavior occurs.

In short, a standards-based approach could make it more difficult for companies to profit from sophisticated strategies designed to exploit complex systems. Standards are useless, however, unless someone has the power and the will to enforce them.

*e. One and Done.* A different approach to reform would be the "one and done" approach, which this author has recommended in other places.<sup>310</sup> One and done is a regulatory approach where a drug would receive only one exclusivity period over the life of the drug. The drug manufacturer could determine which type of exclusivity on their drug, but knowing they could not add any additional exclusivities. While one and done would be effective, expanding judicial doctrines could be a more politically palatable solution. One pathway could be to expand the judicially created doctrine that prevents patent holders from what is known as "obviousness-type double patenting." The doctrine is intended to prevent the approval of claims from a second patent where the new claims are not clearly distinct from those of the first. In theory, one could craft a sister doctrine to prevent secondary patents from the perspective that the core of the invention is no more than the original chemical formulation. Anything else is merely an obvious adaptation of what was the core of the invention, modified with existing technology.

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<sup>307</sup> See FELDMAN & FRONDORF, *supra* note 8, at 47 (describing the Provigil cases).

<sup>308</sup> See *id.*

<sup>309</sup> See 17 C.F.R. § 201.102(e) (2020); see also Robin Feldman, *Comment on the FDA Notice: Administering the Hatch-Waxman Amendments: Ensuring a Balance between Innovation Access; Public Meeting*, REGULATIONS.GOV (Sept. 19, 2017), <https://www.regulations.gov/document?D=FDA-2017-N-3615-0071> [<https://perma.cc/442F-XGV2>] (advocating using the SEC approach as a model for the FDA).

<sup>310</sup> See Feldman, *supra* note 8, at 640.



In designing this approach, one could borrow a page from the Supreme Court's approach in the doctrine of patentable subject matter. That Court has cast doubt on numerous patents by taking an expansive view of what falls within the category of an unpatentable law of nature and then holding that:

[I]f a law of nature is not patentable, then neither is a process reciting the law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.<sup>311</sup>

In other words, the Supreme Court Justices took aim at patents in which they felt that, putting aside what already exists in nature or elsewhere, there is (as Gertrude Stein would say) “no more ‘there’ there.”

The Justices established a two-part test in which one should first determine whether the patent is directed to one of the ineligible categories—abstract ideas, natural phenomena, etc.—and then should look to see if the patent has something more:

We have described step two of this analysis as a search for an “inventive concept” – i.e., an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.”<sup>312</sup>

The Supreme Court's “patentable subject matter” doctrine was greeted by howls of protest, and it has been the subject of repeated attacks by the patent bar and by the Federal Circuit, which has never been known for fealty to the Court.<sup>313</sup> The complaints have argued that the doctrine is confusing and unworkable because it is impossible to pin down how a patent holder can satisfy the Court's two-part test. That, indeed, may be the Court's point: Its quartet of cases may have been intended to eliminate much, if not all, of the types of patent considered in those cases. A similar type of doctrinal development could be applied to the doctrine of obviousness-type double patenting.

Of course, one could argue that many secondary patents are obvious adaptations of the original invention and existing technology, and that, as

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<sup>311</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 77 (2012).

<sup>312</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014) (citing life science case *Mayo v. Prometheus*, 566 U.S. 66, 72 (2012)).

<sup>313</sup> See Robin Feldman, *Coming of Age for the Federal Circuit*, 18 GREEN BAG 27, 30–33 (2014) (describing the history of struggles between the Federal Circuit and the Supreme Court). For modern Federal Circuit resistance against the Alice/Mayo two-part test for patentable subject matter, see, for example, *Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.*, 56 F. Supp. 3d 813 (E.D. Va. 2014) (opining that there is no workable definition of an abstract idea); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1337 (Fed. Cir. 2016) (admonishing that courts must be careful not to apply too high a level of abstraction and moving certain inquiries from the second part of the test into the first, so that the second part of the test is never reached).

such, they should already fail on obviousness grounds anyway. Indeed, a more vigorous and robust application of the current obviousness doctrine could go a long way toward reducing behaviors such as a company piling on additional patents. Either invigorating the doctrine of obviousness or expanding the doctrine of obviousness-type double patenting could be accomplished through judicial or legislative changes. Promoting transparency, reducing market concentration through reimagining markets and competitive policy, utilizing the FTC's investigative authority, adopting simplified rules and standards, and a one-and-done legal approach would all assist in reinvigorating a competitive health care marketplace while reincentivizing market players to lower costs for consumers.

## V. CONCLUSION

As John F. Kennedy explained, “the enemy of the truth is very often not the lie—deliberate, contrived, and dishonest—but the myth—persistent, persuasive and unrealistic.”<sup>314</sup> Nowhere is the fog of myth greater than in the drug industry. Despite all of the parties who should be primed to protect the interests of patients and consumers, including PBMs, pharmacists, health insurers, hospitals, doctors, and patient advocacy groups, the incentive structures align strongly in favor of higher prices. The system not only creates great pain for patients and taxpayers, it also provides convenient levers that allow drug companies to carve out or reinforce competition-free zones.

Numerous small alterations have been, and will continue to be, proposed. Although many may help in small ways, and such tinkering may be all that is politically feasible, high drug prices and persistent pain for patients, governments, and taxpayers are unlikely to ease unless society can fundamentally alter the perverse incentive structures at work. Ensuring that markets are fair, transparent and competitive—in the manner described above—could make great strides in altering the nature of the incentives at work. At the end of the day, if we lack the political will to face the issues head on, we will have ourselves to blame, as well.

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<sup>314</sup> See Norton, *supra* note 267 (using the Kennedy quotation in the context of questioning whether PBMs are good financial stewards of prescription drug plans).